THE EFFECTS OF A SIX-WEEK PRE-OPERATIVE, PHYSIOTHERAPY-LED EXERCISE AND EDUCATION INTERVENTION ON POST-OPERATIVE RECOVERY, IN TERMS OF PAIN AND FUNCTION, IN PATIENTS WITH OSTEOARTHRITIS, UNDERGOING TOTAL KNEE ARTHROPLASTY IN THE WESTERN CAPE

Sara Lee Warren
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Supervisor: A/Professor Romy Parker
Co-supervisor: Mrs. Melissa Saw
Division of Physiotherapy, Department of Health & Rehabilitation Sciences, University of Cape Town

DECLARATION

I, Sara Lee Warren, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abstract

Background: Osteoarthritis (OA) is one of the most common musculoskeletal conditions (MSCs) worldwide, most commonly affecting those over 60 years of age. OA is associated with pain and disability, and also has negative social and emotional effects on the individual. End stage management for OA of the knee, when the individual is no longer receiving adequate relief from conservative measures, is total knee arthroplasty (TKA). Long waiting lists are a challenge globally and in South Africa (SA) where patients often have to wait years to receive their surgery. Evidence suggests that the longer an individual is in pain, the more likely they are to stay in pain and thus long waiting lists may result in poor post-operative outcomes. It has been found that 10-34% of patients undergoing TKA do not gain adequate relief from surgery. Literature suggests that self-management interventions using exercise and education are effective in reducing pain and improving function in patients who are on a waiting list, in a South African context. The current literature on self-management programmes does not include post-operative follow-up and thus the current study was warranted to determine the effects of a six-week pre-operative physiotherapist-led exercise and education intervention on post-operative recovery in patients with OA undergoing total knee replacement.

Methods: A single-blind randomized controlled trial was conducted at Tygerberg Hospital (TBH) in the Western Cape, SA. Pain was the primary outcome measure, with disability (WOMAC), health-related quality of life (EQ-5D-5L), fear of movement (TSK) and function (ALF) as secondary outcomes. Participants were randomly placed into the experimental or control group. The experimental group took part in a six-week, group programme, which they attended at TBH. Classes were two hours long and consisted of education, exercise and relaxation training. The control group's management remained unchanged and they received their usual care. Measurements were taken at recruitment, post-intervention, pre-operatively, post-operatively, and at six weeks and three-months post-operatively by a blinded research assistant. Analysis was by intention to treat. Due to the small sample size, non-parametric analysis was conducted and results are presented as median and range throughout. Effect sizes were calculated with a 95% confidence interval.

Results: There were no significant changes between groups on the primary outcome measure of pain. The only outcome revealing any significant change between groups was the TSK, with a large effect size of 1.39 (0.41 – 2.26 95% CI), indicating that the experimental group performed better than the control group at three months post-operative follow-up.

Conclusion: Participation in the intervention provided no significant benefit to the experimental group over the control group and did not change post-operative outcomes. There were challenges with regard to participation and completion of the measurement tools used, raising questions regarding issues of pain and fear, self-efficacy, social learning, social cohesion and behavior change. The suitability of this intervention for use in a pre-operative population for post-operative benefits, needs to be reviewed; it would appear that what is suitable for those on a waiting list, with no clarity on when surgery will occur, may not necessarily apply to those who are actually due to undergo surgery. Future research should consider modifying the intervention, including information appropriate to pre and post-operative needs of the population. The roles of self-efficacy, social cohesion and social learning in behavior change should be considered and, levels of self-efficacy and fear of movement beliefs assessed prior to randomization, in order to adequately establish the effect of the intervention on these factors.

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List of Abbreviations

OA	Osteoarthritis
MSC	Musculoskeletal condition
SA	South Africa
CS	Central sensitisation
TKA	Total knee arthroplasty
IASP	International Association for the Study of Pain
ICF	International Classification of Functioning
WHO	World Health Organisation
TBH	Tygerberg Hospital
GDP	Gross domestic product
WC	Western Cape
HRQoL	Health-related quality of life
UK	United Kingdom
USA	United States of America
PS	Peripheral sensitisation
CNS	Central nervous system
THA	Total hip arthroplasty
ACR	American College of Rheumatology
EULAR	European League Against Rheumatism
CSI	Central Sensitisation Index
TSK	Tampa Scale of Kinesiophobia
OARSI	Osteoarthritis Research Society International
NICE	National Institute for Health and Clinical Excellence
ESCEO	European Society for Clinical and Economic Aspects for Osteoporosis and Osteoarthritis
TENS	Transcutaneous Electrical Nerve Stimulation
ASMP	Arthritis Self-Management Programme
CDSMP	Chronic Disease Self-Management Programme

RA	Rheumatoid Arthritis
RCT	Randomised control trial
ESCAPE	Enabling Self-Management and Coping with Arthritic Knee Pain through Exercise
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
NRS	Numerical rating scale
VAS	Visual analogue scale
VRS	Verbal rating scale
MPQ	McGill Pain Questionnaire
SF-MPQ	Short form - McGill Pain Questionnaire
ISCOAP	Intermittent and constant Osteoarthritis Pain
BPI	Brief Pain Inventory
HAQ	Health Assessment Questionnaire
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
KOOS	Knee Injury and Osteoarthritis Outcome Score
SIP	Sickness Impact Profile
SF-36	Short form - 36
SF-12	Short form - 12
EQ-5D	Euroqol
TUG	Timed up and go
6MWT	Six minute walk test
SPPB	Short Physical Performance Battery
CS-PFP	Continuous Scale Physical Function Performance
ALF	Aggregated Locomotor Function
PASS	Pain Anxiety Symptoms Scale
FABQ	Fear Avoidance Beliefs Questionnaire

ACSM	American College of Sports Medicine
ANOVA	Analysis of Variance
HREC	Human Research Ethics Committee
CONSORT	The Consolidated Standards for Reporting Trials
PSS	Pain severity score
CI	Confidence interval
PIS	Pain interference score

Glossary of Terms

Acupuncture: A technique used in Eastern medicine where needles are inserted into the patient's skin and muscles.

Ageing index: A calculation used to indicate the rate at which a population is ageing.

Allodynia: Feeling pain when receiving a stimulus which does not usually produce pain.

Apartheid: The system of rule used by the previous government in South Africa. The literal meaning is separateness, and it was a system of racial discrimination.

Arthroplasty: Joint replacement surgery.

Arthroscopic debridement: Minimally invasive surgery to remove damaged tissue from a joint.

Assistive device: A tool used to help an individual to perform a required function (walking sticks, braces, canes, crutches).

Balneotherapy: Immersion in baths containing mineral water.

Biosychosocial: An approach or framework taking into account the biological, psychological and social aspects of a person and their experience.

Biopsychomotor: An approach to pain, viewing behaviour as critical to the experience, rather than a by-product of it.

Central sensitisation: "an amplification of neural signalling within the central nervous system that elicits pain hypersensitivity" [1].

Central nervous system: The brain and spinal cord

Central Sensitivity Index: A tool used to identify central sensitisation and the severity of it.

Chronic pain: Pain that continues beyond normal tissue healing time.

Fear avoidance: The name given to the behaviour associated with negative illness beliefs, resulting in avoidance of behaviours which may reproduce symptoms, but may lead to recovery.

Gross domestic product: The total value of production and services in a country for a year.

Group Areas Act: Discriminatory legislation by the Apartheid government which allocated different areas for different race groups to live and work in.

Health literacy: An individual's level of ability to gather or receive and comprehend health information in order to make decisions regarding their health and use of healthcare services.

Hyperalgesia: Increased pain felt when receiving a usually painful stimulus.

Hypertension: Elevated blood pressure >120/80mmHg

Iatrogenesis: A negative effect on the individual's condition due to the action or interaction with a health professional or medical intervention.

Joint lavage: The cleaning out of a joint.

Lower-bound poverty line: Where people are unable to afford sufficient food and non-food items because they are too poor.

Musculoskeletal conditions: A range of conditions affecting the body's system of muscles, joints and nerves.

Nociceptive/nociception: The stimulation of the nociceptors in the nervous system and the response to this stimulation.

Noxious input: Harmful, damaging or dangerous information.

Neuropathic: Resulting from damaged nerves (usually the peripheral nervous system).

Osteotomy: Cutting into the bone to realign it, by lengthening one side of it.

Peripheral sensitisation: Where nociceptors in the periphery develop increased sensitivity and responsiveness following an injury.

Placebo response: A non-specific benefit derived from a treatment or intervention where the benefit may be as a result of the expectation of a positive outcome, rather than the specific intervention itself.

Rehabilitation: The process of returning an individual to their previous level of function or maintaining their function to prevent further disability.

Secondary care: The second level of healthcare in South Africa where more generalised care may be received and smaller surgeries performed.

Self-management: Active participation in one's own healthcare and decision-making around that care.

Self-efficacy: An individual's belief in their ability to perform the required action to achieve the desired result.

Social cohesion: "the willingness of members of a society to co-operate with each other in order to survive and prosper"[2].

Transcutaneous electrical nerve stimulation: An electrotherapy modality commonly used by physiotherapists, which provides an electrical impulse into the tissues and can be used to relieve pain or stimulate muscle contraction.

Tertiary care: The third level of healthcare in the South African healthcare system. Specialised care and big surgeries are performed at a tertiary level.

Total knee arthroplasty: Replacement of both surfaces of the knee joint using prostheses.

Total hip arthroplasty: Replacement of both surfaces of the hip joint using prostheses.

Windup: An increase in pain from repetitive input from the same stimulus.

Chapter 1: Introduction

1.1 Background

Osteoarthritis (OA) is widely accepted as one of the most common musculoskeletal conditions (MSCs) affecting people globally [3-6]. The age-group most affected by the condition are those over 60 years old [7, 8]. Along with pain, disability is commonly associated with OA [9-11], thus as life expectancy increases both globally and within South Africa (SA), one may expect that the burden of disease of OA will increase, leading to increased levels of disability.

OA is a complex condition affecting the patient not just physically, but socially and emotionally as well [9, 10]. As such, the management of OA is varied and a number of guidelines have been formulated which include conservative strategies, which make use of physiotherapy for rehabilitation, education and exercise, as well as surgical measures when non-surgical management fails to provide adequate relief [12-16]. Although guidelines for the management of people with OA have been put in place, treatment still needs to be individualised to optimise results [17].

Joint replacement surgery is indicated for those who no longer respond to conservative management [13, 16]. Long waiting lists for joint replacements and delayed surgeries are a problem both internationally and within SA in a public health setting where, due to limited resources and increasing patient load, patients may wait years to receive their surgery [18, 19]. There is evidence to suggest that being on a waiting list affects the individual negatively [19], with long waiting periods having the potential to negatively affect post-operative outcomes. It has also been suggested that pain felt by a person in the past, has the ability to affect their functional ability in the future [20]. This is problematic in that the public health sector in SA services the majority of the population (84%) [21] and as such, a large number of patients are spending many years on waiting lists in pain, compromising their post-operative success.

Recent studies have investigated the role of the central nervous system in OA pain, and more specifically, central sensitisation (CS). Evidence suggests that CS may have a major part to play in the chronic pain experienced by people with OA, with about 30% of patients having CS as a component of their clinical picture [22, 23]. Although total knee arthroplasty (TKA) has been found to be effective in managing patients who do not get the desired relief and functional gains from non-surgical interventions, not all patients experience positive pain outcomes and persistent pain following joint replacement is not unusual [24, 25]. In fact, a systematic review found that 10-34% of patients experienced persistent pain following TKA [24]. Unfortunately, the review did not theorise as to what the cause of the persistent pain may be. It was noted however, that there is an association between better general health, physical, emotional and social function, motivation, self-efficacy and lower levels of pre-operative pain, and pain in the rehabilitation period, as well as better short and medium-term outcomes [24].

1.2 Theoretical Framework

Pain is defined by the International Association for the Study of Pain (IASP) as "An unpleasant sensory and emotional experience in response to actual or potential tissue damage" [26]. This definition supports the use of a biopsychosocial model of pain which takes into account the biological, psychological and socio-cultural factors which influence the pain experience [27]. This definition and model will be the reference point when referring to pain throughout this thesis.

The International Classification of Functioning (ICF) was developed by the World Health Organisation (WHO) for use in a variety of applications [28]. It is a useful framework from which to work in both research and clinical practice and because it considers aspects of function, disability as well as contextual factors [28], it is complementary to the biopsychosocial model of pain. Figure 1 illustrates the interactions in the ICF allowing an understanding of the interplay of various factors in the health experience of the individual.

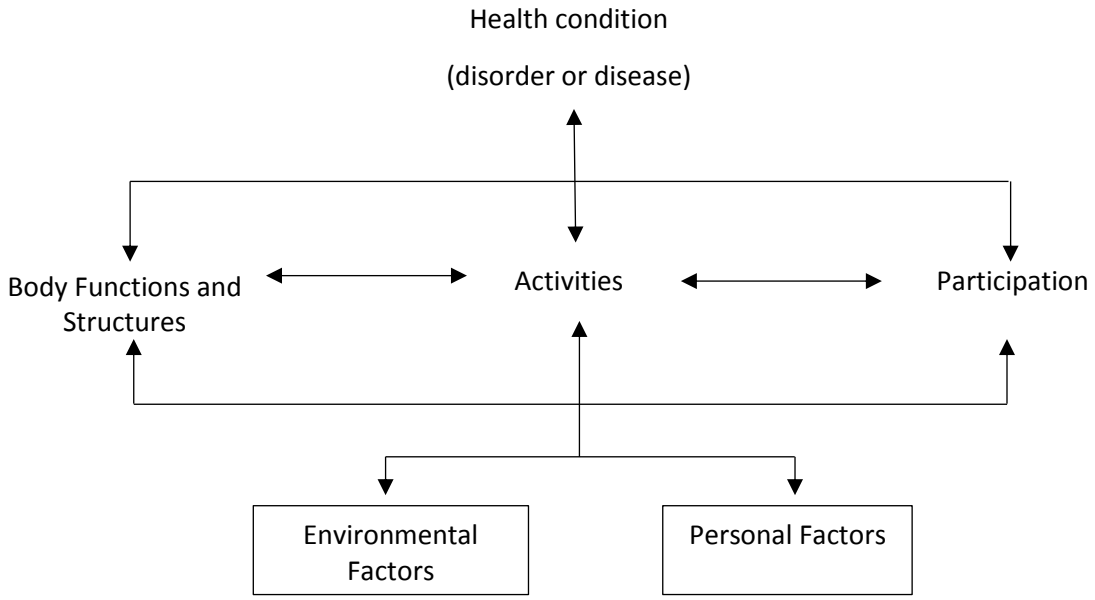


Figure 1: The ICF Framework [28]

The ICF model is helpful in distinguishing between the differences in impairment of a structure and the effect it may have on the individual and their experience of illness. If for example, a patient has OA of the knee, the health condition would be OA knee, whilst the impairments may include reduced muscle strength and loss of range of motion. The activity influenced by these impairments may be walking, which would in turn inhibit the patient's ability to attend church or whatever other social function they may have previously walked to. The patient may feel more comfortable about going to church if they could get a lift in a friend's car, but if there are stairs at church (environmental factors) and the patient is scared that they may fall or be sore after climbing the stairs (personal factors), they may not attend at all.

This distinction between aspects relating to the illness experience facilitates the formulation of effective treatments which take into account the variety of factors influencing this experience. This then allows the health care provider to establish which participation restrictions have meaning for the patient and which environmental and personal factors influence these. They can then focus their treatments on addressing these aspects specifically.

Both the ICF framework and the biopsychosocial model of pain are important tools allowing researchers and clinicians to formulate complex treatments which facilitate changes in not only symptoms, such as pain or reduced range of motion, but more importantly the behaviour of the individual. Changing behaviour to facilitate participation and reduce disability is a vital part of a successful rehabilitation programme for patients with long standing pain, which is part of the first line management of knee OA. The intervention used in this study was previously successfully used in people with OA awaiting joint replacement and is grounded in a biopsychosocial framework. It takes into account the cognitive (education), physical (exercise and relaxation) and social (group learning) factors pertaining to the individual and their illness experience [29]. It also integrates the principles of the ICF in that goal setting involves activity and participation, as well as unpacking personal and environmental factors influencing the individual's experience [29]. The current study was designed to assess whether an intervention which reduced pain in people with end-stage lower limb OA who were on a waiting list for joint replacement, would also improve post-operative outcomes following TKA in people with knee OA receiving treatment through the public health sector at Tygerberg hospital (TBH), Cape Town, SA.

1.3 Research Setting

According to the most recent population data available from the StatsSA 2016 Community Survey, there are 55.6 million people living in SA. The majority are black Africans, making up 80.7% of the population, followed by Coloured (8.7%), White (8.1%) and Indian/Asian (2.5%). There are 11 official languages, with isiZulu (24.6%), isiXhosa (17%) and Afrikaans (12.1%) being the three most commonly spoken languages [30]. Education is poor with the majority of people having only a primary school level education (81.5%) and 7.1% having had no schooling at all. Service delivery is described as inadequate and of the top five challenges identified facing municipalities across SA, four were related to poor service delivery, namely: cost of electricity; inadequate housing; lack of safe and reliable water supply and inadequate roads [30]. The Community Survey reports that 7.7% of the population is disabled, with a sharp increase in disability rates from the 50-54 age group (13.7%) to the 65-69 age group (31.5%) [30].

One of the many challenges of the Apartheid legacy in SA is a fragmented health system, where inequities are common [31]. Although classified as a middle-income country, when comparing SA to other middle income nations, its health outcomes are poor [32]. Of the 8.5% of the gross domestic product (GDP) spent on health, half of this is spent on the private sector. This leaves 4.25% to be spent in the public health sector, which services 84% of the population.

In 2016, life expectancy for males was 59.7 years and for females 65.1 years. The ageing index in SA increased from 23 to 27 between 2001 and 2016, indicating that the population is gradually ageing. The province with the highest ageing index was the Western Cape (WC), indicating that there is a higher proportion of elderly people compared to the rest of the country [33]. In 2011, 76.2% of those 60 years and older were living below the lower-bound poverty line [33]. In 2015 only 22.9% of those aged 60 years and older were part of medical aid schemes [33], meaning that the remaining 77.1% would need to either pay out of pocket for private healthcare, or make use of public health services. The three most common medical conditions in the older population were hypertension, diabetes and arthritis [33]. Looking at arthritis as one of the most common conditions affecting the older population, one may expect that the burden of arthritis to be higher in the WC with a significant portion of that burden being managed in the public health sector.

The composition of the WC population, where the current study is to be conducted, differs slightly from that of the rest of the country in that the most commonly spoken languages are Afrikaans, isiXhosa and English respectively [30]. Hospitals are overburdened and under-resourced, which affects their ability to render services effectively and efficiently [18]. TBH is a tertiary care, public hospital in Parow, Cape Town. The hospital primarily provides services to residents of the WC, however these services are not exclusive to residents. Patients seen in the Tygerberg orthopaedic department are generally referred from surrounding clinics and secondary care facilities for a more advanced level of care.

Therefore, the current study was conducted at TBH, in a population who live in low resource areas who probably have low levels of education, live in poverty and are dependent on the public health sector for care. The public health sector is also resource constrained and struggles to deliver services adequately leading to lengthy waiting lists and systemic challenges to service delivery [18]. It is thus relevant to conduct research which can optimise health care delivery and outcomes in this setting.

1.4 Aims and Objectives

1.4.1 Aim

The aim of this study was to determine the effects of a six-week pre-operative physiotherapist-led exercise and education intervention on post-operative recovery in patients with OA undergoing total knee replacement.

1.4.2 Objectives

The objectives were to establish whether participation in a six-week physiotherapist-led exercise and education intervention pre-operatively causes a significant change in post-operative outcomes in a group of patients undergoing total knee replacement as compared to a control group, with regards to the following outcomes:

1. Pain severity and pain interference [34, 35].
2. Disability [36].
3. Health related quality of life (HRQoL) [37].
4. Function [38].
5. Fear of movement [39].

Chapter 2: Literature Review

2.1. Introduction

This literature review will begin by examining the current global and local information and statistics regarding the epidemiology, prevalence and burden of musculoskeletal conditions, with an emphasis on Osteoarthritis (OA). It will seek to discuss aspects related to the appropriate assessment of OA and to critically analyse the current management strategies available, according to best practice guidelines, as well as related challenges in management, specific to South Africa and health care in a government setting. It will conclude by discussing the proposed measurement instruments for the current study, according to the objectives, and justify their use.

2.2 Epidemiology of musculoskeletal conditions

Musculoskeletal pain is a common problem that most individuals will experience at some point in their lives. This pain may be temporary and mild or may become chronic and disabling [40]. The term musculoskeletal condition (MSC) refers to over 200 conditions which collectively place a major burden on the individual and society, and are known to cause pain and disrupt physical function [8, 41]. MSCs are generally associated with pain and reduced function [8, 42, 43], however, these physical symptoms do not exist in isolation and have psychosocial consequences [44]; affecting mental well-being, ability to function in a social context and ultimately reducing quality of life (QoL) [8]. It is well established that MSCs are a major cause of disability globally [8, 41-43, 45, 46] and in a review by the World Health Organisation (WHO), it was noted that they are the main cause of disability in older age groups [8]. This same report predicted that the growing burden of MSCs would be felt more heavily in developing countries, and with MSCs being the fourth largest burden on health in developed countries and third largest in developing countries, this prediction would appear to be accurate [8, 47].

MSCs impose a great burden on both the individual and healthcare services [42, 48] and are one of the most expensive causes of disability [49]. The direct costs incurred as a result of MSCs are massive and include medications, physiotherapy, doctor's appointments, hospital admissions and surgeries [41]. Of great importance and cost to both the individual and the economy is time spent off work as a result of MSCs. In 2007 more than 20% of incapacity claims in the United Kingdom (UK) were for MSCs and in another UK study from 2009, MSCs were second only to mental health problems in accounting for time off work [41]. The Global Burden of Disease 2016 study had similar findings in disability statistics with MSCs accounting for 17.1% of the total years lived with disability [50].

At any point in time, 20-30% of adults in Europe are affected by some sort of musculoskeletal pain [42]. This is a similar finding to that of American populations where at any given time 30% of adults are affected by pain, swelling or limitation of movement in a joint [8]. According to a UK study, in 2007, 14.3% of individuals reported having some sort of chronic MSC, whilst 12.1% of doctor's visits were for complaints related to the musculoskeletal system [41]. A 2010 study conducted in two under-resourced Cape Town clinics found a 36% prevalence of MSCs [43]. Although these are not definitive prevalence estimates for entire countries, they provide some basis for comparison. Interestingly, there is quite a disparity between the 14.3% of reported chronic MSCs in the UK group and the 36% prevalence reported in the South African population. It has been suggested that poverty and low levels of education are positively associated with knee OA [51] and that lower socio-economic status is positively associated with increased pain, and lower levels of function in adults with knee OA [52]. This may be due to a number of factors, but one may also speculate that this positive association may be related to the type of work which is more easily accessible to those of lower socio-economic position, namely manual labour. Given that OA is one of the most common MSCs affecting people globally [3-6], these findings, along with the higher burden of OA in developing countries [47], would suggest that the higher prevalence for the South African population estimates is in fact appropriate. Unfortunately, there is still a paucity of research looking specifically at the burden of MSCs in South Africa.

There are a number of risk factors for the development of MSCs, such as inactivity and obesity (both of which are modifiable). However, the unavoidable and widely accepted common predisposing factor to the development of MSCs is advanced age [8, 42, 45, 49]. With the increased life expectancy which is now being seen around the world, the prevalence and burden of these conditions is expected to rise [8, 41, 45, 49].

2.3 Osteoarthritis

Of all MSCs, OA is thought to be the most common [3, 5]. Considering this, it is interesting to note that that there are a number of ways in which OA may be defined. The general consensus amongst authors however, is that it is a condition associated with degenerative changes to the articular cartilage, which in turn leads to changes in the underlying bone [3, 7, 8, 40, 53-55]. Risk factors for the development of the condition include old age, female gender, obesity, previous joint injury, repetitive joint use, high bone density, muscle weakness and joint laxity [56].

Prevalence statistics regarding OA are not available for all populations. Prevalence statistics vary greatly throughout the literature and are influenced by the way in which OA is defined [3], making it difficult to determine an exact prevalence of the condition. However, where data are available, prevalence is reported to be high with 9.6% of males and 18.0% of females over the age of 60 affected by OA worldwide [5, 7]. The prevalence of OA is known to increase with age [3, 5, 56]. It is also more common in females than in males as one would assume if being female is a risk factor for the development of OA [3, 56]. This male to female difference in prevalence is rather large with nearly double the percentage of females than males with OA Differences in prevalence between male and female populations in the United States of America (USA) were smaller, with 10% of males and 13% of females over the age of 60 estimated to have OA [56]. Prevalence estimates for OA in females were consistently higher than for those in males in studies conducted in China, Greece, the Netherlands, Spain and the USA [57]. Up to date statistics regarding prevalence of OA in South Africa are lacking, however, the general household survey conducted by Statistics South Africa in 2011 reported that 13.9% of people over the age of 65 years reported having arthritis [58] and in a 1987 report, chronic arthritis was ranked as the leading cause of disability in the metropolitan area of Cape Town [9]. With high prevalence rates globally, and the assumption that South Africa follows the same trend as the rest of the developing world, the financial burden of OA needs to be fully assessed to understand the magnitude of the problem the disease poses to those who are living with it.

A review looking at the costs of OA in the UK as compared to other countries suggested that accurate estimates or figures are similarly difficult to ascertain due to problems in defining OA and therefore in determining its prevalence. It was noted however, that OA is a growing financial burden on all countries, with costs varying from country to country [59]. As found with MSCs as a whole, the costs incurred as a result of OA include both direct (medication, physiotherapy, carers etc.) and indirect costs (time off work, reduced productivity and compensation for disability), of which indirect costs appear to be greatly underestimated [59]. A systematic review by Salmon et al (2015) found that the costs incurred due to OA differed depending on which continent was being assessed and found several limitations in the methods used by the studies they reviewed. Patient selection, as well as what constituted a direct cost were not the same throughout studies, which they noted would possibly bias or skew their results [60]. In North America, direct costs related to hip and knee OA were €10 000 per year, while in Europe these costs were only €1000 per year. They attributed the large difference to increased levels of obesity and comorbid conditions in the USA [60]. Taking the limitations of the review into account, the estimated total global cost of hip and knee OA was €11 100 per patient per year. Direct costs, estimated to be €9 500 per person per year globally, were greater than indirect costs overall, except for in Europe where they accounted for less expenditure than indirect costs. Indirect costs were estimated to be €4 400 per person per year globally [60].

Unfortunately, costs relating to physiotherapy, alternative medicine, emergency room visits and surgery are not always included in these cost estimates, and this may lead to an underestimation of the direct costs [60]. There is a lack of evidence regarding the economic burden of OA in SA, however if it follows the global trend and the population continues to age, one would expect to see an increase in this cost burden over the next few years. This would severely stress an already overburdened healthcare system in South Africa.

2.4 Symptoms of OA

Pain is the most common symptom experienced by patients with symptomatic OA [54, 61]. However, OA is also known to contribute to reduced range of motion and disability [9-11]. As mentioned earlier, the effects of OA are not only physical; it can also have other devastating consequences for the individual affected by the condition. The personal, social and economic burden borne by the individual is significant, and beliefs regarding ill-health can lead to feelings of helplessness, reduced self-efficacy, reduced ability to cope, and depression [44]. This results ultimately in a reduced QoL for the individual living with OA along with increased expenditure on healthcare [11].

2.4.1 Pain mechanisms in OA

Pain and disability show poor correlation with the severity of OA based on joint imaging. Imaging demonstrating OA is often not associated with any clinically important symptoms [62, 63]. A 2011 report suggests that up to 40% of individuals with radiographic evidence of OA experience no pain [64]. This percentage was even higher according to a review published in 2001 where they suggested that as many as 50% of patients with radiographic knee OA do not experience knee pain, and 50% of those who complained of knee pain at the age at which OA is likely to become common, had no conclusive radiographic evidence of OA [65]. It is this nature of evidence which begins to suggest that there are numerous pain mechanisms at play in these patients.

2.4.1.1 Central sensitisation

Abnormal cartilage is one of the defining features of OA, however due to the fact that it is an aneural structure, it is unable to directly generate a nociceptive stimulus which could generate the pain associated with OA [63]. As a result, there have been a number of suggestions as to what peripheral structures and processes may be responsible for the generation and maintenance of pain in OA [22]. Both peripheral sensitisation (PS) and central sensitisation (CS) have been implicated in the pain experienced in people living with OA [22, 66, 67]. PS is thought to produce more localised symptoms, whereas CS creates a more widespread distribution of pain, distal to the actual injury or pathology [67]. The operational definition of CS by Woolf, (2011, p. S5) is “an amplification of neural signalling within the central nervous system (CNS) that elicits pain hypersensitivity” [1]. According to Latremoliere and Woolf (2009), intense, sustained and repeated noxious input is required to induce CS [68]. The gate control theory postulates that pain requires the complex interaction of both ascending and descending pathways and central and peripheral systems in its generation and control by the brain [69]. This theory allows for a greater understanding of how the CNS may have a role in the pain experienced by patients with OA and that those in the sub-group who experience increased and persistent pain may have an imbalance or a dysfunction in these complex interactions which generate pain. Recent studies have investigated the role of the nervous system in OA pain, specifically the CNS. There is growing evidence to suggest that there may be a CS component to OA pain [1, 23, 63]. A systematic review looking at the role of central pain in OA found several studies showing evidence of hyperalgesia, abnormal pain sensitivity and referred pain in patients with OA [63].

When referring to CS, it must be considered that changes occur both in the spinal cord, as well as in the processing of inputs in the brain itself [22]. CS is mediated by a number of processes and ultimately results in a lowered threshold for nociceptive input at the spinal cord as well as the cerebral cortex, increased excitability at the spinal cord, increased receptor field size, windup and decreased function of descending inhibitory pathways [67]. These changes lead to the symptoms of hyperalgesia, secondary hyperalgesia and allodynia [68]. Hyperalgesia refers to increased pain from a usually painful stimulus [23]. Secondary hyperalgesia refers to increased sensitivity to pain in an altered distribution, i.e. distal to the site of injury or pathology [68, 70]. Allodynia is when pain is produced by a usually non-painful or sub-threshold stimulus [1]. These are all indicators of the presence of CS [68]. Taking these changes into account, it is clear that nociception is not necessary for pain to be present in patients with OA and that appropriate management should attempt to address this driver of pain.

In the past, management strategies and treatments for OA have sought to address the disease at the site of the structural problem, but evidence is showing that this may not be enough for all patients as it fails to address the pathology in the CNS which contributes to pain [67]. If one were to assume that the joint pathology in OA is the primary source of pain, then the obvious assumption would be that total joint replacement would completely alleviate the patient's symptoms, as the joint would no longer be damaged. This unfortunately is not the case, as evidenced by a systematic review assessing long-term pain in patients having undergone total hip arthroplasty (THA) or total knee arthroplasty (TKA). The results of the review suggested that in patients undergoing THA 4.8% - 20.5% experienced poor pain outcomes, and in the studies focussing on TKA, a conservative estimate of the percentage of patients who continued to experience long-term pain following surgery was between 10% and 34% [24]. A European study considering primary arthroplasty, bilateral arthroplasty and revision arthroplasty, suggested that the percentage of patients with persistent pain following knee arthroplasty was slightly higher at 35% [25]. This same study found that the intensity of pre-operative pain as well as a delay in the surgical intervention increased the patient's risk of experiencing persistent pain following surgery [25]. Further, in a 2014 review from Lluch and colleagues, they noted that individuals with a higher pain rating and lower pain threshold pre-operatively were at increased risk of experiencing persistent pain following surgery [71].

The failure of a joint replacement to improve pain in these patients further strengthens the plausibility of the suggestion that another mechanism may be the primary driver of their symptoms, namely CS. One of the main drivers theorised to contribute to CS is fear avoidance beliefs. The role of fear avoidance in CS and OA will be discussed prior to a discussion on methods to assess CS. Thorough assessment is important to identify this sub-group of patients with OA of the knee who develop CS, in order to target them specifically to achieve the best possible outcome following surgery.

2.4.1.2 Fear avoidance

Fear and anxiety change an individual's experience of pain, as well as their experience of disability as a result of chronic pain [72]. The fear-avoidance model was developed as a cognitive behavioural model for chronic low back pain to assist understanding in how disability develops as a consequence of chronic pain [73]. The model proposes that pain may be interpreted by the individual in different ways: either as threatening or non-threatening. This interpretation will lead to either an adaptive or a mal-adaptive response, which then has consequences on the individual's ability to recover [73, 74]. A threatening interpretation of pain, e.g. that pain is a sign of damage, may lead the individual to reduce activity based on the understanding that avoidance is necessary to preserve their body. This reduced activity results in deconditioning so that when the individual does attempt activity, it is easier to generate nociception and pain, resulting in further avoidance and the initiation of a disabling cycle [73, 75]. Hurley describes fear-avoidance as dysfunctional behaviour where the patient will avoid activities which they believe to be harmful because of fear of pain and causing further harm [44]. It is important to remember that the behaviours exhibited by patients showing fear-avoidance are not inherently bad, and in the acute phase of an injury, can in fact be useful. It is when the behaviours persist with long-term pain that they become problematic [73] (Figure 2).

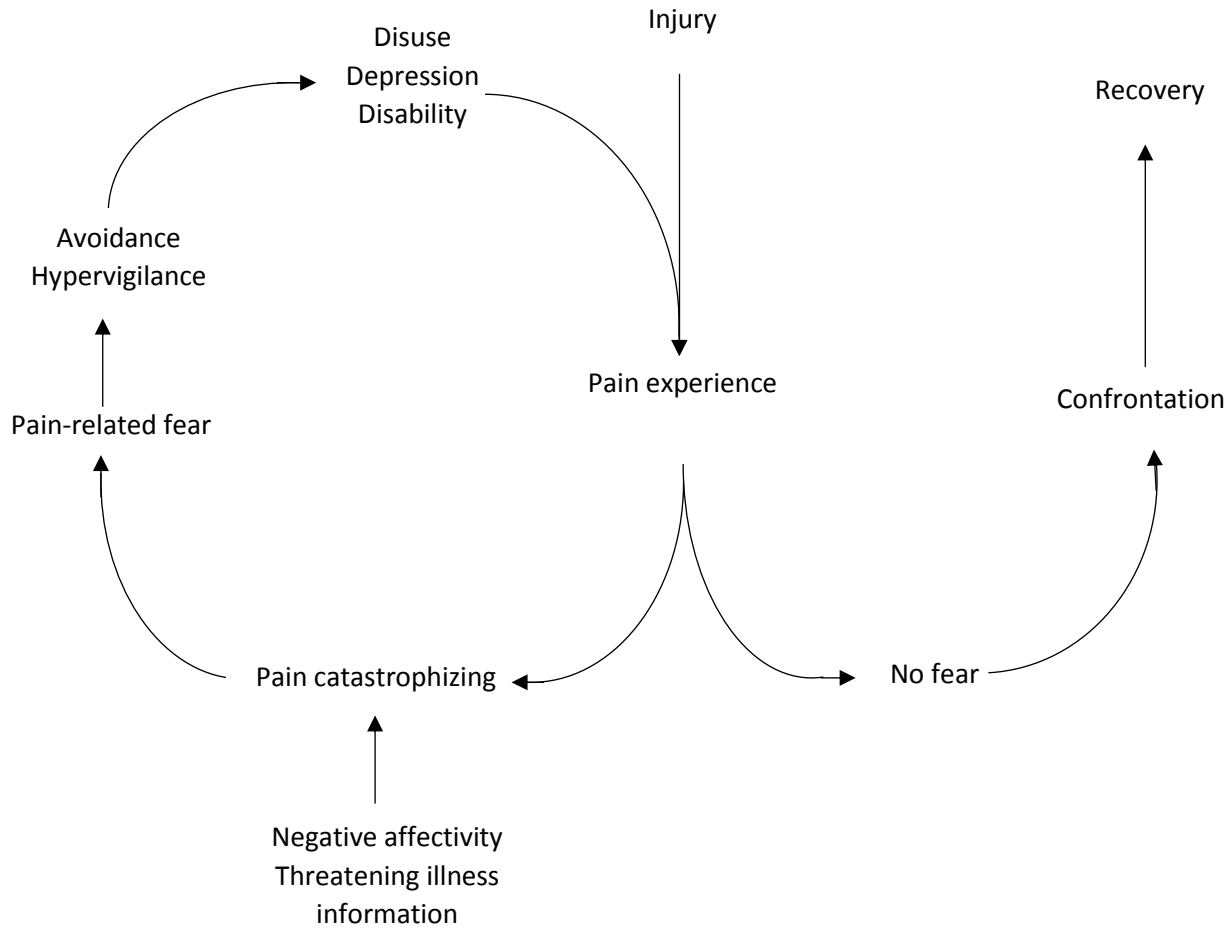


Figure 2: The Fear-Avoidance Cycle [72]

Additionally, the avoidance of activities which may cause pain results in reward for the patient by reduction of fear, anxiety, pain etc., and thus further reinforces this pattern [72]. This cycle of fear avoidance not only creates physical disability and deconditioning, the resulting reduced participation can lead to depression, frustration, and irritability [72], which compound the problem further. Pain-related fear also interferes with cognitive functioning, with a hyper-vigilant patient being unable to draw their attention away from pain related information and attend to basic daily tasks which require some problem solving [72]. Literature, not looking at fear-avoidance specifically, suggests that an individual's current level of pain will influence their future function [20], essentially what the fear-avoidance model is proposing.

In a study from the USA it was noted that higher fear-avoidance beliefs were associated with poorer function, however the study was unable to establish causality between the two [74]. A separate study in the Netherlands similarly did not establish causality, but noted that fear-avoidance was a sizeable problem and was negatively associated with function in patients with OA [76]. Furthermore, it is suggested that based on the results of the Dutch study, treatment strategies for those OA patients in the sub-group who experience high levels of pain-related fear be investigated in order to return them to their best possible level of function [76]. Using the fear-avoidance explanation, one may see that fear may drive CNS processes and contribute to the development of CS.

2.5 Assessment of OA

As mentioned previously, OA is defined in a number of ways, and as such, diagnosis may be made using a number of assessment methods. There are diagnostic recommendations available regarding the diagnosis of OA from both the American College of Rheumatology (ACR) [77] and the European League Against Rheumatism (EULAR) [78]. The Kellgren and Lawrence grading scale is a radiographical grading system used to classify osteoarthritis [79] A diagnosis may be made without radiographical imaging using both the EULAR and the ACR clinical guidelines, however the ACR guidelines have specific subset, which make use of imaging along with various other OA –related symptoms. In the current study, the patients had been diagnosed with OA and imaging had been conducted. None of these available guidelines take into account the potential presence of CS or fear-avoidance beliefs and as such, they are not assessed as part of any diagnostic criteria. Of course, one may not necessarily have CS simply because OA is present, but as already established, there appears to be a sub-group of patients for which this kind of assessment may prove to be crucial in improving their outcomes.

It may be useful to begin to look into assessing for CS and fear-avoidance as part of a diagnostic process in patients with OA, as it would allow for appropriate interventions to be commenced timeously. For a start, questioning regarding symptoms of CS maybe useful for screening those at risk. The Central Sensitivity Index (CSI) was developed with the goal of minimising or completely removing unnecessary diagnostic and treatment procedures by helping clinicians to better assess symptoms thought to be associated with CS and thus categorise syndromes more appropriately, identify sensitivity and severity, and plan treatment optimally [80]. NIjs et al (2014) have also created an algorithm for classifying pain as neuropathic, nociceptive or CS pain [81] This proposed algorithm makes use of the CSI and seeks to classify pain as CS, by excluding neuropathic and nociceptive pain [81]. Along with the CSI, the Tampa Scale of Kinesiophobia (TSK) could be used to assess fear of movement in these patients. The TSK will be discussed in greater detail in the section on outcome measures.

2.6 Current Management of Osteoarthritis

2.6.1 Guidelines for management

Due to the high prevalence of OA and the increased burden it places on the health system, as well as the individual, it is of utmost importance that correct management is implemented. Understanding that each patient is different in terms of their preferences and personality, health teams need to ensure that management strategies are tailored to be acceptable and appropriate in meeting the needs of the individual being treated [15, 17]. There are current guidelines available set out by various expert groups, which cover surgical and non-surgical methods; including pharmacological and non-pharmacological management of the condition. Guidelines have been produced by the ACR, EULAR, OARSI, NICE, and ESCEO.

The 2012 update to the ACR guidelines focused on non-surgical guidelines for knee OA specifically, and include both pharmacological and non-pharmacological interventions [17]. The EULAR similarly offered guidelines for both the pharmacological and non-pharmacological management of OA knee [82]. The guidelines by the Osteoarthritis Research Society International (OARSI), the National Institute for Health and Clinical Excellence (NICE) and the European Society for Clinical and Economic Aspects for Osteoporosis and Osteoarthritis (ESCEO) include both surgical and non-surgical interventions, as well as pharmacological and non-pharmacological interventions for hip and knee OA [13, 83, 84]. The recommendations according to these guidelines for management of OA will be explored in further detail in the following sections, however the pharmacological interventions are not the main focus of this study and have been summarised briefly in Table 1. Notably, there has been an update to the OARSI non-surgical guidelines since 2008, but the surgical guidelines do not appear to have changed since then [85].

Table 1: Pharmacological interventions for OA knee

OARSI **[85]**	NICE **[83]**	ACR **[17]**	EULAR **[82]**	ESCEO **[84]**
Paracetamol	Paracetamol	Acetaminophen (Paracetamol)	Paracetamol	Paracetamol
Oral non-selective NSAIDs or COX-2 selective NSAIDs	Oral NSAIDs (or COX-2 inhibitors with proton pump inhibitor)	Oral NSAIDs (or non-selective NSAIDs or COX-2 inhibitors with proton pump inhibitors)	Oral NSAIDs (or non-selective NSAIDs with gastroprotective agents or COX-2 inhibitors)	Oral NSAIDs (or non-selective NSAIDs or COX-2 inhibitor with proton pump inhibitors)
Topical NSAIDS	Topical NSAID	Topical NSAIDs	Topical NSAIDs	Topical NSAIDs
Capsaicin	Capsaicin		Topical Capsaicin	Topical Capsaicin
Intra-articular corticosteroid injections	Intra-articular corticosteroid injections	Intra-articular corticosteroid injection	Intra-articular corticosteroid injection	Intra-articular corticosteroid injections
	Opioids		Opioids	Opioids
			Intra-articular hyaluronic acid injections	Intra-articular hyaluronate injections
			Glucosamine sulphate	Glucosamine sulphate
			Chondroitin sulphate	Chondroitin sulphate
		Tramadol		
Duloxetine				Duloxetine

According to the OARSI and EULAR recommendations, treatment of knee OA should be aimed at decreasing pain and stiffness in the affected joints, managing joint mobility, improving physical function, raising health-related quality of life, limiting further joint compromise, and teaching patients about OA and its management [13, 82]. There appears to be consensus throughout the guidelines that a combination approach using both pharmacological and non-pharmacological interventions allows for optimum management of patients with knee OA [84]. However, if these guidelines are viewed through the framework of the ICF, they are all lacking in terms of addressing participation in life roles. Perhaps there is an assumption that raising health-related quality of life would include this component of treatment.

More importantly the focuses of this study, are the evidence based non-pharmacological interventions. Information or education, weight-loss when appropriate, and exercise are three core non-pharmacological interventions which feature in all the guidelines reviewed [17, 82-85]. In cases where the patient is not getting the desired relief of symptoms and functional gains from the combined conservative interventions, surgical intervention is recommended [13, 82-84]. A number of other non-pharmacological interventions suggested may be acceptable for use in the management of knee OA. These, along with the aforementioned non-pharmacological and non-surgical interventions will be discussed below.

2.6.2 Non-surgical management

2.6.2.1 Education

Education is recommended specifically by four of the five guidelines reviewed [82-85]. The ACR guidelines do not specifically mention education, but recommend psychosocial interventions as well as the use of self-management programmes, which often rely heavily on education [17]. Education should focus on helping the patient to understand more about their condition, as well as the objectives of management [83, 84]. Though the more recent non-surgical OARSI guidelines recommend education, they do not specify as to what the topics should be [85]. The older OARSI guidelines suggest that along with the focus mentioned previously, education should include information regarding the importance of lifestyle changes (exercise, activity pacing, weight-loss) which may help to offload the affected joint [13] and the EULAR guidelines recommend that education addresses the nature, causes (specific to the individual), consequences and prognosis of OA [15]. The guidelines all seem to emphasise education about the pathology of OA and its management based on an understanding that pain is a consequence of joint damage. The guidelines do not appear to incorporate education about pain mechanisms and ensuring that patients understand that pain may be as a consequence of CS rather than of joint processes. This lack of detail about what educational topics should be provided makes it difficult to implement and evaluate.

Education, in particular education which aims to increase patients' self-efficacy, has been shown to reduce financial costs as it leads to fewer primary care consultations and is beneficial in decreasing pain and improving coping skills in patients with knee OA [82]. Interestingly, in formulating their guidelines, EULAR found that education did not appear to exert any effect on level of function [82]. As mentioned above, this might be related to the educational content or to the educational method not being aimed at increasing self-efficacy. The EULAR results also lead one to consider what other factors are at play which may influence the ability of the individual to translate knowledge into action or behaviour. Thus for optimal management of these patients, treatment needs to be multi-pronged, considering personal and environmental factors to facilitate behaviour change.

2.6.2.2 Exercise

Various types of exercise have been recommended for use in the management of knee OA. Exercises focussing on strengthening of the lower limb and muscles around the knee, joint mobility exercises and general aerobic exercises were recommended by several expert groups [82-85]. Exercise may also be land or water based [17, 82, 84, 85] and may serve as a helpful means of assisting with weight-loss for patients where this is necessary [86]. According to both the EULAR and ESCEO groups, consensus has not yet been reached on the optimum exercise programme or dosage for patients with knee OA [82, 84]. Thus, the intensity, dosage and type of exercise programme to be administered is left to the discretion of the physiotherapist or other healthcare provider administering the programme.

Exercise may be done in group classes, in individual therapy sessions or at home without supervision. Each method of delivery has its own pros and cons, however all three provide effective relief from symptoms [86]. Having said this, the review by Bennell and Hinman (2011) also found that exercise supervision may be associated with improved results and that more than 12 supervised sessions showed better treatment effects than less than 12 supervised sessions [86]. In another review, evidence for the short-term benefits of exercise for patients with OA was overwhelmingly positive, however longer term follow up on these patients revealed that these benefits were not maintained over time [87]. Due to a lack of evidence, authors speculate that the reason for lack of long-term benefits in these patients may be a lack of adherence to exercise [87]. Once again, this emphasises the need for attention to the methods used in the delivery of both educational and exercise interventions to achieve long term behaviour change and symptom management.

2.6.2.3 Other modalities

In addition to education and exercise, recommendations have been made for other modalities to assist in non-surgical management of these patients. These include both medical and alternative options. The more recent OARSI guidelines differ somewhat from all the other groups in that the only other options they recommend are balneotherapy[1] (not mentioned in any of the other guidelines), cane use, and biomechanical intervention (including knee braces, knee sleeves, shoe wedges and insoles) [85]. Heat therapy, walking aids (when necessary) and transcutaneous electrical nerve stimulation (TENS) were recommended by three of the five guidelines [17, 83, 84]. There appeared to reasonable consensus supporting the use of manual therapy [17, 83, 84], bracing, joint support and insoles [17, 82-85]. Acupuncture was recommended in two of the guidelines as a technique for relief of symptoms [17, 84]. These are obviously not core recommendations as are exercise and education, but may be of assistance as additional symptom management for patients seeking greater relief.

2.6.3 Surgical interventions

Surgical options for the management of OA of the knee include total knee arthroplasty (TKA), unicompartmental replacement, high tibial osteotomy, joint lavage and arthroscopic debridement, or total fusion of the joint [13]. For OA limited to a single compartment of the knee, a unicompartmental replacement is recommended by OARSI as an effective treatment, and in young, active patients with severe symptoms from unicompartmental OA, a high tibial osteotomy may delay the need for TKA for several years [13]. Joint lavage and arthroscopic debridement may offer some short-term relief, however there is debate as to whether this is a result of a placebo response or as a result of the surgery itself [13] and according to the NICE guidelines it should not be offered routinely [83]. The possibility of a placebo response being effective may offer some support for the argument that a centrally sensitised system is driving pain in some these patients. In cases where TKA has failed, fusion of the joint may be considered as a final measure [13].

[1] The use of baths containing thermal mineral waters (spa therapy)

Considering the focus of the current study, TKA will be the main discussion point. TKA is a procedure which should only be considered when the patient is no longer receiving the desired relief and functional improvement from conservative and pharmacological management, or when physical function has deteriorated to a point where it is no longer adequate [13, 16]. According to OARSI guidelines, TKA is the most appropriate treatment for patients who no longer respond to non-surgical management [13]. When assessing the success of a TKA in terms of radiographical appearance of the artificial joint, prosthesis survival and outcomes as evaluated by the surgeon, it appears to be a highly successful intervention [24] and this appears to be true for most patients. The problem however, as mentioned earlier, is that there are a noticeable percentage of patients who do not obtain the desired and expected pain relief and improvement in function following surgery [24]. A group of 10% - 34% of patients undergoing TKA and not achieving good outcomes is alarming and requires the attention of clinicians and researchers alike to design and implement management programmes which focus on more than just the physiological impairment but that address the CS aspects for these individuals. One method to address these aspects is education and exercise focussing on reducing the fear of movement.

2.6.3.1 Barriers to surgery

Even though TKA is recommended, there are barriers to this management option. In the South African context, the main barrier is accessibility. Waiting lists are a common problem and the evidence regarding the effects of being placed on a waiting list for joint replacement yield mixed results. Several studies suggest that being placed on a waiting list has a negative effect on an individual which may include reduced levels of activity, reduced quality of life (QoL) and increasing impairment of function [19, 88-92]. Interestingly, a study by Ackerman in Australia found that amongst individuals placed on a waiting list for joint replacement surgery, those with the lowest income had the worst HRQoL, and that those with the lowest income or the lowest level of education experienced the most psychological distress [92]. These findings are particularly relevant in a South African State health setting where the majority of patients are from low-income households with low levels of education and waiting times for surgery often exceed two years[18]. However, the Australian study did not assess HRQoL of individuals prior to being placed on the waiting list, thus making it difficult to assess causality. With these long waiting lists and poor access to surgery, patients require alternative management strategies. Self-management groups may provide a promising alternative.

2.6.4 Self-management groups

Self-management refers to the active participation of a patient in their own health and their ability to manage it on a daily basis [93, 94]. Clark et al (1991) describes self-management as being based on Bandura's social cognitive theory which suggests that human behaviour is governed by the interaction of personal, environmental and cognitive factors [93]. Using this theory as a base from which to work, self-management programmes strive to change the perception of the individual regarding their ability to manage themselves and their health. Perceptions are changed using education about their condition and encouraging discussion around relevant points related to this, goal setting, and monitoring of changes in behaviour [93-95]. For patients with chronic conditions, effective self-management is not simply a once off treatment, but requires life-long commitment to managing themselves and their illness well [94] and unfortunately problems relating to adherence are not uncommon [96].

Self-efficacy, as described by Bandura (1977), relates to an individual's confidence in their own ability to execute a behaviour in order to achieve an outcome [97]. It is this confidence which is referred to in the previous paragraph regarding the individual's perception of their ability to self-manage. As mentioned earlier, beliefs regarding ill-health can lead to feelings of helplessness, reduced self-efficacy, reduced ability to cope, and depression [44]. Along with this, misconceptions around pain, activity and damage, leading to a drop in physical activity to spare the joint, can increase disability in patients with knee OA [75]. As discussed previously, self-management interventions aim to increase self-efficacy [95]. Self-management interventions challenge incorrect beliefs and are important in the provision of alternative, more accurate information on which to base new beliefs , and thus provide facilitation towards more appropriate physical behaviour [75].

Studies evaluating the effectiveness of self-management programmes for people living with OA have yielded mixed results. Two separate systematic reviews have assessed a number of self-management group intervention studies [98, 99]. Notably none of the included studies in the systematic reviews included an exercise component. A small effect size of 0.1 was found [98] and both of the reviews suggested that individuals with OA seem to benefit minimally from self-management education programmes when compared with usual care.

The 25-year old Arthritis Self-Management Programme (ASMP) is an arthritis specific self-management programme which was developed out of a needs assessment conducted on arthritic patients and their rheumatologists [100] and is based on self-efficacy theory [95]. The programme consists of six two-hour sessions, held once a week and led by two trained peer-educators, at least one of whom has a rheumatic condition. Group sessions are not conducted in hospitals or clinics and usually happen at community centres or other community venues. Any patients with rheumatic conditions may enrol, and their partners may also attend. The group sizes are limited to between 10 and 15 participants [100]. Participants receive the Arthritis Helpbook as a reference guide and goal-setting and report-back are important aspects of the course [95]. The programme includes education regarding exercise, but does not include an exercise component during a session [98, 100].

The Chronic Disease Self-Management Programme (CDSMP) is based on the same principles as the ASMP but is a more generic programme which can be applied to a variety of chronic conditions [100]. Participants receive a reference book on Living a Healthy Life with Chronic Conditions [100]. It also runs for six-weeks, however sessions are two and a half hours long and not two hours like the ASMP. It is peer led and community based like the ASMP [100]. It also provides education regarding exercise, but does not include an exercise component in the session [98]. Anyone with a chronic disease is eligible for participation in this programme, resulting in greater heterogeneity in these groups than those of the ASMP [100].

In a study comparing the ASMP and the CDSMP for use by patients with arthritis in the USA, it was found that both were beneficial, however at four months and one year follow-up the ASMP group showed greater improvement in health distress, fatigue and activity limitation than those with arthritis in the CDSMP group [100]. Participants were not excluded if they had arthritis which was not OA and as such this study included those with rheumatoid arthritis (RA) and 'other arthritis'. Though the focus of the study was to compare the two interventions, it may have been useful to include a control group for further comparison. The results of this study appear promising for arthritis-specific programmes, however they are difficult to generalise to a South African population as the literacy levels of the USA populations are higher than the South African average [30].

Another randomised controlled trial (RCT) assessing the ASMP in a UK population found that improvements in perceptions of control, use of health-management techniques (including exercise) and health status were all maintained at four and 12 months follow-up in the ASMP group compared to the control group which was placed on a four-month waiting list. Along with these improvements, patients in the ASMP group needed to visit their general practitioner less often at the 12 month mark than those in the control group [95]. The majority of the sample in this study was female, and in both the control and the experimental group, only 52% of the participants had OA. The remaining 48% included RA and other [95]. Notably, 52% of the participants in each group also had some sort of formal educational qualification, suggesting that there was generally a fairly high level of education in the sample [95]. Interestingly, although an improvement in the use of exercise was noted and maintained at 12 month follow-up, physical function levels remained relatively unchanged in both groups throughout the course of the study, and a small reduction in physical function was even noted in those with OA at 12 month follow-up [95].

The results seem to contradict one another as one might assume that if exercise increased, so should physical function. It is possible that the method of data collection, posted questionnaires, was not an accurate way to evaluate function. It would be more accurate to measure function through physical tests. Once again, this study is not entirely generalizable to the population in in the current study as education levels are vastly different. Increasing exercise participation in the intervention group is finding, despite the findings regarding levels of function. These results however, need testing in populations with lower levels of literacy.

As previously noted, the ASMP does not contain an exercise component, however it does educate patients about exercise [95], which may have a part to play in the success of the programme. The education section of a successful self-management programme aims to teach new skills which facilitate behavioural changes and create a sense of self-efficacy with which the patient can then continue to make good decisions regarding their own health [93, 94]. However, the lack of an active exercise component in the ASMP may limit the effectiveness of the intervention. This separation of education from active participation in exercise within self-management groups was noted by Hurley and Walsh [75]. Based on current evidence suggesting that an exercise component may be a crucial aspect in the creation of a successful self-management programme, this separation poses a problem [11]. This is an interesting omission given that the ASMP is based on self-efficacy theory, as the theory itself suggests that the patient needs the opportunity for personal mastery of a task for the fostering of self-efficacy [97]. Thus, whilst the ASMP and CDSMP yield positive results by providing only education and monitoring of behaviours, there is a gap in providing patients with a regular, structured opportunity to practice exercise in a safe and controlled environment with a trained group leader or health professional.

Though not explicitly stated, the ESCAPE knee pain programme appears to have been developed around the principles of a biopsychosocial framework and is based on the ICF understanding that physiological, psychological, behavioural and socio-economic variables all contribute to the physical function, pain, behaviour, and health-care use of an individual [11]. The programme makes use of education and group discussion, graded exercise, and self-management strategies and aims to change the unhelpful beliefs and behaviours of the participants regarding their condition and their ability to be physically active [101]. The programme may be delivered as an individual intervention or as group rehabilitation, with both modes of delivery yielding improvements in function for up to six months following the intervention [102]. Groups consist of eight participants and are held twice a week for six weeks [102]. The education and discussion section of the sessions typically runs for 15-20 minutes and is followed by 35-45 minutes of an individualised exercise programme for each individual [102].

The ESCAPE-knee programme was found to be more clinically- and cost-effective in a UK cohort than usual care in the short term, and provided benefits which were still evident at 30 months follow-up [11]. As with the previous studies, the sample consisted mainly of females, however education levels were not reported on, leaving a gap in the reader's ability to compare with other literature [11]. Participants were also accepted with a history of more than six months of mild to moderate knee pain and a clinical diagnosis of OA from their doctor, without any imaging to confirm this diagnosis [102]. Follow-up was also only done immediately following the intervention and then 12 months later [101], making it difficult to compare the results of the ESCAPE trial to those of the current study. Interestingly, the ESCAPE study, did not manage to recruit their target number of participants leading one to wonder if this a common problem with studies of this nature in this specific patient population.

A recent study conducted in a Cape Town population awaiting hip and knee arthroplasty [29], made use of a "Living with OA" programme which was based on the ASMP [100], the ESCAPE knee pain programme [102], and the Positive Living Self-Management Programme [103]. The programme includes six sessions held once a week over six weeks in succession. Each class or session runs for two hours and includes an education component, an exercise component and relaxation training (Appendix A). The programme is designed to be facilitated by a physiotherapist who is trained in providing the information and exercise. Groups consist of a maximum of 12 individuals, allowing for the development and fostering of relationships between participants and meaningful discussion, whilst still ensuring that the facilitator maintains coherence [103]. Goal setting on a weekly basis is used to facilitate increases in self-efficacy and behaviour change.

The study by Saw (2015) examined the effects of a six-week physiotherapist-led exercise and education based intervention on patients awaiting total hip and total knee arthroplasty in a Western Cape population. There were positive results in the experimental group when compared to the control group that showed significant improvements in pain severity, pain interference and function. These encouraging results were all maintained at six months follow-up [29]. The sample group in this previous study may be useful for comparison in that it was very similar, with the only real difference being that people with hip OA were included [29]. The most notable difference between the populations in the previous and current studies is that participants in the previous study were still on the arthroplasty waiting list and were not expecting surgery in the near future.

It has already been mentioned that 10%-34% of patients undergoing TKA continue to experience persistent pain following their surgery [24], and it has also been suggested that a possible cause may be the development of CS in these patients [1, 23, 63]. In the state health setting in South Africa waiting lists are known to be lengthy, and as already discussed severe pain and a longer waiting time for surgery put patients at an increased risk of persistent pain following TKA [25]. The evidence above suggests that intervention groups can provide improvements for those on a waiting list, especially if they include an exercise component. These interventions improve pain because they appear to address both peripheral and central pain mechanisms, thus addressing CS in these patients [104]. Perhaps if one could improve pain and function pre-operatively, post-operative outcomes could be improved.

Optimising health status before surgery should be an important feature of pre-operative management [105], and patients on a waiting list for TKA are prime candidates for participation in interventions aiming to minimise pain and maximise function with the objective of optimising surgical outcomes. None of the studies reviewed above have conducted any post-surgical follow-up or have provided the intervention before surgery in the hopes of improving surgical outcomes in these patients. So far, patient self-management interventions have been used in isolation as a means of improving quality of life, pain and function in individuals with knee OA for whom surgery is not imminent. At present there appear to be gaps in the literature relating to the effects of these interventions on post-operative outcomes and the current study aims to take a step in the direction of assessing whether or not the promising results in the available literature may be the same for patients undergoing surgery. To effectively determine whether post-operative outcomes are impacted by an intervention, appropriate outcome measures are needed.

2.7 Outcome measures

There are six primary outcome areas which need to be considered when conducting clinical trials on patients with chronic pain as set out by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) [106, 107]. These six areas include 1) pain, 2) physical functioning, 3) emotional functioning, 4) participant ratings of improvement and satisfaction with treatment, 5) symptoms and adverse events, and 6) participant disposition [108]. Bearing this in mind, consideration was made of various outcome measures in an attempt to most accurately evaluate the above listed areas.

2.7.1 Pain

Since pain is the most noticeable symptom in most people with arthritis, and is the most important factor in determining disability in patients with OA, it is the primary outcome measure in this study [8]. Using the IASP definition of pain, it is accepted that pain is experienced both physically and emotionally at the same time, and that it is a completely subjective experience[26]. This makes measuring pain a difficult task, however a number of tools have been designed to perform this function.

The numerical rating scale (NRS), Visual Analog Scale (VAS) and Verbal Rating Sale (VRS) are all unidimensional tools, measuring pain severity. The NRS is usually scored along a line with the left end being zero (no pain) and depending on the highest number used, the right end is either 10 or 100 (worst pain). The VAS is similar in that the patient is provided with a 10cm line, along which they can mark their pain (lowest to highest). The VRS is more appropriate for patients who may struggle to express their pain using a numerical value, and uses the descriptors of “no pain, mild pain, moderate pain and severe pain”[109]. These tools are useful in that they may be quickly administered and are generally easily understood by patients making them useful clinical bedside tools. However, due to their simple nature they do not assess the other complex aspects of the pain experience [110] such as pain interference with function, impact on QoL, and participation in meaningful life roles. This limits their usefulness in research.

The McGill Pain Questionnaire (MPQ) is a 78-item, multi-dimensional tool used for assessing the sensory and affective aspects of pain [110]. It is administered by an interviewer, and meanings of words are clarified as necessary. It may take up to 20 minutes to complete [110]. The Short-Form McGill Pain Questionnaire (SF-MPQ) was developed by the original designer in response to the realisation that the full MPQ was too long and complicated to be used in most clinical research [111]. Both the MPQ and the SF-MPQ are valid and reliable tools for measuring pain and have been used widely [110], however their use of fairly complex language and the length of time to complete the MPQ make them inappropriate for use in the current research setting. From the available literature, it does not appear that the MPQ or the SF-MPQ have been translated or validated for use with an isiXhosa population in South Africa.

The measure of Intermittent and Constant Osteoarthritis Pain (ICOAP) is another multidimensional tool, developed by Osteoarthritis Research International (OARSI). It was designed to measure the pain experience of people with knee and hip OA specifically. There are separate versions available for the hip and knee [110]. It is easy to understand, and has been translated from English into several other languages. Unfortunately, although translation has been done widely, studies evaluating the validity, responsiveness and reliability of the tool have not been conducted for all those translations [110] and translation has not yet been done into either Afrikaans or isiXhosa.

The BPI is a short, self-administered questionnaire assessing pain severity, and pain interference with function [106, 112]. Originally designed for measuring pain in cancer patients, it has since been validated for use in chronic, non-malignant pain, non-cancer pain and OA [34, 35]. Reliability scores for both pain severity and pain interference scales range between 0.82 and 0.95 [34]. Having been widely used in research and translated and linguistically validated in both Afrikaans and isiXhosa [113, 114], the BPI short form provides a useful tool to be used in measuring pain severity and pain interference in a Western Cape population. The BPI was also used successfully in two recent studies conducted in a South African population with OA, awaiting total hip or total knee replacement [29, 115]. Furthermore, one recent study in particular [29] made use of the BPI in the same population group and setting in which the current study is to be carried out, suggesting that it is indeed an appropriate and reliable tool for measuring pain severity and interference in this study.

2.7.2 Physical Functioning

As prescribed by the IMMPACT group, physical functioning is one of the primary areas needing to be assessed in any clinical trial involving patients with chronic pain [108]. There are a number of tools available to assess physical function and disability, however not all are appropriate for use in patients with OA. The Health Assessment Questionnaire (HAQ) is a 20-question self-report tool in which the higher an individual's score, the greater the level of disability [116]. It has been validated numerous times, translated into over 60 languages and culturally adjusted as appropriate, and has been used in populations with OA [117]. Interestingly however, in a recent study conducted in a Cape Town population where the HAQ was used to assess disability, the author suggested that for future studies the WOMAC (which is OA specific) be considered instead. This suggestion was made to cross-validate the pain interference score on the BPI [29].

The Knee Injury and Osteoarthritis Outcome Score (KOOS) was developed for use in younger populations with knee injury or OA [118]. According to a systematic review by Collins et al (2016), the KOOS was sufficiently valid, reliable and responsive for use in patients with OA of the knee [119]. The reliability, validity and responsiveness of the KOOS for older populations has been studied and it has been established as a suitable tool for use in older patients in Sweden [118] and in the USA [120]. However, the tool has not yet been translated and validated in either Afrikaans or isiXhosa and studies could not be found having used the tool in South African populations.

The WOMAC, having been used widely in research assessing patients with hip or knee OA [11, 101, 102, 121, 122], has proven to be a useful arthritis specific tool when it comes to evaluating disability and level of function. In a UK study comparing the HAQ, the Short Form-36 and the Euroqol, the WOMAC was established as the assessment tool of choice when it came to evaluating the outcome of TKA [123]. It evaluates pain, stiffness and physical function and there are both Likert and Visual Analog Scale (VAS) versions available [36]. It is a valid and reliable tool for use in patients with OA, and has been translated for use into one of the two languages needed for this study; Afrikaans [124]. In a Swedish population awaiting TKA, the internal consistency scores of the pain, stiffness and function sub-scales of the WOMAC were 0.91, 0.91, and 0.98 respectively [125]. The WOMAC at this point, has not been translated and validated in isiXhosa and therefore for the purposes of the current study it will need to be translated into isiXhosa and its reliability and, if possible, validity explored.

2.7.3 Health-related QoL

Health-related quality of life appears to be somewhat difficult to pin down and explain in one definition. There are at least four definitions used throughout the literature according to Karimi and Brazier (2016 p. 646), with the two which appear most appropriate being, "How well a person functions in their life and his or her perceived wellbeing in physical, mental, and social domains of health" and "those aspects of self-perceived well-being that are related to or affected by the presence of disease or treatment" [126]. As suggested in the previous paragraphs, OA may have devastating effects on the individual which are not only physical in nature [44] and in order to treat the patient holistically and appropriately these emotional/ psychosocial aspects should not be neglected.

A number of tools are available for assessing health-related quality of life (HRQoL). The Sickness Impact Profile (SIP) is a broad HRQoL measure designed to be applied to a number of different health conditions, measuring perceived health status [127]. The tool was developed over six years and contains 136 items in the questionnaire [127]. It has been found to be sufficiently valid and reliable for use in a variety of conditions [127], however given the length of this tool and the expected low levels of education in the current sample, it is likely to be inappropriate for measuring HRQoL.

The Medical Outcomes Study 36-Item Short-form Health Survey (SF-36) was designed for use in both research and clinical practice [128]. According to Stewart (2007), it is the most widely used generic health survey [129]. As the name suggests there are 36 items which the patient must respond to in a self-administered questionnaire [129]. The tool has shown adequate validity and reliability for a number of populations and health conditions, including OA [129, 130] and has been standardised [128]. According to campaign.optum.com the tool has also been translated into Afrikaans and isiXhosa [131], both languages spoken by participants in the current study. The source did not provide information regarding the validation in these languages. Although the name suggests brevity of the tool, it is in fact quite a long questionnaire and given the number of tools being used and the lower levels of education in the population being studied, the researcher aimed to use the simplest tool possible as far as language complexity and length, whilst still maintaining valid results.

The abbreviated version of the SF-36, the Short Form 12 (SF-12) is also a general health status questionnaire and was originally developed in the USA [132]. It was developed and tested on a European cohort across nine different countries and found to have a strong correlation with the results on the SF-36, leading the authors to suggest that it is a suitable, more practical alternative to conducting the full SF-36 in those countries [132]. As is the case with the longer version, the SF-12 has been translated into both Afrikaans and isiXhosa, but information regarding the validation in these languages could not be found [131].

The EQ-5D-5L is one of the most commonly used tools for measuring HRQoL [133]. The three-question version (3L) has been validated and its reliability established for use in South Africa, but the five-question version (5L) has not yet been tested [133]. The 5L has been translated into both isiXhosa and Afrikaans, with strict checks and cognitive debriefing having been done to ensure cultural equivalence and face validity of the translations (personal communication Jelsma, 2015). Both of the translated versions are recognised by the EuroQol Group [133, 134].

Both the SF-12 and the EuroQol Instrument (EQ-5D) have been used in research, however no norms exist for either of these tools in a South African population[135]. The closest normative data is for Zimbabwe, another African country, and this is only available for the EQ-5D. When comparing the SF-12 with the EQ-5D-5L, the latter seemed the more appropriate option, given the simplicity and brevity of the tool and that two recent studies in a South African population made use of the EQ-5D 5L successfully, one of which was conducted in a population similar to the one to be studied [29, 115]. Despite the 5L having not yet been tested on this population, it will be used in the current study as it is expected that it will be more sensitive to change over time than the 3L as it provides the respondent with more options to describe their experience [135].

2.7.4 Function

OARSI has recommended that functional performance tests include the 30 second chair-stand test, 40m fast-paced walk test, a stair climb test, a timed up and go test (TUG) and six minute walk test 6MWT [136]. Selection of these tests was carefully considered based on three specific activity themes which are pertinent to patients with OA and which interventions often aim to improve. These were 1) walking tests, 2) stair negotiation tests and 3) sit-to stand tests. Within each theme there were several tests available to assess it and as such aspects of feasibility, measurement evidence and scoring played a role in selection [136]. Importantly, they recommend that these tests are used along with patient report measures as complementary assessments [136].

One measure of function, the Stratford Battery uses four of these tests to assess pain and physical performance in patients with OA. These include a self-paced walking test, a TUG test, a stair test and a 6MWT [137]. All of these appear to be appropriate for assessing lower limb function in patients with knee OA. In the study by Stratford et al (2006), which was unfortunately limited by a small sample size, they suggested that the stair component of the battery be excluded from a composite score analysis as it leads to a less distinct impression of pain and function [137]. They do stress that although it should be excluded from the composite score in order to get the most accurate impression of the patient's pain and function, it should not be left out altogether [137]. This is problematic from a research perspective as it suggests that the Stratford Battery in its entirety is not a suitable tool for assessment of function in clinical trials and according to OARSI's recommendations a stair climb test is one of the core tests that need to be conducted [136]

A large systematic review by Freiberger et al (2012), evaluated the Continuous Scale Physical Performance, MacArthur battery, Modified Timed Movement Battery, Mobility-Related Limitation Index, Physical Capacity Evaluation, Performance-Oriented Mobility Assessment, Performance Based Physical Function Test, Physical Performance Test, Shinkai Summary Performance Score, Short Physical Performance Battery, Task Modification Scale and the Upper Extremity Summary Performance Score [138]. They recommended that the Short Physical Performance Battery (SPPB) be used as it performed best on measures of reliability, validity and responsiveness. The two next best alternatives, according to the authors, were the Physical Performance Test and the Continuous Scale Physical Function Performance (CS-PFP) [138].

The SPPB is made up of balance tasks; side-by-side stand, semi-tandem stand and full tandem stand; an eight meter timed walk test; and a timed five times sit-to-stand-test [139]. As already mentioned it has demonstrated good reliability, validity and responsiveness [138] and has been used in studies on the elderly [139]. The test takes approximately 10-15 minutes to complete [139] which, when one considers that there will be four other questionnaires used in the current study, is quite time consuming. It also has a specific balance component to it, which may not be appropriate for this population. Another problem with the SPPB is that it does not have a stair climb component to it, which, based on the OARSI recommendations, makes it less suitable for the research to be conducted.

The CS-PFP is a long test, made up of 16 household tasks, which the patient performs in a way that they prefer. It takes up to an hour to complete and requires the use of a laboratory space [140]. The tool is valid and reliable for use in a variety of patients [140]. A shorter version, consisting of ten items, has been developed as an alternative [140]. Both are valid and reliable and satisfy the OARSI recommendations for tests of function [140]. The length of both of these versions, as well as the inclusion of aspects unrelated to lower limb function make them inappropriate for use in the current study.

Formerly called the Aggregated Function Performance Time, the ALF has been used successfully in research on patients with OA (Personal communication Hurley, 2015). The tool is valid and reliable for use in patients with OA [38]. Although not validated for use in a South African context specifically, the tasks to be performed are generic and can be applied to any context. The test consists of four timed tasks, namely: a straight line walk, an up and go test, stairs ascent and stairs descent. The total time taken for the four tasks is calculated, and then divided by four, providing the researcher with the mean time for the test. The four tasks in this test, whilst not the exact tests that OARSI recommended, satisfy the themes to be addressed in that there is a walking test, a stair climb test and a sit-to-stand test [136]. The ALF is simple and easy to administer, has been used in OA studies as previously mentioned, and the generic nature of the tasks allows for easy application in the sample population.

2.7.5 Fear of movement

There are a number of tools which have been developed for measuring pain related fear and the constructs thereof [141]. In a review by Lundeberg et al (2011) they state that consensus regarding assessment and thus interpretation of fear related pain has not been reached [141]. According to their review, the current conceptual framework surrounding pain and fear is unclear, however they have made suggestions as to what may appear to measure each construct best. The three most commonly used tools are the Fear Avoidance Beliefs Questionnaire (FABQ), the Pain Anxiety Symptoms Scale (PASS) and the Tampa Scale of Kinesiophobia (TSK) [142].

The FABQ was originally developed for use in patients with low back pain. The original version was made up of 16 questions, divided into two categories, relating to work and physical activity [141, 142]. It has been used widely and in the review, the authors suggest that it is most appropriate for measuring fear-avoidance beliefs [141]. Given the poor description of the underlying conceptual model of fear-avoidance beliefs, they suggest that results be interpreted with caution [141]. Gatchel et al (2016) suggest that the specific reference to "work" in the FABQ may limit its use to those who are working or who have been kept out of work by pain [142]. The majority of the population in the present study are unemployed or retired, making a questionnaire with strong links to work less appropriate for this group.

The PASS was developed to measure pain-related anxiety and fear [143]. The PASS has been found to be a clinically useful tool, with its psychometric properties well established [143]. According to Lundberg et al (2011) it appears to be the best tool for measuring pain-related fear, even though there were issues around the description of the conceptual model of pain related anxiety and fear [141]. Patients provide a response to questions relating to cognitive, physiological or motor aspects [141]. Initially designed as a lengthy 40-item questionnaire, it has since been modified to have a short form for increased ease of use. By reducing each of the four subscales to contain five items instead of ten, they managed create a 20-item questionnaire measuring pain related anxiety and fear [143].The development of this 20-item scale suggested that it maintained the validity and reliability of the longer form version and may be a useful alternative in practice [143]. The current study sought to assess fear-of movement in OA and as such a tool measuring anxiety as a focus was deemed inappropriate. Even though the questionnaire has been abbreviated to 20 questions, there are shorter tools available, which may be able to measure the desired construct more accurately.

The TSK was developed originally for use in patients with chronic back pain, but since its translation for use in a Dutch population, extensive work has been done to ensure it is valid for use in patients with acute back pain, osteoarthritis and fibromyalgia [39]. The full TSK has been shown to have good validity and reliability in populations with chronic lower back pain, acute lower back pain, neck pain, fibromyalgia and shoulder pain [144]. The original TSK consists of 17 items, however it is available in 17, 13, 11 and 4-item versions. According to Lundberg et al (2011) it is the most appropriate tool for measuring kinesiophobia which is described as excessive, irrational fear of movement or activity because of a feeling of vulnerability to injury [141]. There do not appear to be any other appropriate measurement tools for measuring fear of movement as a construct and so although kinesiophobia refers to irrational and phobic feeling, the TSK appears to be a promising option for measuring fear of movement in this population. It is also helpful for use in this population that it is not grounded in work-based references and is valid for use in patients with OA specifically [39].

Chapter 3: Methods

3.1 Research Design

A single-blind, randomised controlled trial was conducted to determine the effects of a six-week pre-operative physiotherapist-led exercise and education intervention on post-operative recovery in patients with OA undergoing total knee replacement. In a study such as this where the patients are active participants in treatment it was not possible to blind patients, thus the research assistant conducting the data collection was blinded to minimise bias in the data collection process.

3.2 Sample

The participants for this study were taken from the population of those diagnosed with knee OA in South Africa, more specifically those diagnosed with knee OA and receiving public healthcare. The sampling frame used was those placed on a waiting list for a TKA at TBH in the Western Cape. The principal investigator was granted access to this waiting list and participants were randomly selected by random number allocation from this list for potential inclusion in the study. To be considered a potential participant, patients were required to be between the ages of 50 and 70 years of age, to have been on the waiting list for at least three months and be deemed suitable to undergo TKA surgery in the next three months. The specific age range of 50-70yrs old was selected based on the study by Saw (2015), as the current study aimed to investigate the same population group, including only TKA patients. Thus, the age requirement was maintained in line with that of the previous research. Those meeting these inclusion criteria were contacted telephonically and if on screening were found to be appropriate to participate in the study, were randomly selected by the principal investigator for inclusion.

Patients who had participated in a similar education and exercise programme (used in a study by Saw et al. (2015) which preceded the current study) were excluded; however, patients in the care of a physiotherapist were not excluded. Receiving routine physiotherapy treatment was recorded but was not used as an exclusion criterion as the treatment was unlikely to be similar to the intervention used in the current study. Use of an assistive device was not a reason for exclusion as it was expected that a large portion of these patients would be using some sort of device for easier mobilisation. Use of assistive devices was simply documented.

The total initial pool for sampling consisted of 455 individuals. Following a screening of those on the waiting list, 313 potential participants remained. As a result of this large pool, random selection was done to begin telephonic recruitment. Full inclusion and exclusion criteria are included in Table 2.

Table 2: Inclusion and Exclusion criteria for participation in the study

Inclusion Criteria	Exclusion Criteria
1. Willing to participate and able to commit to attending the intervention should they be allocated to the intervention group. 2. Between the ages of 50 and 70 years old. 3. Diagnosed with knee OA. 4. On the TKA waiting list for more than three months. 5. Deemed suitable, by the surgical team, for surgery within the next three months. 6. Scheduled to undergo TKA within the next three months. 7. Able to both read and understand either English, Afrikaans or isiXhosa to a Grade 8 level.	1. Previous knee surgery or trauma. 2. Presence of both hip and knee OA. 3. Previous participation in a six-week self-management programme aimed at reducing pain and increasing function. 4. Any diagnosed cognitive impairments. 5. The presence of any other inflammatory condition which may be contributing to their pain or any other leg or back condition which may be contributing to their symptoms. 6. Patient deemed unsuitable for exercise according to the American College of Sports Medicine Guidelines (ACSM) screening (Appendix J) and subsequent inability to complete a 6 minute walk test (6MWT).

Despite several attempts to contact those appropriate to participate in the study, many of the potential participants were unreachable (n=158). Of those with whom telephonic contact was made, a large percentage were unsuitable for further involvement, either simply declining (n=34) or meeting one or more of the exclusion criteria (n=62). Participants who indicated a willingness to participate on the phone, proceeded to meet with the principal researcher as well as a research assistant, to further assess suitability for inclusion in the study. On meeting with those interested in participating, a further 20 participants were excluded. Those suitable for inclusion after this process were enrolled in the study and had baseline measures completed at TBH (Figure 3).

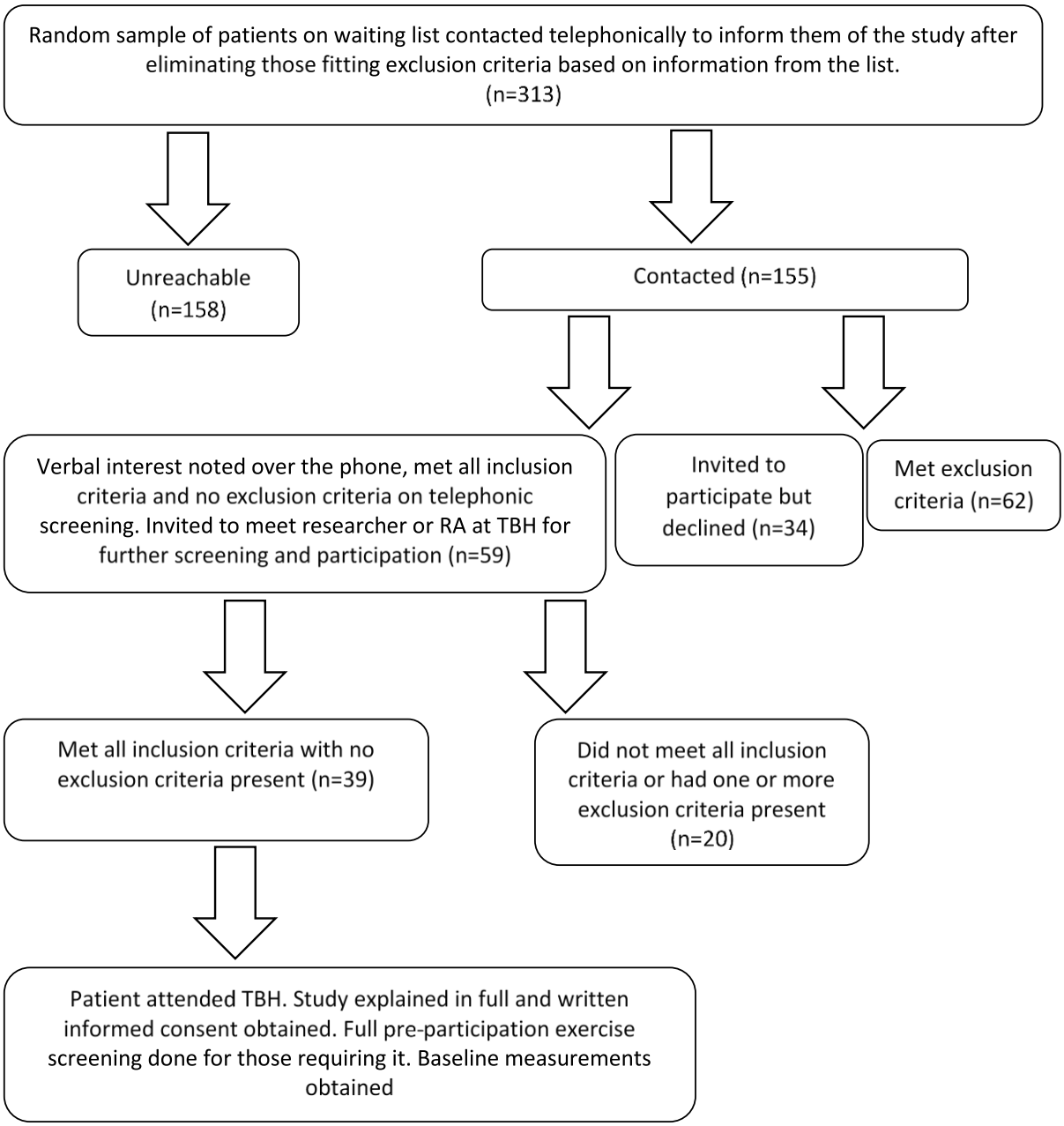


Figure 3: CONSORT diagram of the recruitment process

3.3 Sample size and power analysis

Sample size was calculated using the primary outcome measure of change in pain severity of three points out of a possible ten (a clinically significant change in pain) with a standard deviation (SD) of 2.29 based on the data from the previous study performed at TBH by Saw et al. (2015). Based on six data collection points and using an alpha level of 0.05 and power of 0.9, a minimum of 28 participants was required, with 14 participants in the experimental and control groups respectively. The recommendation for group based treatments is that they utilise a maximum of 12 people per group [103]. To allow for attrition and to optimise group effectiveness it was decided that the target sample would be set at two treatment groups of 12 people each i.e. 24 participants in the experimental group and 24 participants in the control group, meaning the study aimed to recruit a total of 48 participants. After a five-month recruitment period, the total number enrolled into the study was 39 and the decision was made to initiate the study based on the minimum sample size of 28 participants having been obtained.

3.4 Measurements

As participants were from various cultural groups, all instruments were made available to participants in English, Afrikaans and isiXhosa, the dominant languages of the region, to maximise participation. For clarity sake, the following measurements were evaluated.

- Pain was the primary outcome of the current study and the measurement tool chosen was the BPI. The two sub-scores on the BPI were used to measure pain severity and pain interference (Appendix B).
- Disability was a secondary outcome and was measured using the WOMAC. The WOMAC includes pain, stiffness and function sub-scores (Appendix C).
- The EQ-5D-5L was used to measure health-related quality of life as a secondary outcome (Appendix D).
- Function was also used as a secondary outcome and was measured using the ALF (Appendix E).
- The TSK was used to assess fear of movement in participants as a secondary outcome (Appendix F).

3.5 Procedure

The study received ethical approval and once the sample for inclusion had been established, as explained above, measurement instruments were piloted using 10% of the sample (four participants) to establish intra-rater and inter-rater reliability, as well as to allow the researcher to address any logistical issues or issues of understanding for participants. No issues were noted during the pilot study, and the full study commenced. A random sample was taken from the TKA waiting list at TBH using random number selection. Patients selected in the random selection process were then contacted telephonically to explain the nature of the study, offer them the opportunity to ask questions and invite them to participate (Appendix G). Upon verbal indication of willingness to participate over the phone, they were then screened for suitability for inclusion in the study. Using a questionnaire (Appendix H), the researcher performed an initial telephonic screening to exclude those who met any of the exclusion criteria.

Patients fulfilling inclusion criteria for the study and none of the exclusion criteria as per the questionnaire, were invited to meet with the researcher or the research assistant, as well as an interpreter (where necessary) at TBH. Unfortunately over the course of the study and due to unforeseen circumstances, the research assistant changed several times. In total there were five different assistants who were all recruited through the UCT Department of Physiotherapy. Three of the five were qualified physiotherapists, the fourth was a final year physiotherapy student, and the fifth had a BA (Hons) in medical anthropology and a BA in health care studies with extensive research experience. Of course this may have impacted the accuracy of the information gathered, but all of them were trained in using the outcome measures chosen for the study before they commenced so as try and minimise this impact.

At the first meeting, the study was explained in full and participants, as well as any family members or caregivers in attendance, were encouraged to ask questions to ensure that all involved had a thorough understanding of what taking part in the study entailed. Patients who wished to consider their involvement before committing were given the opportunity to go home and think it through, with the option of telephoning the researcher to inform them of their decision. Once participants had agreed to take part, and on condition that they met all the inclusion criteria and none of the exclusion criteria on further screening at TBH, written informed consent was obtained (Appendix I) and initial measurements were performed. Patients who were excluded over the phone or at initial meeting at TBH, or declined participation in the study, but wanted to receive usual care physiotherapy were offered a referral for physiotherapy at their nearest clinic. An exercise screening test was conducted by the researcher or research assistant, using the ACSM guidelines on

participants at initial meeting at TBH if there was concern regarding their ability to exercise safely (Appendix J). If there was concern in completing the ACSM, a six-minute walk test was performed to further evaluate suitability for inclusion.

The study procedure is illustrated in Figure 4. Due to logistical and financial constraints, initial baseline measurements were taken at the time of recruitment. Participants were assisted in filling out the required questionnaires, with the researcher or research assistant (and interpreter where required) offering clarity on any misunderstanding or misinterpretation of questions. Interpreter bias was reduced by utilising tools which use numerical data. At this point it was noted that it was important to reassure participants that there was no correct answer and that the only person looking at the results would be the researcher, as some participants were hesitant in answering the questions. The research assistant was present at all follow-up sessions to provide assistance as needed by participants.

After recruitment, participants were randomised by the researcher into a control group and experimental group using computer-generated, random number allocation. Participants were informed of the importance of the research assistant remaining blinded in the study to ensure that they did not reveal their group assignment at follow up sessions and compromise the integrity of the data gathered. Those allocated to the control group received no new intervention, but continued to receive their standard pharmacological and non-pharmacological treatment whilst on the arthroplasty waiting list, as decided by their treating doctor.

The intervention group continued to receive the standard pharmacological and physical intervention they had been receiving prior to the study commencing, as well as beginning the six-week exercise and education intervention provided by the researcher, a qualified physiotherapist, trained and experienced in delivering the intervention. Patients received a workbook which was used by the researcher to teach and ensure understanding of the content (https://open.uct.ac.za/handle/11427/12697). Measurements were taken from both groups once the intervention had been completed at six-weeks. Patients then continued to wait for their surgery (which was scheduled to be done in the next three months).

On admission, prior to undergoing surgery, measurements were repeated as well as within a week of discharge from hospital. Following this, measurements were taken at six weeks post-surgery and final measures were taken three months post-surgery. [2]

[2] Ethical approval for six months follow-up was given for publication purposes, but not for the purposes of the MSc degree

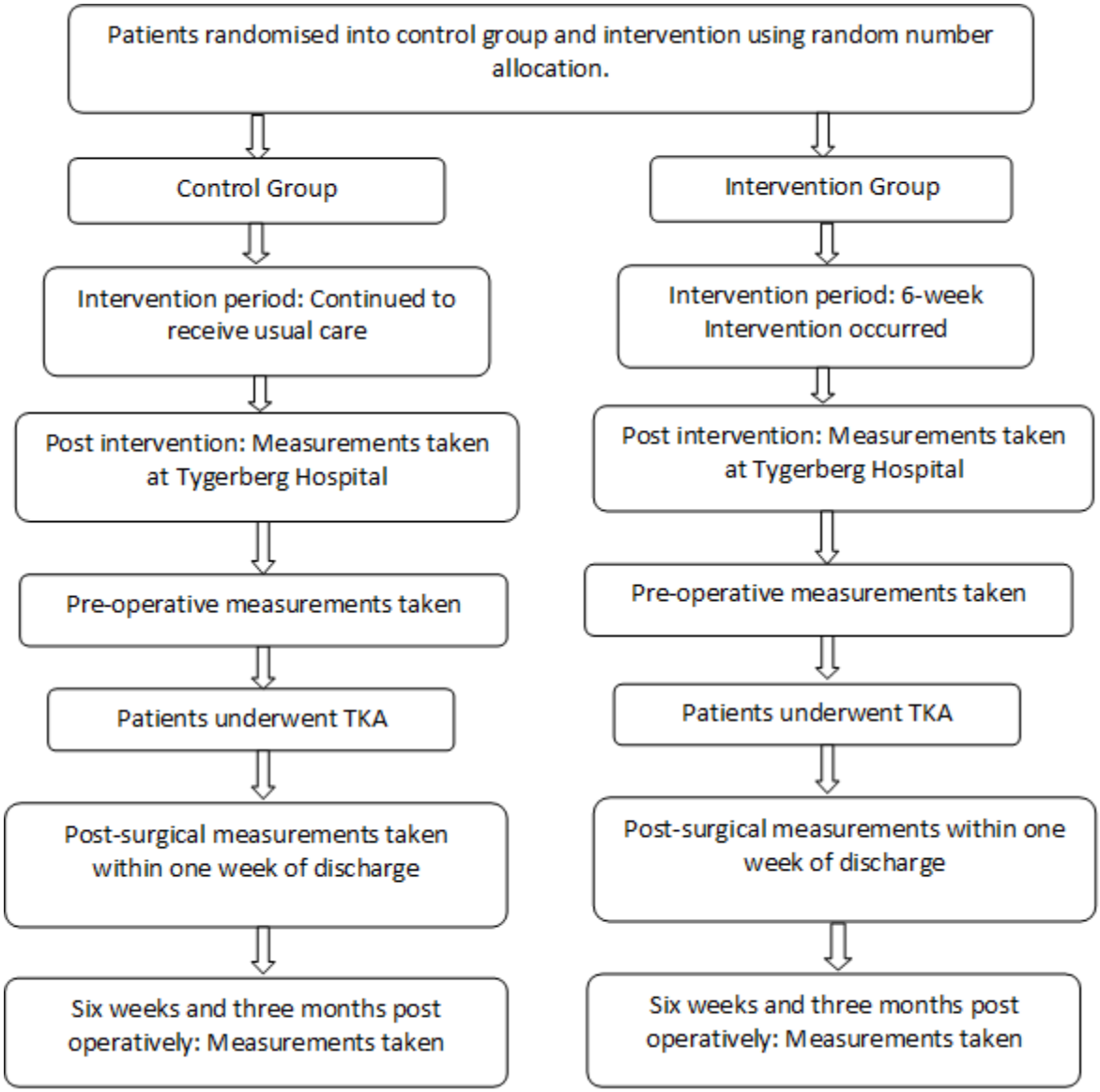


Figure 4: CONSORT diagram of the study procedure

3.6 Intervention

The intervention was the same as that used in a previous pre-operative study performed at TBH on a similar population of patients on a waiting list [29].

As discussed in the literature review, the classes were held for two hours, once a week for six weeks. Refreshments of tea, coffee, water and biscuits were provided at every session. An isiXhosa interpreter was required for the one intervention group, and attended all six sessions to provide translation for participants during these sessions. The first class was run as a group of 12, and the second as a group of seven. Unfortunately, attendance was inconsistent in the first group, with some participants attending less than half of the sessions and no excuses being made for not attending. These participants were followed-up after missed sessions and reminded to please attend the following sessions. The second intervention group had less absenteeism and participants seemed to try very hard to attend and provided valid reasons if they were unable to attend or running late.

Participants were not required to keep a log of exercise or physical activity during the six-week intervention, as the focus of the study was not on exercise levels, but on post-operative pain and function. Some participants did choose to keep track of their activity levels using their goal setting sheets as it helped them to monitor one aspect of their progress. On completion of the course participants received a certificate stating that they had successfully completed the intervention.

3.7 Statistical analysis

Data were analysed using Statistica software [145]. A clinically significant reduction in pain (a change in pain of more than 3 out of a possible 10 on a numerical rating scale) was used to classify treatment as successful or unsuccessful. Due to the small sample size, non-parametric analysis was done and results are presented as median and range throughout. The Mann-Whitney U and the Chi-squared (χ2) tests were used to determine differences in socio-economic, demographic and clinical characteristics of the experimental and control groups. The Mann-Whitney U was used to analyse for change in prevalence of pain between groups. The effect of the intervention on pain within group was analysed using a one-way analysis of variance (ANOVA). Effect sizes were calculated between groups where appropriate, using Cohen's D[3] with 95% confidence intervals. The following formula was used: $ES = \frac{experimental\ mean\ change - control\ mean\ change}{pooled\ baseline\ SD}$. Analysis was by intention to treat with missing data managed by carrying forward the last observed measurement. Statistical significance was accepted as $p \leq 0.05$.

3.8 Ethical considerations

Ethical approval was granted by the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee (HREC Ref: 651/2015) (Appendix K), as well as the Western Cape Department of Health and TBH (Ref: 651/2015) (Appendix L). Subsequent amendments were also approved (Appendix M). This study upheld the Declaration of Helsinki, regarding the ethical principles of beneficence, non-maleficence, autonomy and justice [146]. Patients contacted were given an outline of the study and intervention, as well as any possible benefits or risks associated with participating in the study. Participants were given the opportunity to give a verbal indication of willingness to participate over the phone, followed by written informed consent, in their preferred language, on meeting with the researcher or RA. It was also clearly explained to the participants that they may withdraw from the study at any time, for any reason at all, without experiencing any penalty or negative effect on their usual care, with some patients choosing to do so. Any questions were answered before informed consent was signed.

[3] Cohen's D is an estimate of size of effect. 0.2 is a small effect size, 0.5 is moderate and 0.8 is large,

Studies mentioned previously have shown that exercise and education-based interventions have positive results on patients' symptoms and further research should be conducted to explore post-operative outcomes. These positive changes are what the researcher aimed to reproduce and as such maintain beneficence and non-maleficence in this study. The aim of the programme was to benefit participants by educating them about their condition and improving coping skills, as well as educating them about exercise and how they could be active. A further benefit was that with exercise they could become fitter and stronger, thereby improving their ability to cope physically with everyday tasks.

There are risks associated with exercise, however these were minimised or eliminated as far as possible. Intervention sessions were led by a qualified physiotherapist, and potential participants were screened according to the ACSM guidelines for exercise participation to ensure safe participation in the intervention. Participants were warned that post-exercise stiffness or soreness is normal and may occur, especially for those unaccustomed to exercise. This was managed as best as possible by establishing a good, accurate baseline from which exercise was built up in the sessions. Provision was made so that if, during the course of the study, any participant experienced an unacceptable increase in pain they could be referred for physiotherapy assessment and treatment, as well assessment and pharmacological management by the attending doctor. Their participation would then be reassessed, either adjusting their exercise as necessary or removing them from the study completely. Participants were advised that should anyone become medically unstable during the course of the intervention, and therefore unfit for participation in an exercise programme, they would be removed from the study for their own safety and managed further by the attending doctor.

Participation in the study, regardless of group allocation, had no effect on their usual care and patients in both groups continued to attend their usual follow-up visits, with the addition of the researcher testing visits. Their place on the arthroplasty waiting list was potentially positively affected to facilitate study completion, however patients were not informed of this potential so as not to coerce them into participating. Should this programme be shown to be successful, recommendations will be made that patients on waiting lists receive this intervention in future, ensuring that justice is upheld.

Confidentiality was maintained by the researcher, by allocating each patient a code and therefore not using any names for the recording of results. Results cover the group responses and nothing that would make a participant identifiable is shared. Furthermore, participant data was stored on an external password protected device, and locked away when not in use, so as not to compromise the identity of the participants. All participants were required to sign a confidentiality agreement when signing informed consent to ensure that if they were randomised into the intervention group they kept the identities and details of fellow group members confidential. The researcher can never guarantee absolute confidentiality as that relies on group members themselves. Therefore, all participants were made aware of this fact and the need for taking confidentiality seriously was emphasised. Patients did not receive any payment for participating in the study and as such any coercion was avoided. Due to financial constraints on the study, the cost of transport to and from the intervention sessions, and the measurement sessions could only be partially subsidised, and every attempt was made to perform measurements on days when the participants were attending the hospital to make use of other services.

Chapter 4: Results

The Consolidated Standards for Reporting Trials (CONSORT) [147] diagram below illustrates the study process from enrolment of participants to analysis of the data (Figure 5).

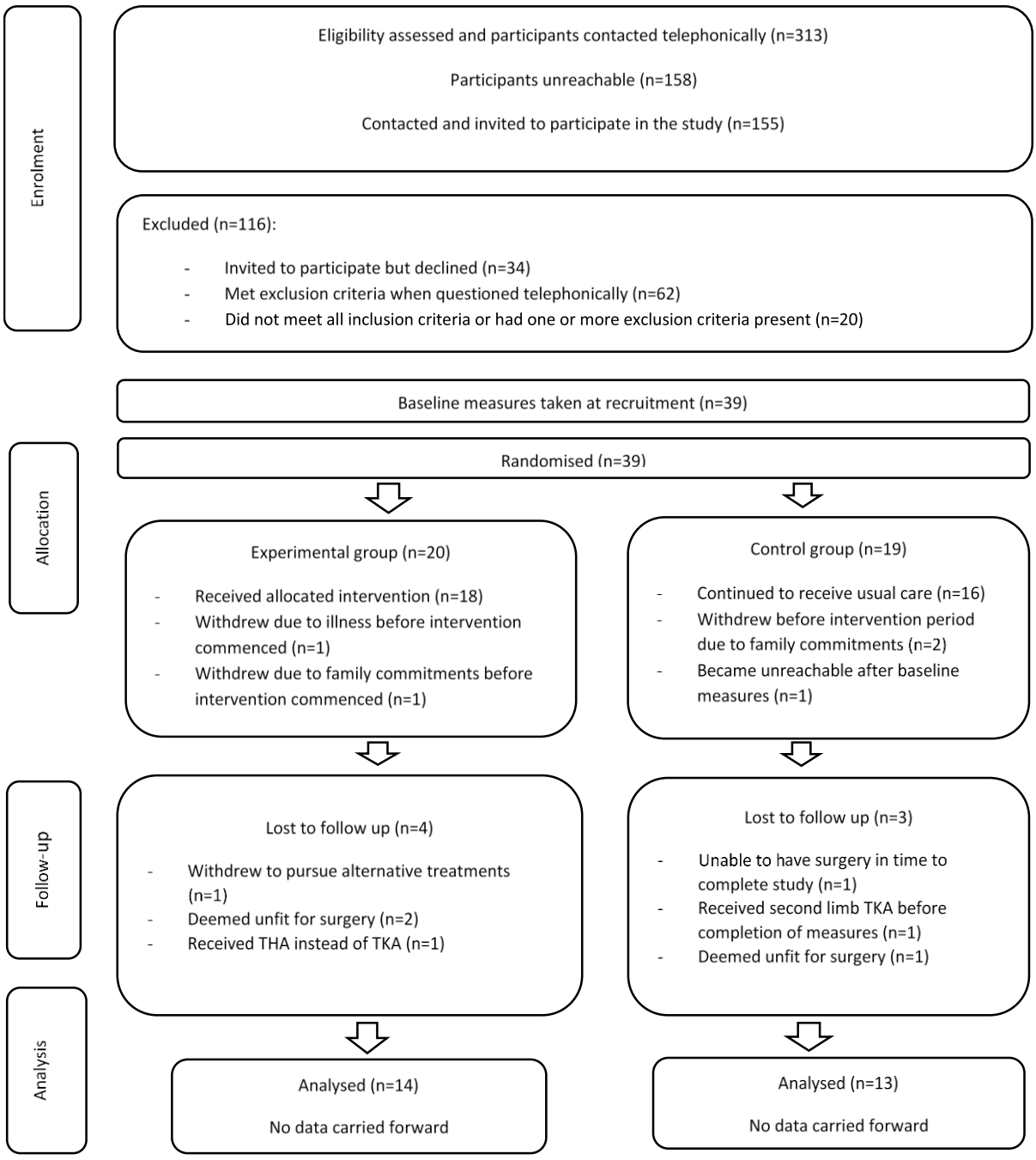


Figure 5: CONSORT diagram of the study process with numbers of participants in attendance at data collection points

4.1 Socio-demographic profile of participants

Socio-demographic information was gathered using a simple questionnaire (Appendix O). The study participants (N=27) were randomly divided into the control (n=13) and experimental (n=14) groups. The median age of the sample was 63 years (54-70). There was no significant difference between the groups for age [61.5 (54-69) vs 63 (55-70); U=76.5; p=0.5].

There were no significant differences between groups for home language, sex, level of education, employment and time on the waiting list (Table 3). The majority of the participants were female (n=21), Afrikaans speaking (n=16) and unemployed (n=18) with a grade nine level of education or less (n=11).

Table 3: Socio-demographic characteristics of the study participants (N=27)

	Participants (N=27)	Experimental (n=14)	Control (n=13)	Statistical analysis
Home language				χ^2 =3.83; p=1.5
Afrikaans	16	6	10	
English	6	5	1	
isiXhosa	5	3	2	
Sex				χ^2=0.01; p=0.92
Male	6	3	3	
Female	21	11	10	
Level of education				χ^2=2.84; p=0.24
Grade 9 or less	13	7	6	
Grade 10-12	9	6	3	
Tertiary	5	1	4	
Employment				χ^2=3.48; p=0.18
Unemployed	18	10	8	
Volunteer	2	2	0	
Employed	7	2	5	
Waiting time				χ^2=5.35; p=0.15
1-2 years	16	9	7	
3-4 years	5	4	1	
5-6 years	3	0	3	
7-8 years	3	1	2	

4.2 Pain severity and pain interference

4.2.1 Pain Severity Score (PSS)

The control group's scores on the PSS were significantly lower than those of the experimental group at recruitment (U=49.5; p=0.05), post-intervention (U=33; p=0.01) and at 6-week post-operative follow-up (U=22.5; p=0.01). Both groups had a significant within group reduction in PSS over time (control group χ^2=11.85; p=0.02 and experimental group χ^2=10.54; p=0.03) (Figure 6). The effect size for the PSS was -0.23 (-1.06 – 0.61 95%CI)[4] indicating no difference between groups.

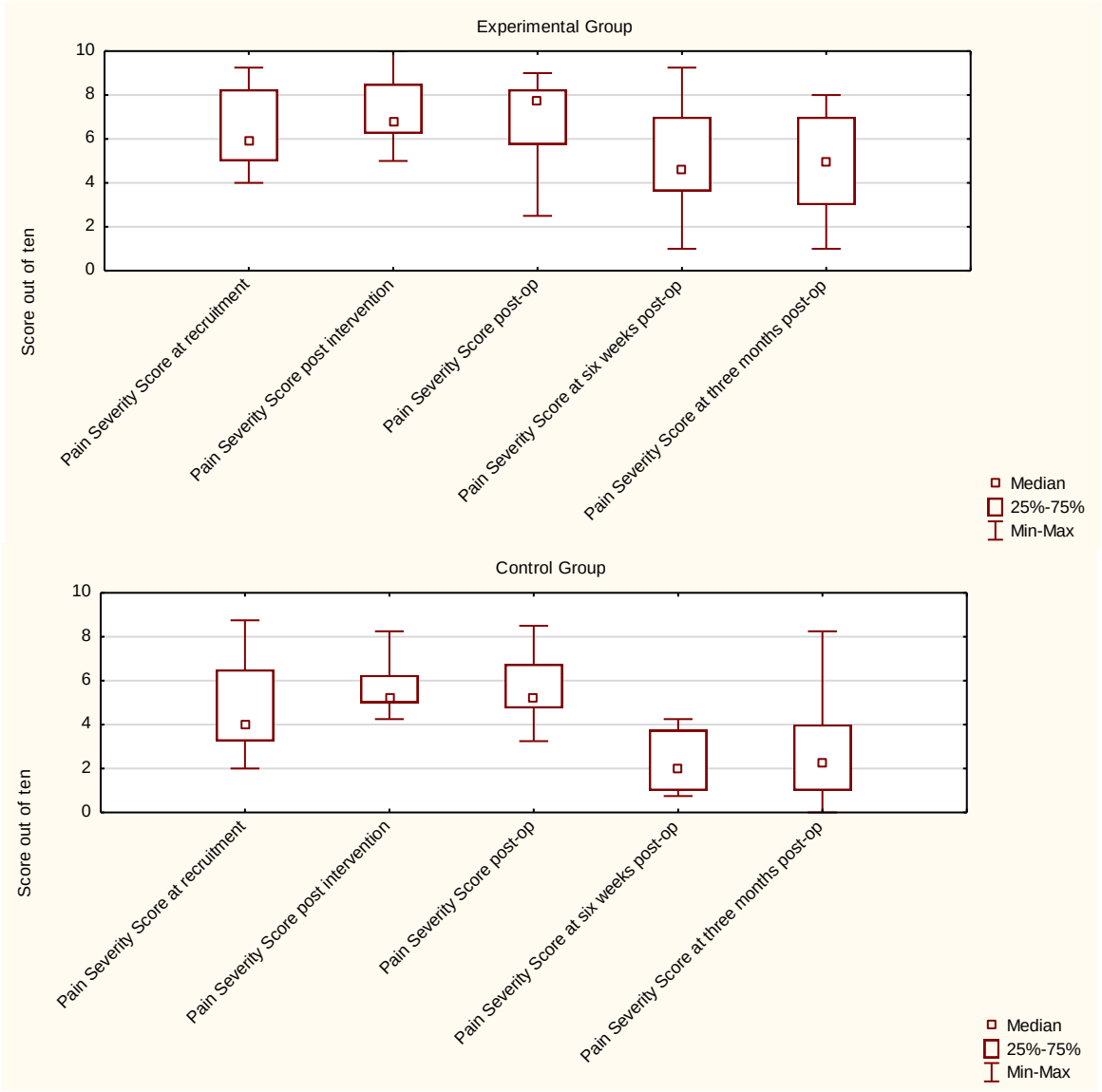


Figure 6: PSS for the experimental group and the control group from recruitment to three months post-operative follow-up

[4] A 95 % confidence interval which crosses 0 suggests that there is no significant difference.

4.2.1.1 Least pain

The “least pain” scores were not significantly different between groups at recruitment, however the control group had significantly better least pain scores at both immediate post-operative follow-up (U=33; p=0.01) and at six weeks post-operative follow-up (U=19.5; p=0.01). The control group improved significantly over time (χ^2=11.25; p=0.02), whilst the experimental group got significantly worse over time (χ^2=10.57; p=0.03). The effect size for the “least pain” score was -0.53 (-1.36 – 0.34 95%CI) indicating no difference between groups.

4.2.1.2 Pain right now

The “pain right now” scores were not significantly different between groups at recruitment. Scores for the control group were significantly better than those of the experimental group at post-intervention (U=33.5; p=0.01), six weeks post-operative (U=20.5; p=0.01) and three months post-operative follow-up (U=25.5; p=0.02). Both groups showed significant improvement over time (control group χ^2=10.99; p=0.03 and experimental group χ^2=10.51; p=0.03). The effect size for the “pain right now” score was -0.45 (-1.48 – 0.41 95%CI) indicating no difference between groups.

The data for the two subsections above may be found in Appendix N.

4.2.1.3 Worst pain

"Worst pain" scores for the control group were significantly lower than those of the experimental group at recruitment (U=31.5; p=0.05). Both groups displayed a significant within group reduction in their "worst pain" scores over time (control group χ^2=13.31; p=0.01 and experimental group χ^2=18.56; p=0.01) (Figure 7). The effect size for the "worst pain" score was 0.37 (-0.49 - 1.2 95%CI) indicating no difference between groups.

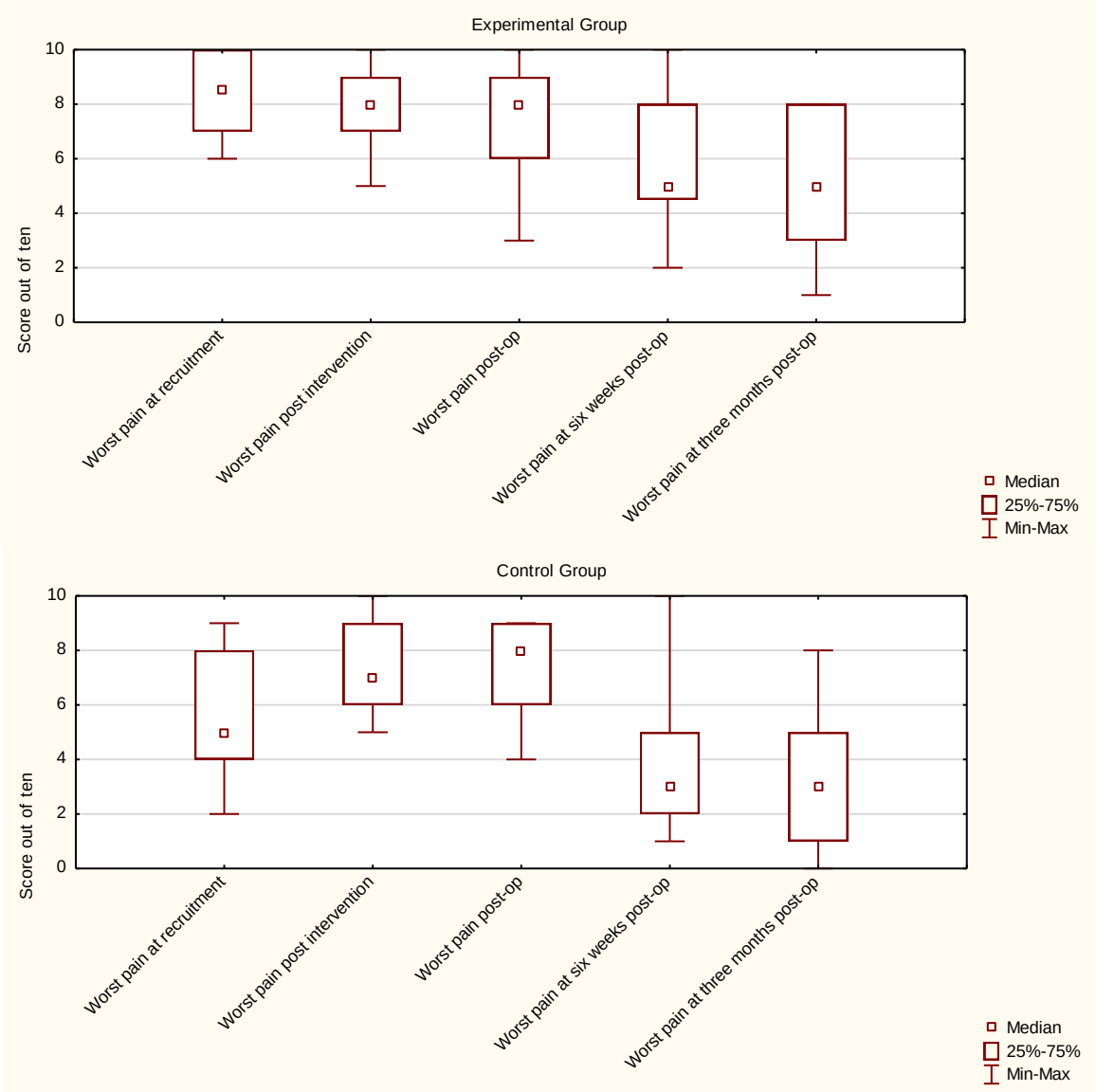


Figure 7: "Worst pain" scores for the experimental group and the control group from recruitment to three months post-operative follow-up

4.2.1.4 Average pain

The “average pain” scores for the control group were significantly lower than those of the experimental group at recruitment (U=44.5; p=0.03), post-intervention (U=28; p=0.05), post-operatively (U=27; p=0.02) and at six weeks post-operative follow-up (U=26; p=0.03). Both groups experienced a significant within group improvement in their “average pain” score over time (control group χ^2=9.3; p=0.05 and experimental group χ^2= 11.77; p=0.02) (Figure 8). The effect size for the “average pain” score was 0.03 (-0.81 - 0.87 95%CI) indicating no difference between groups.

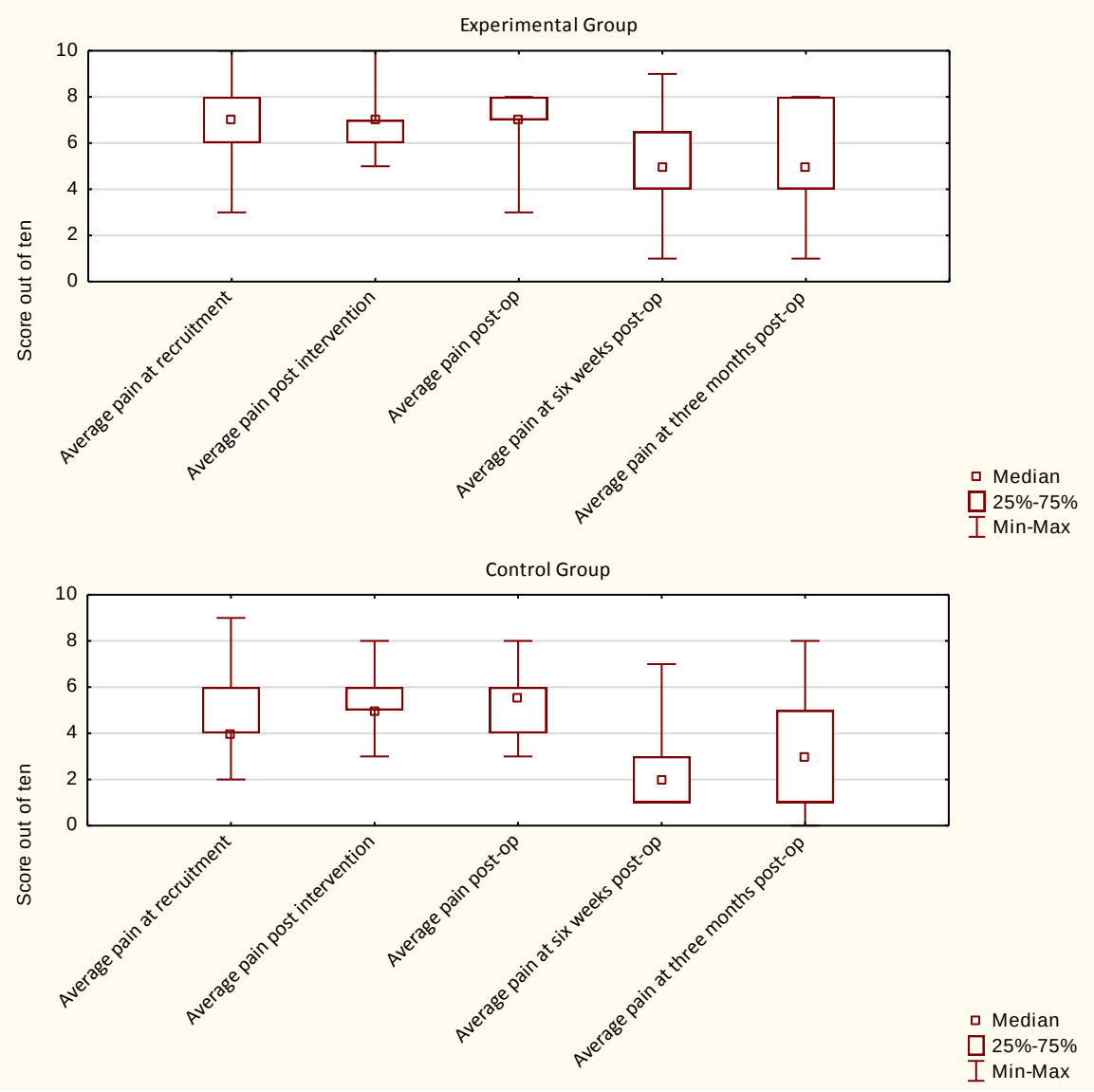


Figure 8: "Average pain" scores for the experimental group and the control group from recruitment to three months post-operative follow-up

Table 4 shows the median and range of scores on the “worst pain” and “average pain” items of the BPI for each group, comparing the differences at each data collection point and indicating where there were significant differences between groups by means of an asterisk (*).

Table 4: "Worst pain" and "average pain" scores for the control group and the experimental group from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Participants (N=27)	Experimental (n=14)	Control (n=13)	Statistical analysis
Recruitment				
Worst pain	8 (2-10)	8.5 (6-10)	5 (2-9)	U=31.5; p=0.05*
Average pain	6 (2-10)	7 (3-10)	4 (2-9-)	U=44.5; p=0.03*
Post intervention				
Worst pain	7.5 (5-10)	8 (5-10)	7 (5-10)	U=72; p=0.54
Average pain	6 (3-10)	7 (5-10)	5 (3-8)	U=28; p=0.05*
Post-operative				
Worst pain	8 (3-10)	8 (3-10)	8 (4-9)	U=62.5; p=0.9
Average pain	6 (3-8)	7 (3-8)	5.5 (3-8)	U=27; p=0.02*
6 weeks post-operative				
Worst pain	5 (1-10)	5 (2-10)	3 (1-10)	U=32.5; p=0.08
Average pain	4 (1-9)	5 (1-9)	2 (1-7)	U=26; p=0.03*
3 months post-operative				
Worst pain	5 (0-8)	5 (1-8)	3 (0-8)	U=35.5; p=0.11
Average pain	4 (0-8)	5 (1-8)	3 (0-8)	U=32; p=0.07

4.2.2 Pain Interference Score (PIS)

Scores on the PIS were significantly lower for the control group than the experimental group at both recruitment (U=50; p=0.05) and at 6-week post-op follow-up (U=21.5; p=0.01). Both groups achieved a significant within group reduction in their PIS over time (control group χ^2=12.81; p=0.01 and experimental group χ^2=9.47; p=0.05) (Figure 9). The effect size for the PIS was 0.02 (-0.82 - 0.85 95%CI) indicating no difference between groups. Table 5 shows the change in PSS and PIS for both groups and whether there were any significant differences at each data collection point.

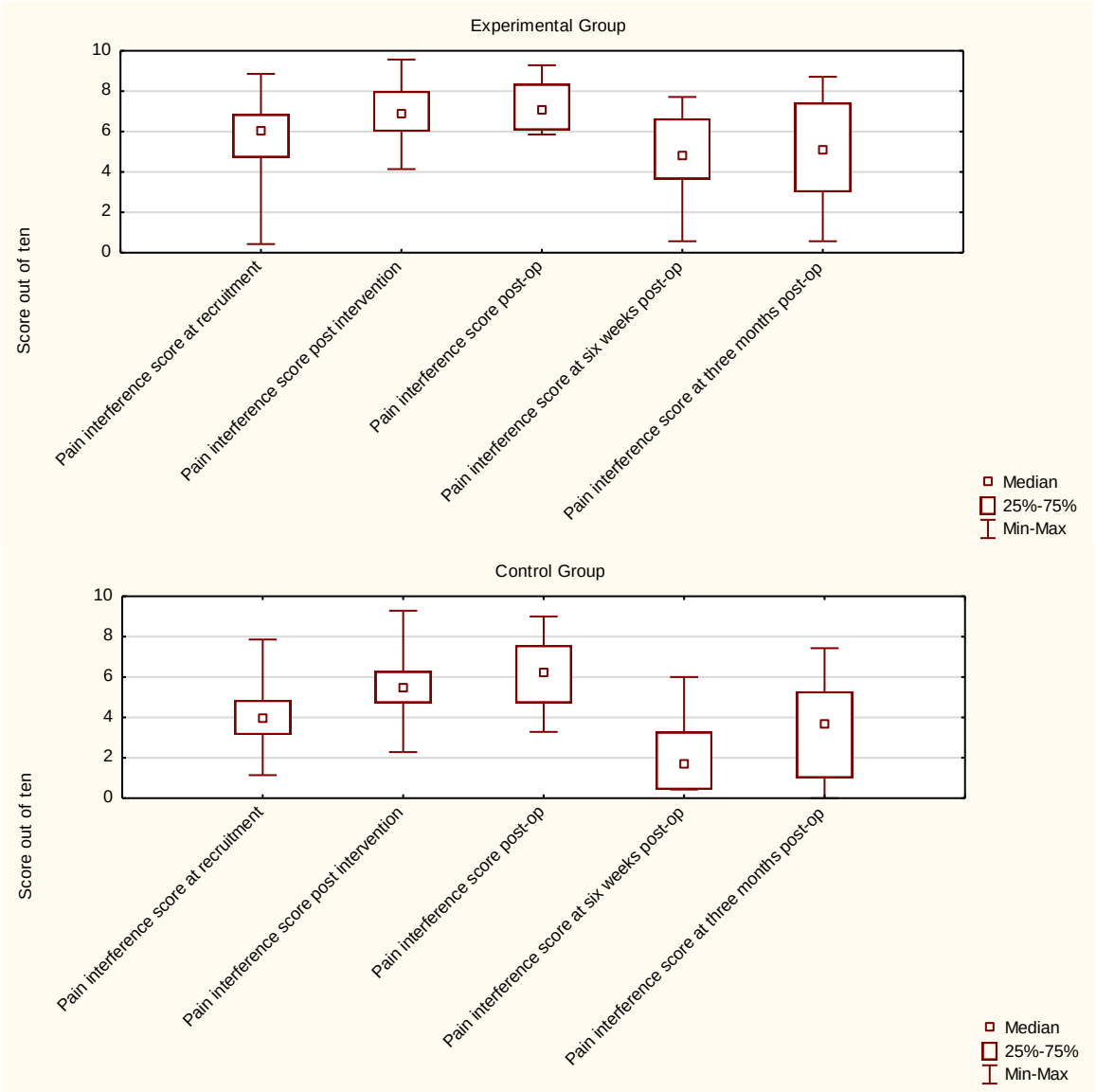


Figure 9: PIS for the experimental group and the control group from recruitment to three months post-operative follow-up

Table 5: PSS and PIS for the control group and the experimental group from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Participants (N=27)	Experimental (n=14)	Control (n=13)	Statistical analysis
Recruitment				
PSS	5.5 (2-9.25)	5.88 (4-9.25)	4 (2-8.75)	U=49.5; p=0.05*
PIS	4.86 (0.43-8.86)	6.07 (0.43-8.86)	4 (1.14-7.86)	U=50; p=0.05*
Post intervention				
PSS	6.25 (4.25-10	6.75 (5-10)	5.25 (4.25-8.25)	U=33; p=0.01*
PIS	6.07 (2.29-9.57)	6.86 (4.14-9.57)	5.43 (2.29-9.29)	U=50; p=0.08
Post-op				
PSS	6.5 (2.5-9)	7.75 (2.5-9)	5.25 (3.25-8.5)	U=40; p=0.13
PIS	6.43 (3.29-9.29)	7.07 (5.86-9.29)	6.21 (3.29-9)	U=35.5; p=0.11
6 weeks post-op				
PSS	3.75 (0.75-9.25)	4.63 (1-9.25)	2 (0.75-4.25)	U=22.5; p=0.01*
PIS	3.71 (0.43-7.71)	4.86 (0.57-7.71)	1.71 (0.43-6)	U=21.5; p=0.01*
3 months post-op				
PSS	3.5 (0-8.25)	5 (1-8)	2.25 (0-8.25)	U=31.5; p=0.06
PIS	3.93 (0-8.71)	5.14 (0.57-8.71)	3.71 (0-7.43)	U=42.5; p=0.25

4.2.2.1 Individual item scores on the PIS

The control group achieved significant improvement over the experimental group at six weeks post-op on five of the seven items on the pain interference scale [general activity (U=28; p=0.04), walking ability (U=22.5; p=0.02), normal work (U=15; p=0.01), relations with others (U=21; p=0.01), and sleep (U=19; p=0.01)]. They also showed significant improvement over the experimental group on the normal work item at post-intervention (U=44.5; p=0.04) and post-op measures (U=27.5; p=0.04), and on the enjoyment of life item at post-intervention follow up (U=45.5; p=0.05).

The control group achieved significant improvement over time on the items of general activity (χ^2=15.25; p=0.01), walking ability (χ^2=10.33; p=0.04), relations with others (χ^2=10.17; p=0.04), and sleep (χ^2=9.92; p=0.04). Although significantly worse than the control group on almost every item in the PIS, the experimental group showed significant within group improvement over time on three of these [general activity (χ^2=10.02; p=0.04), walking ability (χ^2=9.67; p=0.05) and normal work (χ^2=10.81; p=0.03)].

Full tables for these items can be found in appendix N

4.3 Disability

4.3.1 WOMAC total score

There was no significant difference between groups at any point in time. Both groups achieved a significant improvement on the WOMAC at three months post-op follow up (control group χ^2=11.71; p=0.02 and experimental group χ^2=14.19; p=0.01) (Figure 10). The effect size for the total score was 0.41 (-0.45 – 1.24 95%CI) indicating no difference between groups.

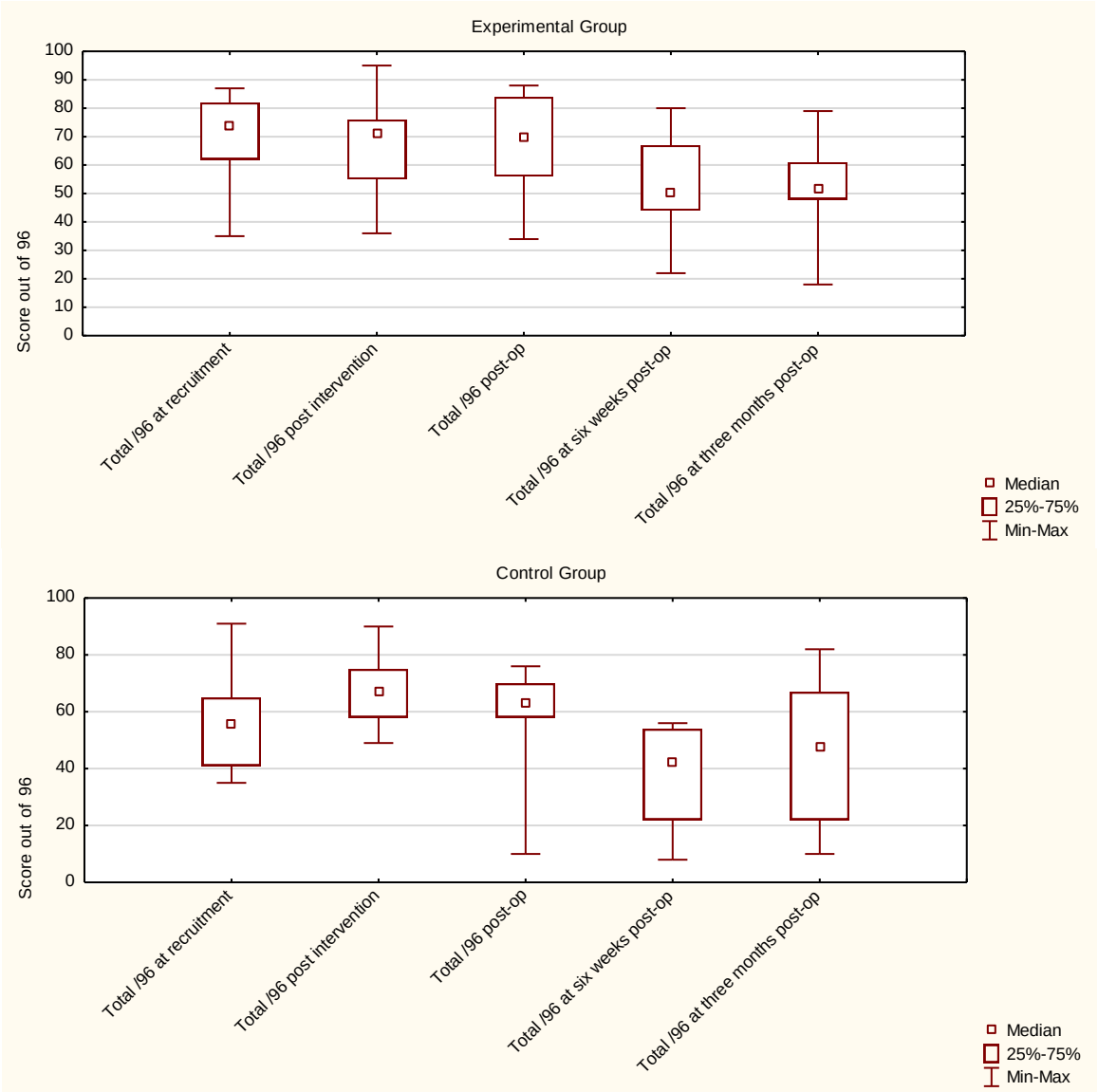


Figure 10: WOMAC total score for the experimental group and the control group from recruitment to three months post-operative follow-up

4.3.1.1 WOMAC pain score

As with the PSS, the control group had significantly lower levels of pain than the experimental group at recruitment (U=45; p=0.03). The control group showed a significant improvement over time (χ^2=9.52; p=0.05), whereas the experimental group did not (χ^2=8.47; p=0.08). The effect size was 0.02 (-0.82 – 0.85 95%CI) indicating no difference between groups. The data tables for this subsection may be found in appendix N.

4.3.1.2 WOMAC stiffness score

There were no significant differences between groups at any point in time. The experimental group achieved a significant change in stiffness over time (χ^2=16.47; p=0.01), but the control group did not (χ^2=6.92; p=0.14). The effect size was 0.72 (-0.17 – 1.55 95%CI) indicating no difference between groups. Figure 11 compares the stiffness scores between groups.

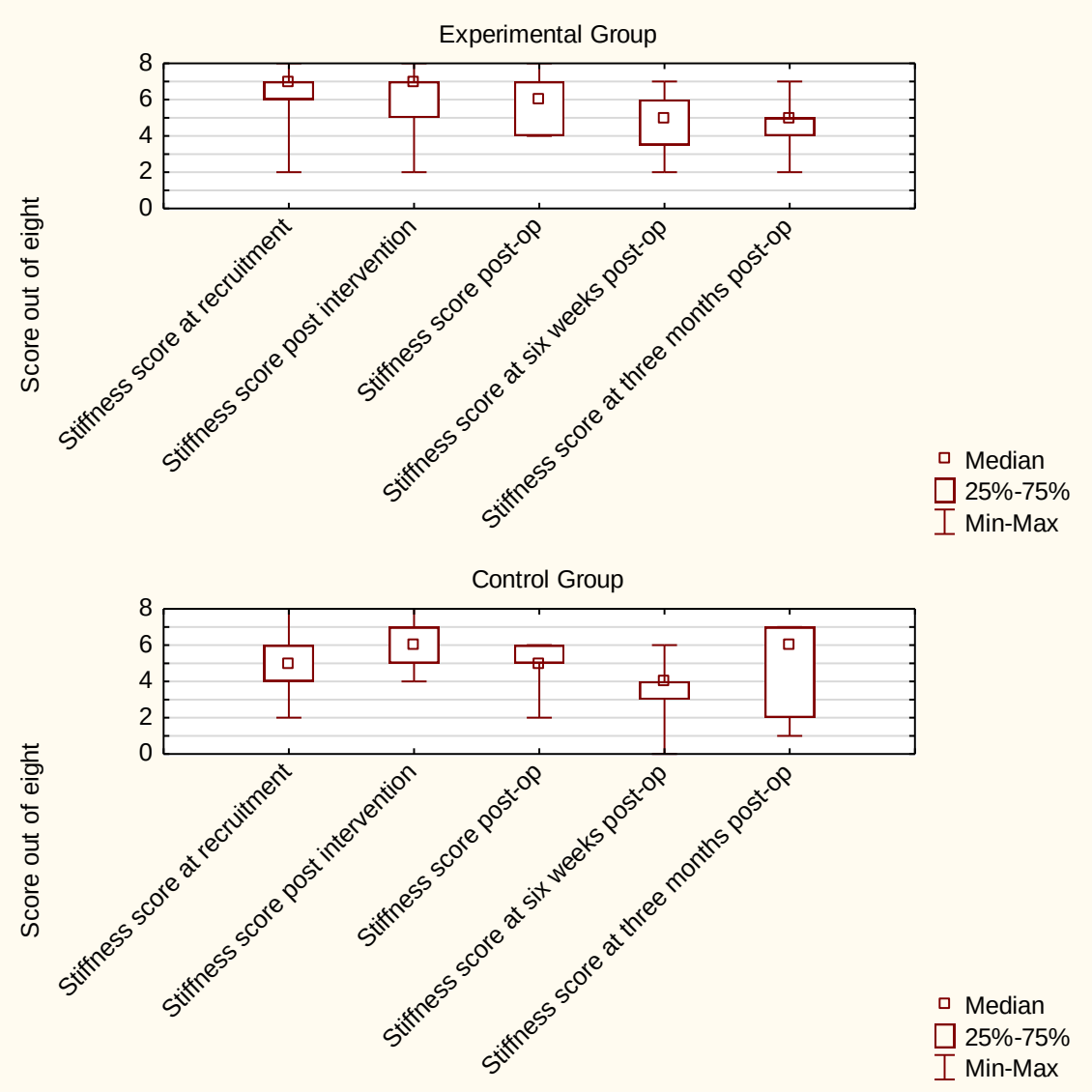


Figure 11: WOMAC stiffness score for the experimental group and the control group from recruitment to three months post-operative follow-up

4.3.1.3 WOMAC function score

There was no significant difference between groups at any point in time. Both groups showed a significant improvement at three months post-operative follow up (control group χ^2=10.1; p=0.04 and experimental group χ^2=12.91; p=0.01) (Figure 12). The effect size was 0.44 (-0.42 – 1.27 95%CI) indicating no difference between groups.

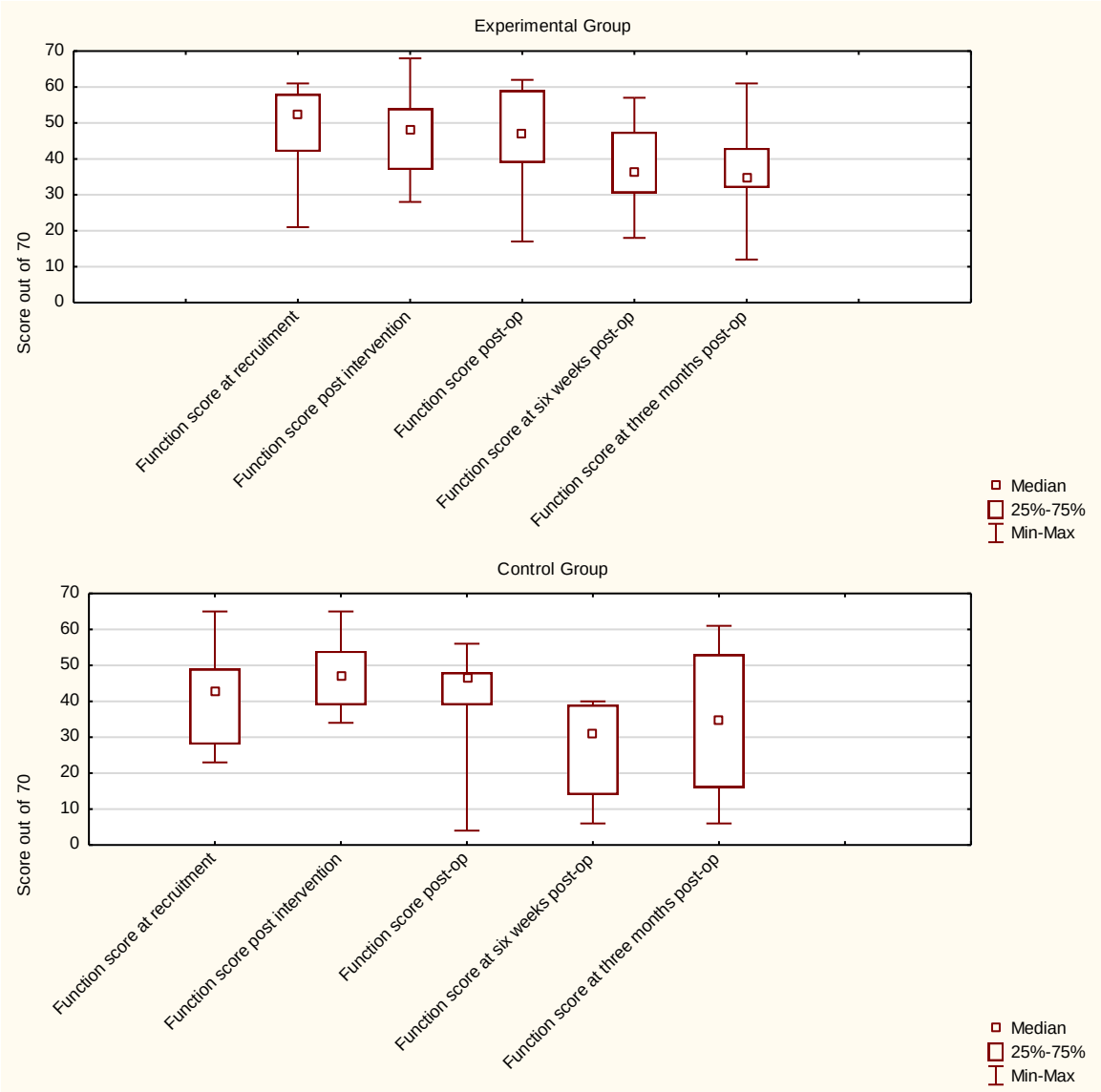


Figure 12: WOMAC function scores for the experimental group and the control group from recruitment to three months post-operative follow-up

4.4 Health related quality of life (HRQoL)

4.4.1 The EQ-5D-5L

There were no significant differences between groups on the VAS of the EQ-5D at any point in time during the study, and neither of the two groups achieved a significant within group change to their VAS rating of health-related quality of life over the study period (control group χ^2=7.87; p=0.09 and experimental group χ^2=3.2; p=0.52). The effect size was -0.45 (-1.28 – 0.41 95%CI) indicating no difference between groups.

The mobility section of the EQ-5D-5L assessed for degree of difficulty in mobility. The graphs below show the changes in the mobility scores, with the numbers in both groups reporting inability or severe disability reducing over time (Figure 13).

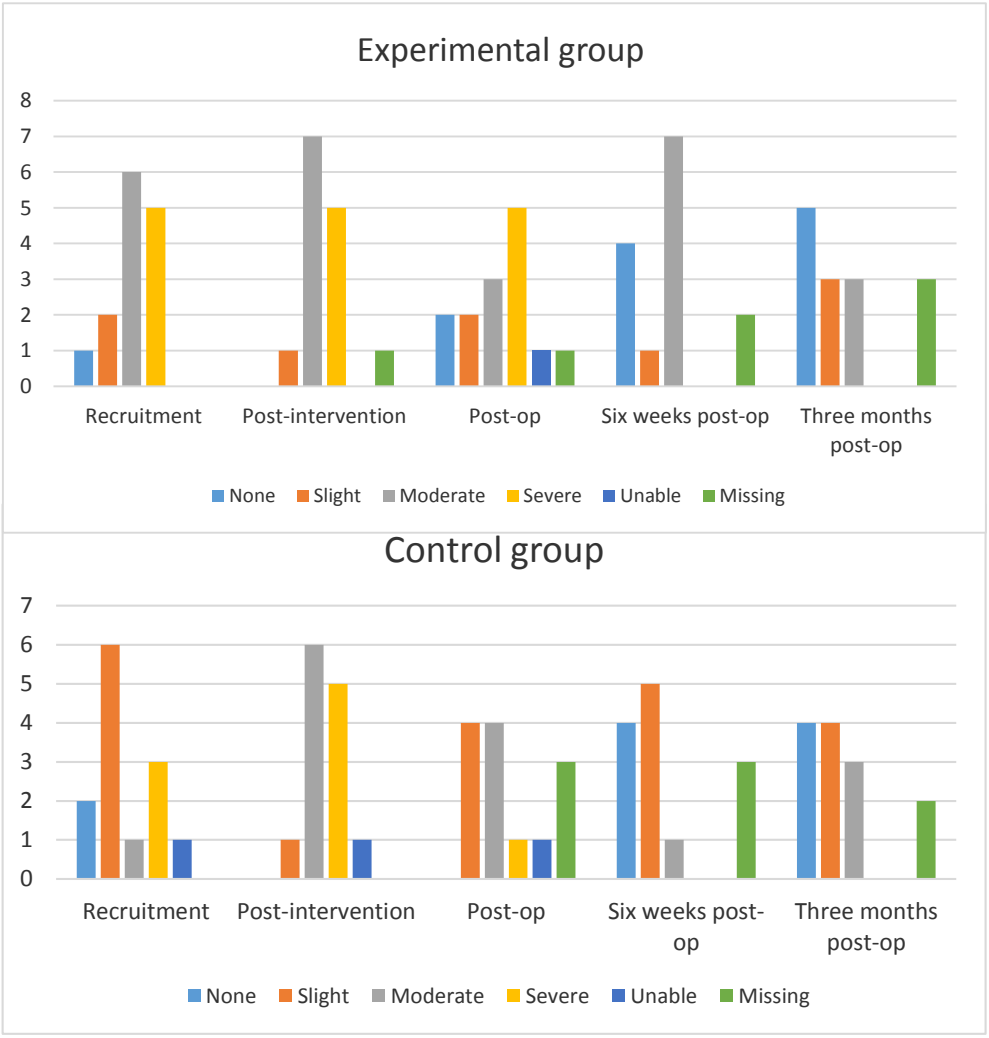


Figure 13: EQ-5D-5L mobility scores for the experimental group and the control group from recruitment to three months post-operative follow-up

The usual activities section of the EQ-5D-5L assessed for the degree of difficulty associated with conducting usual activities for the participant. The graphs below show the change in usual activity scores over time (Figure 14). There was more variation of scoring evident in the experimental group than in the control group.

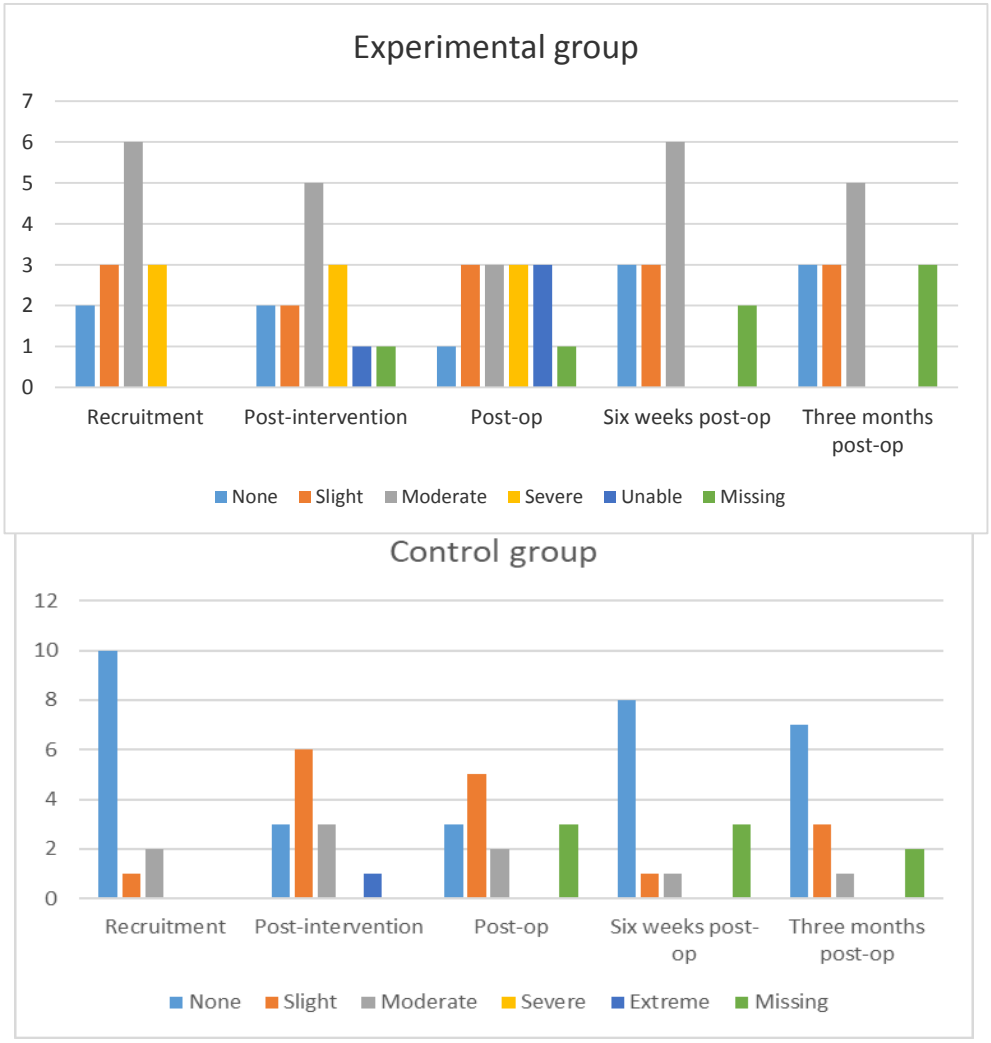


Figure 14: EQ-5D-5L usual activity scores for the experimental group and the control group from recruitment to three months post-operative follow-up

The graphs below show the change over time in scores on the pain/disability section of the EQ-5D-5L (Figure 15). In both groups pain reduced over time.

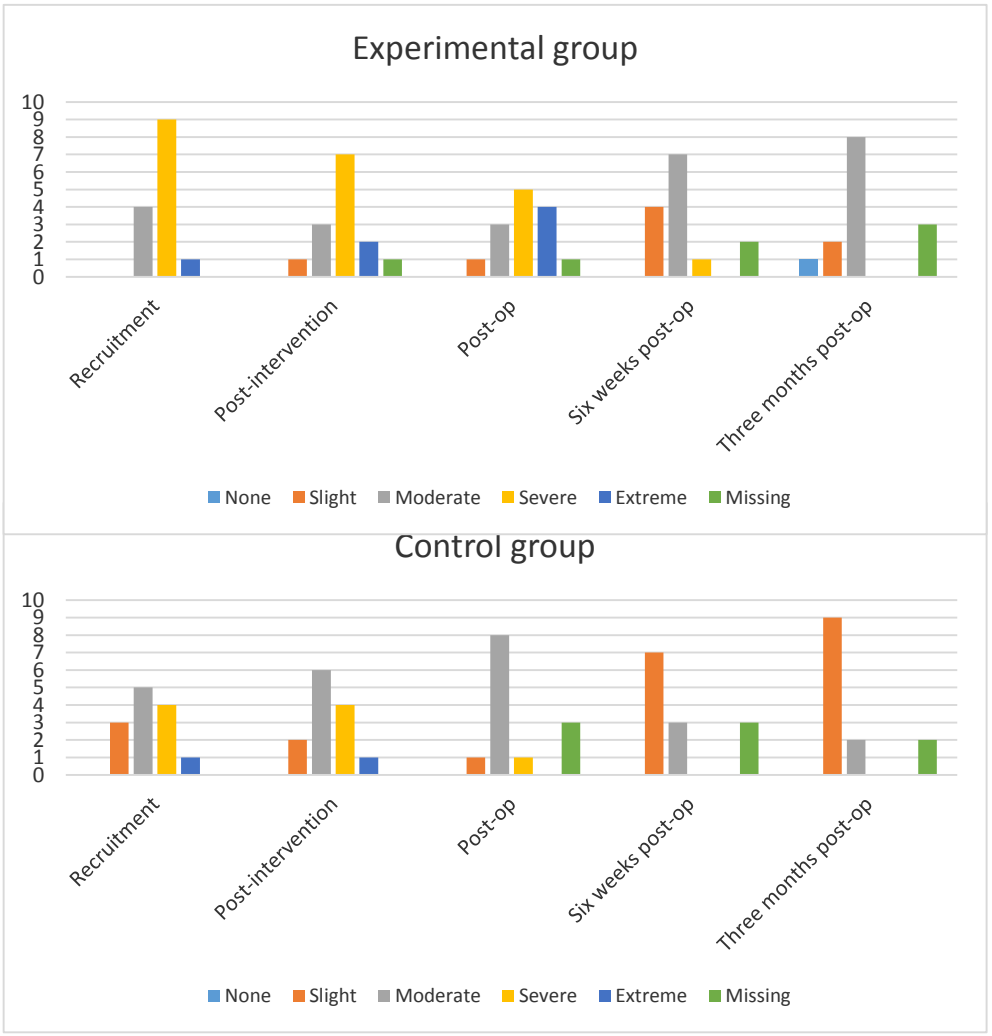


Figure 15: EQ-5D-5L pain/discomfort score for the experimental group and the control group from recruitment to three months post-operative follow-up

The three aspects of the EQ-5D-5L presented above link most closely with the parameters being assessed in the other outcome measures and as such are presented here. The self-care and anxiety/depression scores can be found in Appendix N.

4.5 Function

4.5.1 The Aggregated Locomotor Function Score (ALF)

There was no significant difference between the groups on the ALF at any point. The experimental group improved significantly over time (χ^2=17.73; p=0.001), whereas the control group showed no significant change (χ^2=7.2; p=0.13) (Figure 16). The effect size was -0.26 (-1.09 – 0.59 95%CI) indicating no difference between groups.

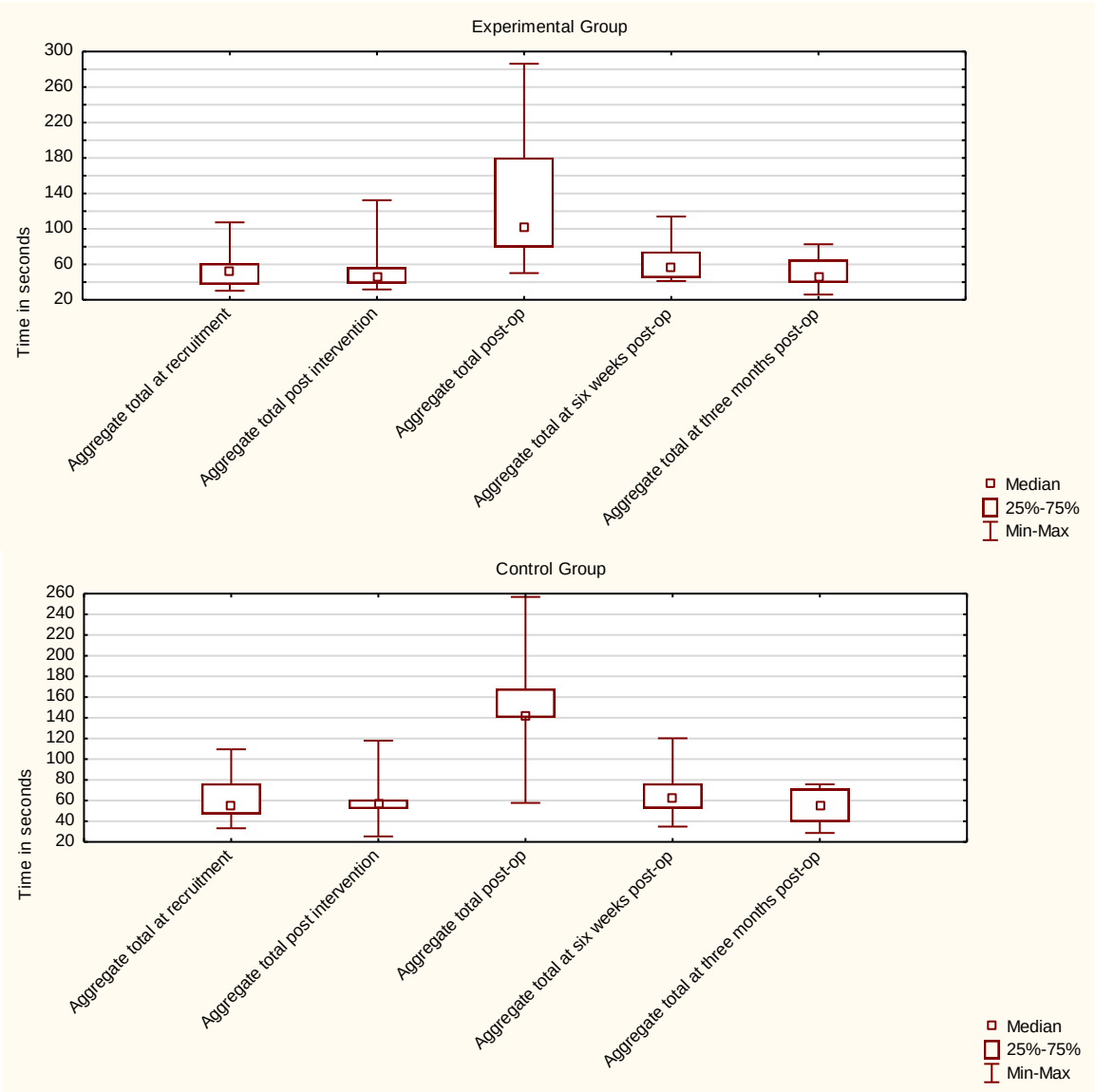


Figure 16: ALF scores for the experimental group and the control group from recruitment to three months post-operative follow-up

4.6 Fear of movement

4.6.1 TSK scores

Both groups achieved a significant within group improvement over time on their TSK scores (control group χ^2=10.88; p=0.03 and experimental group χ^2=13.24; p=0.01). The experimental group showed significant improvement over the control group post-intervention, with a lower TSK score (U=42; p=0.03) (Figure 17). The effect size was 1.39 (0.41 – 2.26 95%CI) indicating a difference between groups, with the intervention group performing better than the control group.

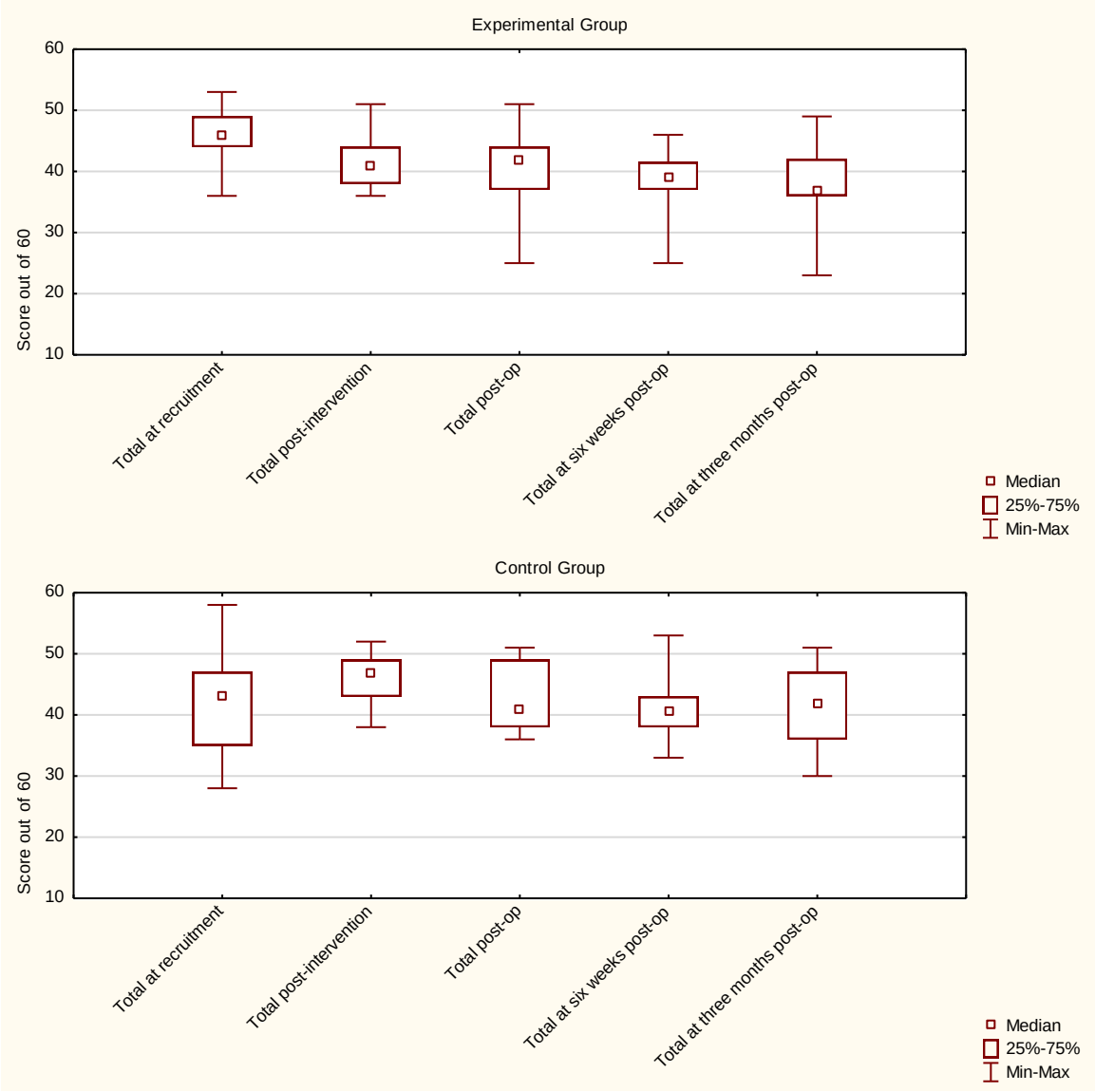


Figure 17: TSK scores for the experimental group and the control group from recruitment to three months post-operative follow-up

4.7 Summary of results

Although the current intervention may have been beneficial in a previous study on a similar population while waiting for an arthroplasty [29] the current study's results suggest that the benefits experienced while on a waiting list may not be incurred when patients know that their surgery is imminent nor impact post-operative outcomes. The results were mixed but suggest that for every outcome measure, excluding the TSK, there was no difference between the two groups at three months post-operative follow-up when effect sizes were calculated with a 95% CI. The TSK was the only tool which indicated a difference at three months post-operative follow-up, with the experimental group achieving significantly better results than the control group.

Chapter 5: Discussion

The aim of this study was to evaluate the effects of an exercise and education based intervention on post-operative pain and function for patients with knee OA, awaiting TKA at Tygerberg Hospital in the Western Cape. The intervention employed in the current study had been used successfully in a previous study conducted on the same population on an arthroplasty waiting list [29]. The previous study did not assess post-operative outcomes, thus the current study aimed to assess post-operative pain and function outcomes in patients undergoing TKA. Overall, results suggest that the pre-operative intervention did not influence post-operative outcomes and there were no differences between groups at the three-month post-operative follow-up, except for the results of the TSK, which was used to measure fear of movement as a secondary outcome. The study was not powered for the fear of movement results, but the experimental group achieved significant improvements compared to the control group in this aspect of testing. These results, relating to pain and function, are not consistent with the previous research in a similar population [29], however it is important to note that the focus of the previous study was whether benefits were achievable prior to surgery. This leads one to question not only the appropriateness of the intervention itself in terms of achieving post-operative benefits, but also of the measurement tools used for this study.

From these results, there are some useful insights and interesting points are raised which warrant further discussion. The specific difficulties associated with conducting research in a public health setting in South Africa on a population waiting long periods for surgery, and how it differs from previous research are discussed. Possible improvements to the intervention to make it more appropriate for use in this group (who are aware that their surgery is imminent) are discussed to assist with formulating interventions for future research and clinical application.

To provide context and evaluate generalizability of the results, the socio-demographics of the participants in this study will be compared to and contrasted with those of participants in other studies of this nature, as well as the global socio-demographics of patients undergoing TKA for OA. This will be followed by a review of the measurement tools used, and the appropriateness thereof. Factors influencing non-participation and the large amount of missing data will also be considered, as well as potential explanations for seemingly conflicting results. Finally, the strengths and limitations of the study will be discussed, including recommendations regarding practical changes and improvements to the intervention to make it more appropriate for this group of patients.

5.1 Socio-demographic profile of the participants

The socio-demographic characteristics of the participants were similar to those in the study conducted by Saw et al (2015), which is not unexpected, given that the study was conducted in the same setting.

Levels of education in the population were low, but consistent with those reported in the 2016 South African community survey conducted by Statistics South Africa, which reported that the majority of survey respondents had some secondary schooling, but have not completed Grade 12 [30]. The percentage of unemployed participants in the present study was 66.66%, which is much higher than the 27.7% reported by Statistics South Africa [148]. This high level of unemployment may be due to the setting, or as a result of the sample population used. The study was conducted in a state hospital in South Africa, a country where 84% of the population rely on the national health sector for the sole provision of their healthcare needs [21]. Given that this is the uninsured portion of the population [21], it might make sense to assume that their levels of unemployment would be higher than if one were to take into account the national population, including the 16% of South Africans who have health insurance. The study being conducted on participants with a median age of 63 years and the inclusion of patients over 65 years of age, which, although not legislated, is widely accepted as retirement age in South Africa [149] may have also influenced the reported levels of unemployment.

The age range of patients undergoing TKA or total hip replacement, according to a large systematic review by Ethgen et al (2004), was 41 years to 73 years old [150]. The current sample is similar in that the median age falls within this grouping. As was the case in the interventions reviewed, patients in the present study had a mix of diagnoses with those with OA and RA being placed in the same groups, with the outcome of the surgery being the point of focus, not necessarily the disease mechanism. The similarities in age and disease profile makes comparison of results possible, however, many of the previous studies assessing patients with OA and those having TKA have been conducted in developed countries which should be considered when attempting to compare results.

5.2 Outcome measures

5.2.1 Pain

The primary outcome of the study was pain. In this study, the intervention did not produce an effect on pain severity or pain interference in this sample. Analysis of the results from the study and evaluation of the responses to the questionnaires themselves led to questions regarding the suitability of the assessment tool for this group. Although the research assistant was present at all data collection points and available to help with the completion of the questionnaires, there were a number of data collection points where the responses provided suggest a lack of understanding of the questions being asked, which may have affected the accuracy of the results e.g. in several instances every single item on the BPI was scored as a zero and all options on EQ-5D-5L were crossed off for each category. This is surprising given that the tool has been translated and validated for use in all three languages encountered in the sample group [113]. The effects of low levels of education and health literacy and how these relate to the current study will be discussed later.

Although there was no significant improvement by the experimental group over the control group on either of the sub-scales of the BPI, both groups experienced a reduction in their pain severity and interference scores following their surgeries. This suggests that the surgery alone was successful in reducing pain and that although the experimental group in the study by Saw et al (2015) showed promising results in a waiting list population, those same effects were not achieved in a group undergoing surgery soon after intervention. The sensitivity of the BPI to a change in pain in this group may then suggest that the lack of positive result from the intervention may be a combination of factors. One factor worth considering is that the control group scored significantly better than the experimental group on the both PSS and PIS at recruitment and thus perhaps the lack of positive result from the study was simply that the experimental group had too much ground to make up in order to achieve any significant improvement over the control group.

The above being considered, there were still clear instances of misunderstanding of the tool and how to complete it. Having defined pain as more than simply a unidimensional experience [26], it is impossible to assess using a tool which doesn't take this into account. As such, in future studies on similar populations or where literacy is a concern it may be useful to provide participants with training on how to complete the required questionnaires, before they have to do so or use the questionnaires by interview. Another option may be to provide a new and thorough explanation as to how to complete the questionnaires at every single follow-up session. The current study assumed that the participants would grow familiar with the tools and as such would not require fresh explanation at every follow-up. Given what is now known regarding literacy levels and their health literacy that may have been an assumption too far. It may be time consuming to implement these suggestions, but by reducing the room for error, it may ultimately improve the validity of the findings.

5.2.2 Secondary outcome measures

The same lack of significant change between groups was evident on the WOMAC, EQ-5D-5L and the ALF. These measures did not reveal any difference between the two groups.

5.2.2.1 The WOMAC

The WOMAC, much like the BPI revealed within group changes over time, with both groups improving. The findings for the experimental group were consistent in that both their WOMAC function score and their ALF score improved concurrently, whereas the control group showed improved scores on WOMAC function, but not on the ALF. This is surprising as one would assume that as self-reported levels of function improved, so should observed measures of function. As with the BPI, the control group had a significantly better starting point at recruitment than the experimental group, and showed significant improvement over time. Ultimately there were no differences found between the groups on the WOMAC total score or any of the sub-scores at three months post-operative follow-up as was the finding with most of the other outcomes in this study. As is suspected with the BPI, there may have been issues of understanding related to this tool. It may have also been inappropriate for this particular group, with several participants struggling to answer questions which were related to activities that they do not do regularly.

5.2.2.2 The EQ-5D-5L

As discussed in the literature review, the EQ-5D-5L has not been validated for this sample, however the 3L had been validated. It was expected that the 5L, although not validated would still be suitable for use and would be more sensitive to change over time in this group [135].The scores on the VAS of the EQ-5D revealed no change between groups or within groups, however there were issues encountered regarding the completing of this section by the participants, as much like the BPI, the numerical rating scale seemed confusing for some. Once again, the instrument showed within group changes, but significance was not established due to the nature of the data, with no norms available for the South African population nor formulae for converting the data to numerical values. Notably on the EQ-5D-5L there were a lot of missing data, particularly in the final data collection period. This was a consequence of a number of participants failing to follow-up. But this may have been compounded by difficulty in completing the questionnaire. Once again, participants may have benefited from some training or repetitive explanation on how to complete the questionnaire or the questionnaire should have been administered by interview. In future, it may be advisable to use the 3L, despite its limited sensitivity to change over time as it is less complex to complete, has normal values and formulae to convert to numerical data.

5.2.2.3 The TSK

The TSK was the only tool indicating any meaningful change over time. This result is interesting, considering the lack of change on any of the other outcome measures and will be discussed in the following section within the context of pain and fear and how they influence behaviour.

5.3 Pain and Fear

The lack of clinically meaningful change on the BPI as well as the WOMAC, coupled with the reduction in fear of movement revealed on the TSK provide an interesting area to explore. This is noteworthy because it suggests that even though participants experienced little difference in both the changing of their pain severity and disability, fear of movement in the experimental group reduced significantly. Based on a biomedical model of pain [151] one might assume that fear of movement would only become less if pain severity were reduced, thus these findings would appear to contradict each other. They may however be explained using the biospsychomotor-model of pain [152].

The biopsychomotor-model of pain postulates that pain is a multi-dimensional system and differs from the biopsychosocial model in that behaviour is a defining and central feature and is not simply a result of cognitive, social or emotional influences[152]. In the paper by Sullivan (2008 p. 282), pain behaviour refers to "specific body movement enacted during the experience of pain" [152]. "Such movement might include facial or postural configuration, actions oriented toward protection or care of an injury, and actions oriented toward the pain-related stimulus or pain-relevant environment" [152]. Communicative behaviours are an integral part of the pain system and verbal responses are a major aspect of these communicative behaviours [152]. Although the current study made use of questionnaires with specific rating scales, these could still be considered opportunities for communicative behaviours relating to pain as they provide an opportunity for the individual to express their suffering experience.

Thus, using the biopsychomotor model, it could be suggested that because these individuals are less fearful of movement (potentially performing more physical activity than they may have previously), they may feel the need to verbally express their pain "more loudly" in order to convey their suffering and have it recognised and understood. Thus, they show no change in their pain reports, despite a change in their beliefs around movement. What this may not explain is the lack of change on the WOMAC scores, as based on the fear-avoidance model put forward earlier, fear avoidance beliefs should influence behaviour, thereby reducing disability [72]. This leads one to the question of whether changing beliefs alone is enough to bring about a sustainable change in behaviour. The results of this study suggest that the answer is no, changing beliefs will not result in sustainable changes in behaviour. If this is the case, there are factors influencing behaviour change and thereby a reduction in disability which require further consideration. Such factors include self-efficacy and social learning.

Self-efficacy was not an outcome in this particular study, however looking at the results and the demographic profile of the participants, one might consider that low levels of self-efficacy may have played a role in limiting change in disability in these patients, despite the change in fear of movement. Although the fear-avoidance model suggests that fear-avoidance beliefs are an important mediator of disability, one of its shortcomings is that it does not appear to take into account the influence of self-efficacy in the process of behaviour change [72]. There is growing evidence to suggest that self-efficacy is an important mediator of the relationship between fear-avoidance beliefs and disability [153, 154]. This evidence suggests that without adequate levels of self-efficacy, an intervention such as the one offered in the current study is unlikely to be successful in changing disability, or the behaviour of those patients receiving it. Figure 18 below shows the

modified Fear-Avoidance Model developed by Woby [154], which includes self-efficacy and illustrates the effect it has on the relationships between beliefs and behaviour change.

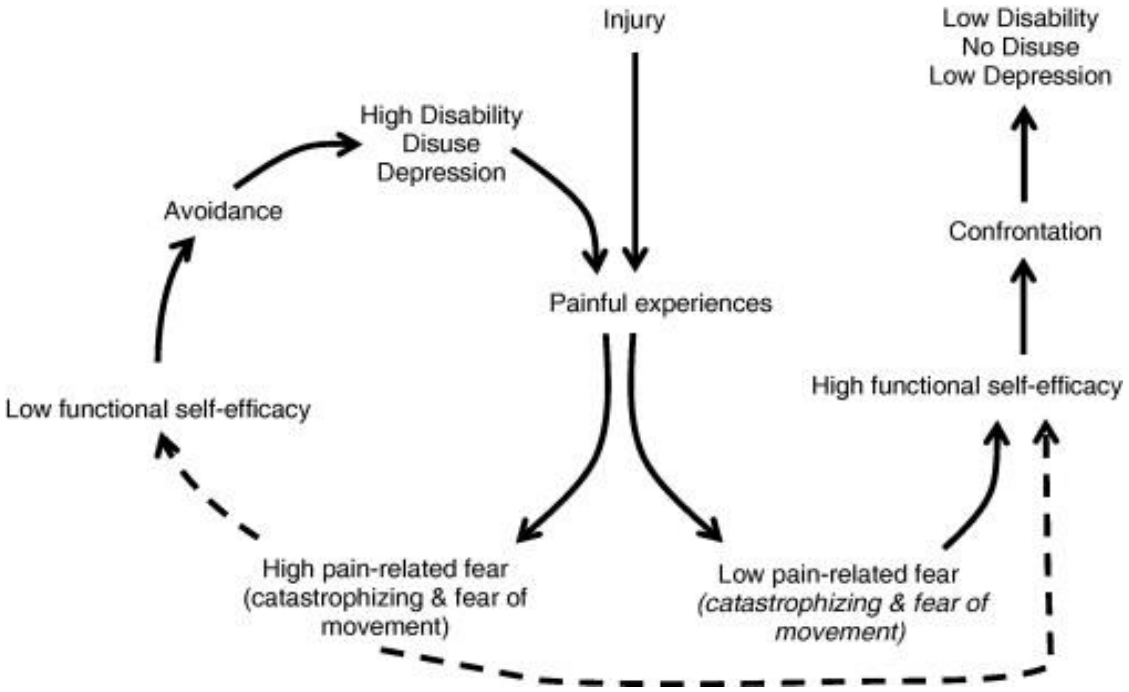


Figure 18: Woby's fear-avoidance model [154]

Self-efficacy, as already discussed, relates to an individual's confidence in their own ability to execute a behaviour in order to achieve an outcome [97]. Based on Bandura's self-efficacy theory, it depends on four factors, namely: performance accomplishments, vicarious experience, verbal persuasion, and physiological states [97]. These vicarious experiences in particular are important as social learning opportunities. Bandura suggests that by watching a peer engage in an activity which is feared by the individual, and seeing that there is no negative consequence encountered, that individual's fear may be alleviated, which should guide their actions to less fearful behaviours [155]. In a tertiary health-care setting, patients engage with others who are not from their immediate community and whom they may not identify with; essentially the opportunity for peer-learning may be reduced. It may thus be postulated that a lack of common identity, limited the potential for social learning to take place in the experimental group, and hindered the development of adequate self-efficacy to effect a change in behaviour.

As mentioned in the introduction to this section, the results of this study suggest that changing beliefs does not always change behaviour. The role of self-efficacy in mediating behaviour change

has been broadly accepted; however, the important roles of social cohesion and social learning in the process of enhancing self-efficacy may be more complex. Social learning would appear to be a major driver of behaviour change through the development of self-efficacy in group interventions. If there is no social cohesion, one may expect that social learning will not take place. It has been proposed that there is a minimum requirement for the level of social cohesion needed to gain positive health effects [156], further supporting the notion that it is an important determinant of whether or not social learning will take place. In future, consideration of factors which increase social cohesion needs to be made when allocating patients to groups for interventions such as the one used in this study. This has been previously recommended in groups for managing pain in people living with HIV with consideration made for age, gender and cultural group to enhance cohesion and provide a common identity amongst patients [103]. In looking at the factors surrounding the development of self-efficacy, and facilitating behaviour change and social learning, one may look to the strengths and limitations of the study to assess how things may be done better in future research and clinical practice.

5.4 Limitations and Strengths

5.4.1 Limitation: Inconsistent research assistance

Logistics surrounding research assistance in this study proved challenging. As the primary researcher was only able to perform the intervention and not the data collection due to blinding constraints, a research assistant had to be used. Unfortunately, the research assistant changed several times through the course of the study. Though training was done on how to administer the measures, it is possible that the lack of continuity affected the results.

5.4.2 Limitation: Non-participation

The study encountered many problems with recruitment of participants and target numbers for recruitment were not met. There were a large number of individuals who were on the waiting list, however when telephonic contact was attempted, they were unable to be reached. Of those contacted telephonically, approximately one fifth of those were uninterested in participating in the study. These challenges were not dissimilar to those of a previous study conducted at the same hospital on patients on the arthroplasty waiting list [29]. The greatest challenge was the participants who enrolled in the study and then could not be contacted (or agreed to come and did not arrive), or those who had received their surgery and then simply failed to arrive for their follow up.

The other big challenge regarding non-participation was poor attendance of the group intervention. As already mentioned, some members of the first group attended less than half of the sessions. This obviously poses a challenge when trying to assess to the effect of an intervention which is not received in its entirety.

Due to the fact that this study assessed post-operative outcomes, the number of participants lost may have been slightly higher than if it was only assessing pre-operatively. In a setting such as the current one, where patients have waited for several years to have their surgeries, and hospital resources are limited and inconsistent, the constraints involved need to be taken into account and possibly a larger sample should have been considered to allow for greater loss to follow-up. As seen in the results (Figure 5), there were a number of unforeseen circumstances leading to exclusion and therefore loss of participants. These included: the patient being scheduled for the incorrect surgery; patient not being able to have their surgery in time (according to the patient, as informed by the hospital, this was due to an inconsistent electrical supply to theatres, and back-up generators not working properly, making it unsafe to perform surgery); patients deemed unfit for surgery only at pre-operative assessment; and patients being scheduled for their other limb to have arthroplasty, which given the waiting time, they could not be expected to pass up for the sake of completing a study.

As a result of withdrawal, exclusion and loss of several participants during the course of the study the sample size was small and therefore the study lacked the numbers needed to be adequately powered. This may mean that future studies will require larger samples in order to yield generalizable results. Aside from the obvious logistical problems associated with the hospital and processes related to the waiting lists, some suggested reasons for non-participation are discussed in the following sections.

5.4.2.1 Loss of Social Cohesion

In a paper by Stanley (2003), social cohesion is defined as “the willingness of members of a society to co-operate with each other in order in order to survive and prosper”[2]. The definition of Social Cohesion proposed by Chan et al (2006), providing perhaps a more thorough understanding, is “a state of affairs concerning both the vertical and the horizontal interactions among members of society as characterized by a set of attitudes and norms that includes trust, a sense of belonging and the willingness to participate and help, as well as their behavioural manifestations”[157].

An understanding of the history of segregation and oppression in South Africa may help to explain the lack of social cohesion that this country still experiences today. Apartheid was used to create a society divided along racial lines and using the Group Areas Act, the government of the time managed to force people to live only with those of the same allocated race group [158]. This may have increased social cohesion within each race or even cultural group, however it created division between groups, which is still felt today [159]. As discussed earlier, this lack of intersectional cohesion may have reduced the potential for social learning within the experimental group during the intervention period as groups included participants from various cultural backgrounds and differing communities and in doing so may have limited the ability of the intervention to achieve the desired outcomes [156]

There were several participants who enrolled in the study who failed to participate adequately, attending less than four group sessions (for the purposes of the study) with no reason given for those sessions missed, and others who made other plans for the time allocated to the sessions. Using the definition of social cohesion above, one could suggest that this may have to do with a lack of social cohesion in the sample population. Understandably, these patients had all been on the waiting list for some time and probably would have done almost anything to receive their surgeries in a more timeous fashion. Once they were made aware that they would get their surgeries in the following three months, it became quite clear that for a few of them, they had received what they needed from the study. It should be noted that commitment to the full six weeks was emphasised at recruitment, in an attempt to prevent this problem, but obviously participants could not be forced to arrive at appointments and given the levels of unemployment in the participants, perhaps poverty contributed to lack of participation.

5.4.2.2 Poverty

Lack of finances for transport was a common problem experienced throughout the study, making it difficult to gather data. The majority of this sample was unemployed and the researcher could only provide transport money once the participant arrived at the hospital to complete their measures. This made it difficult for those who were willing, but financially unable to get to the hospital to collect their money. Solutions to this problem may be quite difficult to work out as funding is often limited in the studies themselves and one cannot hand over money in anticipation of a transport need, as there is the possibility that the participant will still not attend and that money will not be used for its intended purpose. A possible option to be investigated would be making use of allocated private transport, which would bring participants to and from the hospital on the desired days. This

may prove to be more expensive than using public transport, however it may be more reliable in ensuring that participants arrive for measurement visits.

Lower literacy levels [160], as well as lower levels of health literacy specifically [161] have been associated with poorer health outcomes. It may be that the initial low levels of health literacy were so severe that the intervention designed was not sufficient to change health outcomes. There was a high degree of educational poverty in this study. As a result, health-literacy in the present cohort may have been limited, possibly influencing the results negatively. Low levels of health literacy could negatively impact results in two ways, firstly due to the nature of the outcome measures used and secondly as a consequence of health literacy limiting interaction with the intervention. Although literacy was not assessed specifically in this study, it would be useful to do this in future research of this nature so as to provide the most appropriate assistance for participants when filling out questionnaires.

With regards to the outcome measures, four of the five outcome measures used were self-report questionnaires requiring comprehension by the patient. Even with assistance, it became clear throughout the course of the study that there were gaps in understanding, with participants frequently asking questions to clarify meaning and appearing unsure about how to answer correctly. This may have been because even though the researcher attempted to make use of the simplest and yet most effective tools, the large number of questionnaires (four), may have increased the response burden on these patients. Potential solutions to dealing with this problem in future research have been discussed previously.

In terms of health literacy limiting interaction with the intervention, a systematic review assessing the effectiveness of musculoskeletal education interventions on patients with low literacy levels, found that engagement with these patients was poor [162]. It has also been reported that patients with low levels of health literacy may struggle to act on the information being given to them in a health education context [163]. This supports the notion that these patients would therefore struggle to achieve one of the main goals of the intervention, which is behaviour change, due to a lack of adequate engagement or an inability to respond appropriately. It may be valuable in future research to assess levels of health literacy and not only level of schooling completed to evaluate whether patients are able to engage with educational behaviour-change interventions The intervention itself may also need to be addressed to make it more appropriate for populations with low levels of health literacy.

5.4.3 Limitation: The intervention

The specific intervention and coursework book used in the present study has never before been used in a group where surgery is imminent. The studies making use of this intervention previously [29, 115] used it in patients who were awaiting surgery and did not know when (if ever) they would be offered the surgery. This is obviously very different to the current participants who knew that they would be receiving their surgery soon. A patient's expectation about their treatment can affect the outcome positively or negatively [164]. Using this premise one could speculate that the patients in the previous studies by both Saw et al (2015) and Kruger-Jakins et al (2015) did well with the current intervention as they considered it their only option or solution. It is likely that their expectations were low as far as actually receiving their surgery was concerned, having been on waiting lists for up to five years. This in turn may have increased their expectations regarding results to be achieved using the group intervention, thus positively influencing the outcome of the study [165].

In the current study, the participants were already anticipating surgery and so perhaps on a subconscious level, were not inclined to place as much hope on the intervention offered as it was perceived more as an interim activity which was a means to an end (that being surgery). This could potentially have influenced the degree to which they benefitted from the intervention [165].

The intervention used does not dedicate time to explaining the surgery or post-surgical pain. One of the key messages delivered in the intervention is that pain is not equal to tissue damage with exercise being safe despite pain. This message is not wrong, however it may appear contradictory and even confusing to those undergoing surgery who then experience post-surgical pain due to trauma to the body. Having been told that pain doesn't mean damage in terms of the chronic osteoarthritis pain, patients may now have doubted that information or become confused when faced with the very clear evidence of pain in the presence of acute tissue damage following surgery. There is evidence to support iatrogenesis in chronic pain patients, with inappropriate information or advice causing anxiety and distress [166]. Taking into account the low levels of education and limited health-literacy of the sample, it may be that an intervention for a group who will be receiving their surgery soon after, should include surgical education and perhaps avoid creating confusion around the pain and damage relationship by addressing post-surgical pain specifically and not only chronic OA pain.

In both of the previous studies evaluating the effect of this intervention in people living with OA, self-efficacy was assessed at baseline and six months follow-up, with no significant differences seen between groups [29, 115]. This leads one to question whether or not the current intervention addresses self-efficacy at all. If the intervention is not adequately addressing self-efficacy and patients are starting off with low levels of self-efficacy as is suspected in this instance, then behaviour change is likely to continue to fail. This, along with the suggested lack of common identity and reduced social learning in a tertiary setting, may render this intervention ineffective in a population undergoing TKA. It may be worth considering delivering this intervention in a primary healthcare setting, which is more community orientated, to patients who have been diagnosed with knee OA, but who are not due for surgery, or perhaps are not even on a waiting list yet. This may have the potential to yield better outcomes as the intervention message is consistent with self-management and the setting will enhance social cohesion.

5.4.4 Limitation: Post-operative follow-up care

Due to post-operative rehabilitation being out of the study's control, inconsistencies in the amount or timing of exercises done and functional rehabilitation done were possible. Follow up in the outpatient department was also generally done at six week follow up with the surgeon with no interim follow-up with any member of the team. This long period of time might be inadequate for those patients with high fear-avoidance beliefs around movement. In future, post-operative follow-up care should be standardised for all patients involved. This would hopefully further validate results by removing variability in this area.

Post-operative rehabilitation following TKA should seek to increase self-efficacy to facilitate behaviour change following surgery. When looking at "performance accomplishments" as a source of efficacy information, one could compare the four stages of performance accomplishments to a model for graded activity [97]. Rehabilitation following injury is essentially a graded activity programme with the patient being required to progress in load and difficulty as they improve. If this is done well following surgery and strategies to enhance self-efficacy (such as performance accomplishments and verbal persuasion) are employed, then maybe self-efficacy is being addressed. Interestingly, despite a number of factors mentioned above, which should have prevented these patients from enjoying positive post-operative outcomes, both groups improved. This improvement in both groups may have been as a result of the Hawthorne Effect.

Despite the limitations experienced as a result of the cultural and socio-demographic diversity in this population, there were also several strengths.

5.4.4 Strength: Cultural practices

South Africa is an ethnically and culturally diverse nation [167]. According to estimates from 2007, 72% of the black African population in South Africa make use of traditional medicine [168]. During the current study, one participant completed the entire intervention and then, being given his date for surgery, he decided that a more traditional approach was preferable. Throughout the course of the intervention he had continued with his traditional interventions, but engaged fully with the content. Interestingly, it was only the surgery which he chose to abandon, and his respected position in the community put him in a position where he was motivated to take the new knowledge and skills gained from the intervention back into his community.

Although the above-mentioned patient withdrew from the study to pursue traditional medicine options, his desire to continue with sharing his knowledge in his community raises an important point for future research and interventions being conducted in similar settings. Whilst a lack of intersectional social cohesion may have been a limitation of the study, the level of social cohesion within each community or social group should be considered and used to the benefit of that community. As mentioned earlier, the setting of the intervention should be considered. It may be more beneficial to deliver an intervention of this nature at a primary healthcare level, rather than a tertiary level. At primary health clinics, patients are more likely to be functioning within their own community. Perhaps an intervention like this delivered at a primary care level would be able to make better use of the social cohesion within communities and thus increase the social learning taking place through peer interaction, reducing the need for surgical referral, thereby reducing the burden on the healthcare system.

5.6 Recommendations

It may be helpful to make use of simpler measurement tools when dealing with participants with lower levels of education such as these. With the suspected confusion regarding the completion of the BPI as well a number of incomplete instruments submitted, it would be worthwhile to identify or develop other tools which offer a simpler rating system, but still evaluate the biopsychosocial aspects of pain. Based on personal communication with participants in the experimental group, there was perceived benefit from the intervention, with increased levels of exercise and reduced levels of disability being reported in conversation almost routinely at each session. The results however do not mirror this.

It would also be advantageous to ensure that a consistent research assistant or interpreter is used throughout the entire process to manage, as well as to reduce the possibility of the introduction of any errors or differences in how the tests or questionnaires are administered.

The course material used in the intervention may need to be re-examined for use in future studies in a pre-operative sample, due to undergo their surgery soon. It may be more beneficial for those involved if it contains more appropriate information regarding surgery specifically, as well as perhaps placing more emphasis on explaining the difficult idea that nociception and pain are different and not equal to one another.

The current study should be replicated in different settings with an optimised curriculum targeting at risk patient groups in order to thoroughly assess its merit for use in a pre-operative population. It may be useful to assess levels of social cohesion within groups before beginning so that should they be found to be low as was suspected but not assessed in the current study, the researcher could address that early on.

Chapter 6: Conclusion

The current study was undertaken in response to a gap in the literature regarding the use of education and exercise based interventions to improve post-operative outcome in patients undergoing TKA. The efficacy of this intervention and those similar to it is well established in groups who are not due to undergo surgery in the near future, however as mentioned, post-operative follow-up was lacking [29, 95, 102, 115]. The aim of the study was to assess the effects of a six-week physiotherapist-led exercise and education based programme on post-operative outcomes in terms of pain and function in patients undergoing TKA at TBH in the Western Cape. The objectives were to establish whether participation in this intervention pre-operatively caused a significant change in post-operative outcomes in a group of patients undergoing total knee replacement as compared to a control group, with regards to the outcomes of pain, disability, HRQoL, physical functioning and fear of movement.

The results showed no significant differences between groups at three months post-operative follow-up on any of the outcomes except for fear of movement. These results are in contrast to those achieved previously in people with end stage OA on the waiting list for arthroplasty [29]. Although fear of movement scores for the experimental group were significantly better than the control group at three months post-operative follow-up, these results did not translate into any functional change or reduction in disability. Possible reasons for this have been discussed in the context of the biopsychomotor-model of pain [152],as well as using social learning [155] and self-efficacy theory [97].These surprising results suggest that changing beliefs is not enough when it comes to trying to produce behaviour change and postoperative pain and that there are several factors which need to be addressed to enhance effects.

What is also important to note is that perhaps these results suggest that one cannot simply apply an intervention designed for those on a waiting list, to those who are going to have surgery. The needs of the surgical group are obviously different to the non-surgical group and need to be assessed fully in order to provide effective and meaningful interventions for these patients. Another notion to consider is that perhaps these interventions shouldn't be conducted in a pre-operative population at all as the expected benefits of prehabilitation in patients undergoing TKA are not well established [169]. Instead, to improve social cohesion and social learning, which were identified as potential barriers to success in this instance, these interventions should be conducted at a primary care level with the objective of reducing pain and enhancing function with the potential of reducing the need for surgery.

References

1. Woolf, C.J., *Central sensitization: implications for the diagnosis and treatment of pain.* Pain, 2011. **152**(3 Suppl): p. S2-15.
2. Stanley, D., *What Do We Know about Social Cohesion: The Research Perspective of the Federal Government's Social Cohesion Research Network.* Canadian Journal of Sociology, 2003. **28**(1): p. 5-17.
3. Pereira, D., et al., *The effect of osteoarthritis definition on prevalence and incidence estimates: a systematic review.* Osteoarthritis Cartilage, 2011. **19**(11): p. 1270-85.
4. Glyn-Jones, S., Palmer, A.J.R, Agricola, R, Price, A.J, Vincent, T.L, Weinans, H & Carr, A.J, *Osteoarthritis.* Lancet, 2015. **386**: p. 376-387.
5. Reginster, J.Y., *The prevalence and burden of arthritis.* Rheumatology (Oxford), 2002. **41 Supp 1**: p. 3-6.
6. Neogi, T., *Structural correlates of pain in osteoarthritis.* Clinical and Experimental Rheumatology, 2017. **35**: p. S75-S78.
7. Organisation, W.H. *Chronic rheumatic conditions fact sheet*. Chronic diseases and health promotion September 2008 [cited 2015 08 March]; Available from: www.who.int/chp/topics/rheumatic/en.
8. Woolf, A.D. and B. Pfleger, *Burden of Major Musculoskeletal Conditions.* Bulletin of the World Health Organisation, 2003. **81**: p. 646-656.
9. Brown, G.M.M., et al., *Important problems identified by patients with chronic arthritis.* South African Medical Journal, 1987. **72**: p. 126-128.
10. Grant, S., W. St John, and E. Patterson, *Recovery from total hip replacement surgery: "it's not just physical".* Qual Health Res, 2009. **19**(11): p. 1612-20.
11. Hurley, M.V., et al., *Long-term outcomes and costs of an integrated rehabilitation program for chronic knee pain: a pragmatic, cluster randomized, controlled trial.* Arthritis Care Res (Hoboken), 2012. **64**(2): p. 238-47.
12. Zhang, W., et al., *OARSI recommendations for the management of hip and knee osteoarthritis, part I: critical appraisal of existing treatment guidelines and systematic review of current research evidence.* Osteoarthritis Cartilage, 2007. **15**(9): p. 981-1000.
13. Zhang, W., et al., *OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines.* Osteoarthritis Cartilage, 2008. **16**(2): p. 137-62.
14. Zhang, W., et al., *EULAR evidence based recommendations for the management of hip osteoarthritis: report of a task force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT).* Ann Rheum Dis, 2005. **64**(5): p. 669-81.
15. Fernandes, L., et al., *EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis.* Ann Rheum Dis, 2013. **72**(7): p. 1125-35.
16. Hochberg, M.C., et al., *American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee.* Arthritis Care & Research, 2012. **64**(4): p. 465-474.
17. Moskowitz, R.W., *The 2012 ACR guidelines for osteoarthritis: Not a cookbook.* Cleveland Clinic Journal of Medicine, 2013. **80**(1): p. 26-32.
18. Government, W.C. *Analysis Of Service Pressures at Health Facilities Across the Province*. 2014 21-02-2014 [cited 2018 08-01-2018]; Available from: https://www.westerncape.gov.za/news/analysis-service-pressures-health-facilities-across-province.
19. Mascarenhas, R., *The Manitoba arthroplasty waiting list: impact on health-related quality of life and initiatives to remedy the problem.* J Eval Clin Pract, 2009. **15**(1): p. 208-11.

20. Davis, A.M., et al., *The trajectory of recovery and the inter-relationships of symptoms, activity and participation in the first year following total hip and knee replacement.* Osteoarthritis Cartilage, 2011. **19**(12): p. 1413-21.
21. Mayosi , B.M. and S.R. Benatar *Health and Health Care in South Africa — 20 Years after Mandela.* New England Journal of Medicine, 2014. **371**(14): p. 1344-1353.
22. Lluch Girbes, E., et al., *Pain treatment for patients with osteoarthritis and central sensitization.* Phys Ther, 2013. **93**(6): p. 842-51.
23. Jensen, T., S. and Finnerup, N.B., *Allodynia and hyperalgesia in neuropathic pain: clinical manifestations and mechanisms.* The Lancet Neurology, 2014. **13**(9): p. 924-935.
24. Beswick, A.D., et al., *What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients.* BMJ Open, 2012. **2**(1): p. e000435.
25. Puolakka, P.A., et al., *Persistent pain following knee arthroplasty.* Eur J Anaesthesiol, 2010. **27**(5): p. 455-60.
26. *Pain, I.A.f.t.S.o. IASP Taxonomy*. 2012 22 May 2012 [cited 2015 29 December]; Available from: http://www.iasp-pain.org/Taxonomy#Pain.
27. R.J Gatchel, Y.B.P., M.L Peters, P.N Fuchs, D.C Turk, *The Biopsychosocial Approach to Chronic Pain: Scientific Advances and Future Directions.* Psychological Bulletin, 2007. **133**(4): p. 581-624.
28. Organisation, W.H., *International Classification of Functioning, Disability and Health*. 2001, Geneva: World Health Organisation.
29. Saw, M., *The Effects of a Six-Week Physiotherapist-Led Exercise and Education Intervention in Patients With Osteoarthritis, Awaiting an Arthroplasty in South Africa*, in *Faculty of Health Sciences*. 2015, University of Cape Town.
30. Africa, S.S., *Community Survey 2016 in Brief*. 2016, Statistics South Africa.
31. Gilsoni, L., et al., *Development of the health system in the Western Cape: experiences since 1994.* South African Health Review, 2014: p. 59.
32. Rispel, L., *Analysing the progress and fault lines of health sector transformation in South Africa.* South African health review, 2016. **2016**(1): p. 17-23.
33. Africa, S.S., *Media release: Social profile of older persons 2011-2015 report* 2017.
34. Keller, S., et al., *Validity of the brief pain inventory for use in documenting the outcomes of patients with noncancer pain.* Clin J Pain, 2004. **20**(5): p. 309-18.
35. Tan, G., et al., *Validation of the Brief Pain Inventory for chronic nonmalignant pain.* J Pain, 2004. **5**(2): p. 133-7.
36. McConnell, S., P. Kolopack, and A.M. Davis, *The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): a review of its utility and measurement properties.* Arthritis Rheum, 2001. **45**(5): p. 453-61.
37. EuroQol. [cited 2015 15 April]; Available from: http://www.euroqol.org/.
38. McCarthy, C.J. and J.A. Oldham, *The reliability, validity and responsiveness of an aggregated locomotor function (ALF) score in patients with osteoarthritis of the knee.* Rheumatology (Oxford), 2004. **43**(4): p. 514-7.
39. French, D.J., France, C.R., Vigneau, F., French, J.A. & Evans, R.T, *Fear of movement/(re)injury in chronic pain: A psychometric assessment of the original English version of the Tampa scale for kinesiophobia (TSK).* Pain, 2007. **127**: p. 42-51.
40. Mody, G.M. and A.D. Woolf, *The Global Burden of Musculoskeletal Disorders. Business Briefing: European Pharmocotherapy 2003: 1-5.* 2003.
41. Parsons, S. and D. Symmons, *The Burden of Musculoskeletal Condtions.* Medicine, 2009. **38**(3): p. 3.
42. Woolf, A.D. and K. Akesson, *Can we reduce the burden of musculoskeletal conditions? The European action towards better musculoskeletal health.* Best Pract Res Clin Rheumatol, 2007. **21**(1): p. 1-3.

43. Parker, R. and J. Jelsma, *The prevalence and functional impact of musculoskeletal conditions amongst clients of a primary health care facility in an under-resourced area of Cape Town.* BMC Musculoskelet Disord, 2010. **11**: p. 2.
44. Hurley, M.V., H.L. Mitchell, and N. Walsh, *In osteoarthritis, the psychosocial benefits of exercise are as important as physiological improvements.* Exerc Sport Sci Rev, 2003. **31**(3): p. 138-43.
45. Brooks, P.M., *The burden of musculoskeletal disease--a global perspective.* Clin Rheumatol, 2006. **25**(6): p. 778-81.
46. Palazzo, C., et al., *The burden of musculoskeletal conditions.* PLoS One, 2014. **9**(3): p. e90633.
47. Hoy, D.G., et al., *Reflecting on the global burden of musculoskeletal conditions: lessons learnt from the global burden of disease 2010 study and the next steps forward.* Ann Rheum Dis, 2015. **74**(1): p. 4-7.
48. Akesson, K. and A.D. Woolf, *How to develop strategies for improving musculoskeletal health.* Best Pract Res Clin Rheumatol, 2007. **21**(1): p. 5-25.
49. Conaghan, P.G. and P. Brooks, *How to manage musculoskeletal conditions.* Best Practiice & Research Clinical Rheumatology, 2008. **22**(3): p. 287-394.
50. Collaborators, G.D.a.I.I.a.P., *Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016.* The Lancet, 2017. **390**: p. 1211-1259.
51. Callahan, L.F., Cleveland, R.J, Shreffler, J, Schwartz, T.A, Schoster, B, Randolph, R, Renner, J.B & Jordan, J.M. , *Associations of educational attainment, occupation and community poverty with knee osteoarthritis in the Johnston County (North Carolina) osteoarthritis project.* Arthritis Research and Therapy, 2011. **13**(5): p. 9.
52. Cleveland, R.J., Luong, M.N, Knight, J.B, Schoster, B, Renner, J.B, Jordan, J.M & Callahan, L.F, *Independent associations of socioeconomic factors with disability and pain in adults with knee osteoarthritis.* BMC Musculoskeletal Disorders, 2013. **14**: p. 10.
53. Symmons, D., C. Mathers, and B. Pfleger, *Global Burden of osteoarthritis in the year 2000.* Global Burden of Disease 2000.
54. Sinusas, K., *Osteoarthritis: diagnosis and treatment.* Am Fam Physician, 2012. **85**(1): p. 49-56.
55. Vincent, T.L. and F.E. Watt, *Osteoarthritis.* Medicine, 2009. **38**(3): p. 6.
56. Zhang, Y. and J.M. Jordan, *Epidemiology of osteoarthritis.* Clin Geriatr Med, 2010. **26**(3): p. 355-69.
57. Busija, L., et al., *Osteoarthritis.* Best Pract Res Clin Rheumatol, 2010. **24**(6): p. 757-68.
58. Lehohla, P., *Use of health facilities and levels of selected health conditions in South Africa: Findings from the General Household Survey, 2011*. 2013: Statistics South Africa Pretoria.
59. Chen, A., et al., *The Global Economic Cost of Osteoarthritis: How the UK Compares.* Arthritis, 2012. **2012**: p. 698709.
60. Salmon, J.H., Rat, A.C, Sellam, J, Michel, M, Eschard, J.P, Guillemin, F, Jolly, D & Fautrel, B., *Economic impact of lower-limb osteoarthritis worldwide: a systematic review of cost-of-illness studies.* Osteoarthritis and Cartilage, 2016. **24**: p. 1500-1508.
61. Gooberman-Hill, R., et al., *Assessing chronic joint pain: lessons from a focus group study.* Arthritis Rheum, 2007. **57**(4): p. 666-71.
62. Staud, R., *Evidence for shared pain mechanisms in osteoarthritis, low back pain, and fibromyalgia.* Curr Rheumatol Rep, 2011. **13**(6): p. 513-20.
63. Mease, P.J., et al., *Pain mechanisms in osteoarthritis: understanding the role of central pain and current approaches to its treatment.* J Rheumatol, 2011. **38**(8): p. 1546-51.
64. Sofat, N., V. Ejindu, and P. Kiely, *What makes osteoarthritis painful? THe evidence for local and central pain processing.* Rheumatology, 2011. **50**: p. 8.
65. Peat, G., R. McCarney, and P. Croft, *Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care.* Ann Rheum Dis, 2001. **60**(2): p. 91-7.

66. Lee, Y.C., Nassikas, N.J & Clauw, D.J., *The role of the central nervous system in the generation and maintenance of chronic pain in rheumatoid arthritis, osteoarthritis and fibromyalgia.* Arthritis Research and Therapy, 2011. **13**(2): p. 10.
67. Murphy, S.L., et al., *The role of the central nervous system in osteoarthritis pain and implications for rehabilitation.* Curr Rheumatol Rep, 2012. **14**(6): p. 576-82.
68. Latremoliere, A. and C.J. Woolf, *Central sensitization: a generator of pain hypersensitivity by central neural plasticity.* J Pain, 2009. **10**(9): p. 895-926.
69. Melzack, R. and P.D. Wall, *Pain mechanisms: a new theory.* Science, 1965. **150**(3699): p. 971-9.
70. Battaglia, A.A., *An Introduction to Pain and its relation to Nervous System Disorders*. 2016: Wiley.
71. Lluch, E., Torres, R, Nijs, J & Van Oosterwijck, J., *Evidence for central sensitization in patients with osteoarthritis pain: A systematic literature review.* European Journal of Pain, 2014. **18**(10): p. 1367-1375.
72. Vlaeyen, J.W. and S.J. Linton, *Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art.* Pain, 2000. **85**(3): p. 317-32.
73. Leeuw, M., et al., *The fear-avoidance model of musculoskeletal pain: current state of scientific evidence.* J Behav Med, 2007. **30**(1): p. 77-94.
74. Scopaz, K.A., et al., *Relationships of fear, anxiety, and depression with physical function in patients with knee osteoarthritis.* Arch Phys Med Rehabil, 2009. **90**(11): p. 1866-73.
75. Hurley, M.V. and N.E. Walsh, *Effectiveness and clinical applicability of integrated rehabilitation programs for knee osteoarthritis.* Curr Opin Rheumatol, 2009. **21**(2): p. 171-6.
76. Heuts, P.H., et al., *Pain-related fear and daily functioning in patients with osteoarthritis.* Pain, 2004. **110**(1-2): p. 228-35.
77. Wu, C.W., et al. *Validation of American College of Rheumatology classification criteria for knee osteoarthritis using arthroscopically defined cartilage damage scores*. in *Seminars in arthritis and rheumatism*. 2005. Elsevier.
78. Zhang, W., et al., *EULAR evidence based recommendations for the diagnosis of knee osteoarthritis.* Annals of the rheumatic diseases, 2009.
79. Kellgren, J. and J. Lawrence, *Radiological assessment of osteo-arthrosis.* Annals of the rheumatic diseases, 1957. **16**(4): p. 494.
80. Mayer, T.G., et al., *The development and psychometric validation of the central sensitization inventory.* Pain Practice, 2012. **12**(4): p. 276-285.
81. Nijs, J., et al., *Applying modern pain neuroscience in clinical practice: criteria for the classification of central sensitization pain.* Pain physician, 2014. **17**(5): p. 447-457.
82. Jordan, K.M., *EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT).* Annals of the Rheumatic Diseases, 2003. **62**(12): p. 1145-1155.
83. Conaghan, P.G., et al., *Care and management of osteoarthritis in adults: summary of NICE guidance.* BMJ, 2008. **336**(7642): p. 502-3.
84. Bruyere, O., et al., *An algorithm recommendation for the management of knee osteoarthritis in Europe and internationally: a report from a task force of the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO).* Semin Arthritis Rheum, 2014. **44**(3): p. 253-63.
85. McAlindon, T.E., et al., *OARSI guidelines for the non-surgical management of knee osteoarthritis.* Osteoarthritis Cartilage, 2014. **22**(3): p. 363-88.
86. Bennell, K.L.a.H., R.S, *A review of the clinical evidence for exercise in osteoarthritis of the hip and knee.* Journal of Science and Medicine in Sport, 2011. **14**(1): p. 4-9.
87. Marks, R.a.A., J.P., *Chronic Osteoarthritis and Adherence to Exercise: A Review of the Literature.* Journal of Aging and Physical Activity, 2005. **13**(4): p. 434-460.

88. McHugh, G.A., et al., *Pain, physical functioning and quality of life of individuals awaiting total joint replacement: a longitudinal study.* J Eval Clin Pract, 2008. **14**(1): p. 19-26.
89. Bachrach-Lindstrom, M., et al., *Patients on the waiting list for total hip replacement: a 1-year follow-up study.* Scand J Caring Sci, 2008. **22**(4): p. 536-42.
90. Ostendorf, M., et al., *Waiting for total hip arthroplasty: avoidable loss in quality time and preventable deterioration.* J Arthroplasty, 2004. **19**(3): p. 302-9.
91. Ackerman, I., K. Bennell, and R. Osborne, *Decline in Health-Related Quality of Life reported by more than half of those waiting for joint replacement surgery: a prospective cohort study.* BMC Musculoskelet Disord, 2011. **12**: p. 108.
92. Ackerman, I.N., et al., *Severely compromised quality of life in women and those of lower socioeconomic status waiting for joint replacement surgery.* Arthritis Rheum, 2005. **53**(5): p. 653-8.
93. Clark, N.M., Becker, M.H., Jans, N.K., Lorig, K., Rakowski, W. & Anderson, L. , *Self-Management of Chronic Disease by Older Adults A Review and Questions for Research.* Journal of Aging and Health, 1991. **3**(1): p. 3-27.
94. Lorig, K.R.H., H.R., *Self-Management Education: History, Definition, Outcomes and Mechanisms.* Annals of Behavioural Medicine, 2003. **26**(1): p. 1-7.
95. Barlow, J.H., A.P. Turner, and C.C. Wright, *A randomized controlled study of the Arthritis Self-Management Programme in the UK.* Health Educ Res, 2000. **15**(6): p. 665-80.
96. Newman, S., L. Steed, and K. Mulligan, *Self-management interventions for chronic illness.* The Lancet, 2004. **364**(9444): p. 1523-1537.
97. Bandura, A., *Self-efficacy: Toward a Unifying Theory of Behavioral Change.* Psychological Review, 1977. **84**(2).
98. Nolte, S. and R.H. Osborne, *A systematic review of outcomes of chronic disease self-management interventions.* Qual Life Res, 2013. **22**(7): p. 1805-16.
99. Kroon, F.P., et al., *Self-management education programmes for osteoarthritis.* Cochrane Database Syst Rev, 2014. **1**: p. CD008963.
100. Lorig, K., P.L. Ritter, and K. Plant, *A disease-specific self-help program compared with a generalized chronic disease self-help program for arthritis patients.* Arthritis Rheum, 2005. **53**(6): p. 950-7.
101. Jessep, S.A., et al., *Long-term clinical benefits and costs of an integrated rehabilitation programme compared with outpatient physiotherapy for chronic knee pain.* Physiotherapy, 2009. **95**(2): p. 94-102.
102. Hurley, M.V., et al., *Clinical effectiveness of a rehabilitation program integrating exercise, self-management, and active coping strategies for chronic knee pain: a cluster randomized trial.* Arthritis Rheum, 2007. **57**(7): p. 1211-9.
103. Parker, R., J. Jelsma, and D.J. Stein, *The Development of an Intervention to Manage Pain in amaXhosa Women Living with HIV/AIDS.* South African Journal of Physiotherapy, 2014. **70**(1): p. 5.
104. Louw, A., et al., *The effect of neuroscience education on pain, disability, anxiety, and stress in chronic musculoskeletal pain.* Arch Phys Med Rehabil, 2011. **92**(12): p. 2041-56.
105. Gill, S.D. and H. McBurney, *Does exercise reduce pain and improve physical function before hip or knee replacement surgery? A systematic review and meta-analysis of randomized controlled trials.* Arch Phys Med Rehabil, 2013. **94**(1): p. 164-76.
106. Dworkin, R.H., et al., *Core outcome measures for chronic pain clinical trials: IMMPACT recommendations.* Pain, 2005. **113**(1-2): p. 9-19.
107. Dworkin, R.H., et al., *Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations.* J Pain, 2008. **9**(2): p. 105-21.
108. Turk, D.C., et al., *Identifying important outcome domains for chronic pain clinical trials: an IMMPACT survey of people with pain.* Pain, 2008. **137**(2): p. 276-85.

109. Younger, J., McCue, R. & Mackey, S, *Pain Outcomes: A Brief Review of Instruments and Techniques.* Curr Pain Headache Rep, 2009. **13**(1): p. 39-43.
110. Hawker, G.A., et al., *Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP).* Arthritis Care Res (Hoboken), 2011. **63 Suppl 11**: p. S240-52.
111. Melzack, R., *The McGill Pain Questionnaire From Description to Measurement.* Anesthesiology, 2005. **103**(1): p. 199-202.
112. Cleeland, C.S., *The Brief Pain Inventory User Guide*. 1991.
113. Parker, R., *Pain in HIV/AIDS: Characteristics, contributing factors and the effects of a six-week peer-led exercise ans education intervention*, in *Faculty of Health Sciences*. 2013, University of Cape Town.
114. *The University of Texas MD Anderson Cancer Centre. The Brief Pain Inventory (BPI)*. [cited 2015 08 February]; Available from: http://www.mdanderson.org/education-and-research/departments-programs-and-labs/departments-and-divisions/symptom-research/symptom-assessment-tools/brief-pain-inventory.html.
115. Kruger-Jakins, T., *The Effects of a Six-Week Physiotherapist-Led Exercise and Education Intervention in Patients with Osteoarthritis Awaiting Arthroplasty in Gauteng*, in *Faculty of Health Sciences*. 2015, University of Cape Town.
116. Fransen, M., et al., *A revised group exercise program for osteoarthritis of the knee.* Physiother Res Int, 1997. **2**(1): p. 30-41.
117. Bruce, B. and J.F. Fries, *The Stanford Health Assessment Questionnaire: dimensions and practical applications.* Health Qual Life Outcomes, 2003. **1**: p. 20.
118. Roos, E.a.T.-L., S., *Knee injury and Osteoarthritis Outcome Score (KOOS) – validation and comparison to the WOMAC in total knee replacement.* Health and Quality of Life Outcomes, 2003. **1**(17).
119. Collins, N., Prinsen, CAC, Christensen, R, Bartels, EM, Terwee, CB, & Roos, EM, *Knee Injury and Osteoarthritis Outcome Score (KOOS): systematic review and meta-analysis of measurement properties.* Osteoarthritis and Cartilage, 2016. **24**: p. 1317-1329.
120. Gandek, B.a.W., JE, *Validity and Responsiveness of the Knee Injury and Osteoarthritis Outcome Score: A Comparative Study Among Total Knee Replacement Patients.* Arthritis Care and Research, 2017. **69**(6): p. 817-825.
121. Wallis, J.A. and N.F. Taylor, *Pre-operative interventions (non-surgical and non-pharmacological) for patients with hip or knee osteoarthritis awaiting joint replacement surgery--a systematic review and meta-analysis.* Osteoarthritis Cartilage, 2011. **19**(12): p. 1381-95.
122. Lamb, S.E., F. Toye, and K.L. Barker, *Chronic disease management programme in people with severe knee osteoarthritis: efficacy and moderators of response.* Clin Rehabil, 2008. **22**(2): p. 169-78.
123. Brazier, J.E., et al., *Generic and condition-specific outcome measures for people with osteoarthritis of the knee.* Rheumatology (Oxford), 1999. **38**(9): p. 870-7.
124. *WOMAC Osteoarthritis Index*. [cited 2015 15 April]; Available from: http://www.womac.org/womac/index.htm#other.
125. *American College of Rheumatology. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)*. 2012 [cited 2015 01 July]; Available from: www.rheumatology.org/Practice/Clinical/Clinicianresearchers/Outcomes_Instrumentation/Western_Ontario_and_McMaster_Universities_Osteoarthritis_Index_(WOMAC)/#womac01.
126. Karimi, M. and J. Brazier, *Health, Health-Related Quality of Life, and Quality of Life: What is the Difference?* PharmacoEconomics, 2016. **34**(7): p. 645-649.

127. Bergner, M., Bobbit, R.A, Carter, W.B & Gilson, B.S, , *The Sickness Impact Profile: Development and Final Revision of a Health Status Measure.* Medical Care, 1981. **19**(8): p. 787-805.
128. Ware Jr, J.E.a.D.S., C., *The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual Framework and Item Selection.* Medical Care, 1992. **30**(6): p. 473-783.
129. Stewart, M., *The Medical Outcomes Study 36-item short-form health survey (SF-36).* Australian Journal of Physiotherapy, 2007. **53**: p. 208.
130. Kosinski, M., et al., *The SF-36 Health Survey as a generic outcome measure in clinical trials of patients with osteoarthritis and rheumatoid arthritis: relative validity of scales in relation to clinical measures of arthritis severity.* Medical care, 1999: p. MS23-MS39.
131. Optum. *Surveys and Translation Tables*. Generic Health Surveys 2018 [cited 2018 05-02-2018]; Available from: http://campaign.optum.com/content/optum/en/optum-outcomes/what-we-do/health-survey-translation/surveys-translation-tables.html.
132. Gandek, B., et al., *Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project.* Journal of clinical epidemiology, 1998. **51**(11): p. 1171-1178.
133. Jelsma, J. and G. Ferguson, *The determinants of self-reported health-related quality of life in a culturally and socially diverse South African community.* Bull World Health Organ, 2004. **82**(3): p. 206-12.
134. Jelsma, J., et al., *The reliability and validity of the Xhosa version of the EQ-5D.* Disabil Rehabil, 2004. **26**(2): p. 103-8.
135. Kastien-Hilka, T., Rosenkranz, B., Sinanovic, E., Bennett, B. & Schwenkglenks, M., *Health-related quality of life in South African patients with pulmonary tuberculosis.* PLOS One, 2017. **12**(4).
136. Dobson, F., Hinman R.S., Roos E.M., Abbott J.H, Stratford, P., Davis, A.M., Buchbinder, R., Snyder-Mackler, L., Henrotin, Y., Thumboo, J., Hansen, P. & Bennell, K.L., *OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis.* Osteoarthritis and Cartilage, 2013. **21**: p. 1042-1052.
137. Stratford, P.W., D.M. Kennedy, and L.J. Woodhouse, *Performance measures provide assessments of pain and function in people with advanced osteoarthritis of the hip or knee.* Phys Ther, 2006. **86**(11): p. 1489-96.
138. Freiberger, E., et al., *Performance-based physical function in older community-dwelling persons: a systematic review of instruments.* Age Ageing, 2012. **41**(6): p. 712-21.
139. Guralnik, J.M., et al., *A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission.* Journal of gerontology, 1994. **49**(2): p. M85-M94.
140. Cress, M.E., et al., *Continuous-scale physical functional performance test: validity, reliability, and sensitivity of data for the short version.* Physical Therapy, 2005. **85**(4): p. 323-335.
141. Lundberg, M., Grimby-Ekman, A, Verbunt, J & Simmonds, M. J., *Pain-Related Fear: A Critical Review of the Related Measures.* Pain Research and Treatment, 2011. **2011**.
142. Gatchel, R.J., Neblett, R, Kishino, N & Ray, C.T., *Fear-Avoidance Beliefs and Chronic Pain.* Journal of Orthopaedic and Sports Physiotherapy, 2016. **46**(2): p. 38-43.
143. McCracken, L.D., L., *A short version of the Pain Anxiety Symptoms Scale (PASS-20): Preliminary development and validity.* Pain Research Management, 2002. **7**(1): p. 45-50.
144. Hapidou, E.G., O'Brien, MA., Pierrynowski, M.R., de las Heras, E., Patel, M & Patla, T., *Fear and Avoidance of Movement in People with Chronic Pain: Psychometric Properties of the 11-Item Tampa Scale for Kinesiophobia (TSK-11).* Physiotherapy Canada, 2012. **64**(3): p. 235-241.
145. Statsoft, I., *STATISTICA, Data Analysis Software System*. 2004.

146. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. 64th WMA General Assembly, Fortaleza, Brazil*. October 2013 [cited 2015 17 March]; Available from: http://www.wma.net/en/30publications/10policies/b3/.
147. Schulz, K.F., Altman, D.G & Moher, D., *CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials.* BMC Medicine, 2010. **8**(18).
148. Africa, S.S. *Work and Labour Force*. 2017 [cited 2018 03/01/2018]; Available from: http://www.statssa.gov.za/?page_id=737&id=1.
149. Labour, N.D.o. *Know your retirement age rights*. 2017 [cited 2018 30-01-2018]; Available from: https://www.westerncape.gov.za/general-publication/know-your-retirement-age-rights.
150. Ethgen, O., et al., *Health-related quality of life in total hip and total knee arthroplasty: a qualitative and systematic review of the literature.* JBJS, 2004. **86**(5): p. 963-974.
151. Bendelow, G., *Chronic Pain Patients and the Biomedical Model of Pain.* American Medical Association Journal of Ethics, 2013. **15**(5): p. 455-459.
152. Sullivan, M.J.L., *Toward a Biopsychomotor Conceptualization of Pain Implications for Research and Intervention.* Clinical Journal of Pain, 2008. **24**(4): p. 281-290.
153. Denison, E., A˚senlo¨f, P. & Lindberg, P., *Self-efficacy, fear avoidance, and pain intensity as predictors of disability in subacute and chronic musculoskeletal pain patients in primary health care.* Pain, 2004. **111**: p. 245-252.
154. Woby, S.R., Urmston, M. & Watson, P.J., *Self-efficacy mediates the relation between pain-related fear and outcome in chronic low back pain patients.* European Journal of Pain, 2006. **11**: p. 711-718.
155. Bandura, A. and R.H. Walters, *Social learning theory.* 1977.
156. Lippman, S.A., Leslie, H.H, Neilands, T.B, Twine, R, Grignon, J.S, MacPhail, C, Morris, J, Rebomboi, D, Sesane, M, El Ayadi, A.M, Pettifor, A, & Kahn, K, *Context matters: Community social cohesion and health behaviors in two South African areas.* Health and Place, 2018. **50**: p. 98-104.
157. Chan, J., To, HP. & Chan, E., *Reconsidering Social Cohesion: Developing a Definition and Analytical Framework for Empirical Research.* Social Indicators Research, 2006. **75**(2): p. 273-302.
158. Mabin, A., *Comprehensive segregation: the origins of the Group Areas Act and its planning apparatuses.* Journal of Southern African Studies, 1992. **18**(2): p. 405-429.
159. Meiring, T. *South Africa's Perpetual Struggles with Reconciliation and Social Cohesion: "It's The Economy, Stupid"*. 2017 [cited 2018 05-02-2018]; Available from: https://www.ijr.org.za/2017/03/07/south-africas-perpetual-struggles-with-reconciliation-and-social-cohesion-its-the-economy-stupid/.
160. DeWalt, D.A., Berkman, N.D, Sheridan, S, Lohr, K.N & Pignone, M.P, *Literacy and Health Outcomes: A Systematic Review of the Literature.* Journal of General Internal Medicine, 2004. **19**: p. 1228-1239.
161. Berkman, N.D., Sheridan, S.L, Donahue, K.E, Halpern, D.J, & Crotty, K., *Low Health Literacy and Health Outcomes: An Updated Systematic Review.* Annals of Internal Medicine, 2011. **155**(2): p. 97-107.
162. Lowe, W., et al., *Effectiveness of musculoskeletal education interventions in people with low literacy levels: a systematic review.* Arthritis care & research, 2013. **65**(12): p. 1976-1985.
163. Kindig, D.A., A.M. Panzer, and L. Nielsen-Bohlman, *Health literacy: a prescription to end confusion*. 2004: National Academies Press.
164. Bingel, U., Wanigasekera, V., Wiech, K., Mhuircheartaigh, R.N., Lee, M.C., Ploner, M. & Tracey, I. *The Effect of Treatment Expectation on Drug Efficacy: Imaging the Analgesic Benefit of the Opioid Remifentanil*. Science Translational Medicine, 2011. DOI: 10.1126/scitranslmed.3001244.

165. Bialosky, J.E., M.D. Bishop, and J.A. Cleland, *Individual expectation: an overlooked, but pertinent, factor in the treatment of individuals experiencing musculoskeletal pain.* Physical therapy, 2016. **90**(9): p. 1345-1355.
166. Kouyanou, K., C.E. Pither, and S. Wessely, *Iatrogenic factors and chronic pain.* Psychosomatic Medicine, 1997. **59**(6): p. 597-604.
167. Thomas, A.B., M., *The Management Implications of Ethnicity in South Africa.* Journal of International Business Studies, 2000. **31**(3): p. 507-519.
168. Mander, M., Ntuli, L., Diederichs, N. & Mavundla, K., *Economics of the Traditional Medicine Trade in South Africa.* South African Health Review, 2007. **2007**(1): p. 189-196.
169. Peer, M., et al., *Pre-surgery exercise and post-operative physical function of people undergoing knee replacement surgery: a systematic review and meta-analysis of randomized controlled trials.* Journal of rehabilitation medicine, 2017. **49**(4): p. 304-315.

Appendices

Appendix A: Course content (Workbook lodged with FHS HREC under HREC Ref 378/2013)

Week 1: Osteoarthritis, self-management and exercise

- Pathology of OA
- What is meant by "self-management"
- Self-management steps
- Action plans, goal setting
- Exercise dos and don'ts
- Types of exercise
- Steps to success with exercise
- An exercise routine

Week 2: Managing common symptoms

- Physiology of acute and chronic pain
- Pain and flare ups of pain
- Swelling
- Joint protection, assistive devices
- Pacing and activity /resting cycles
- Fatigue
- Frustration
- Isolation

Week 3: Stress management

- What is stress?
- Managing stress
- Sleep management
- Communication with your health carer
- Relaxation skills

Week 4: Eating well

- Balanced nutrition
- Dealing with barriers to eating well
- Food safety
- Weight loss benefits

Week 5: Medication and disease related problem solving

- Making informed treatment decisions
- Appropriate use of medications
- Link between a healthy lifestyle, good nutrition and exercise

- Communicating effectively with family, friends and health professionals with regards to your problems

Week 6: Continuing as a successful self-manager

- Recap of key components of successful self-managing
- Action planning for the future
- Reflection on changes

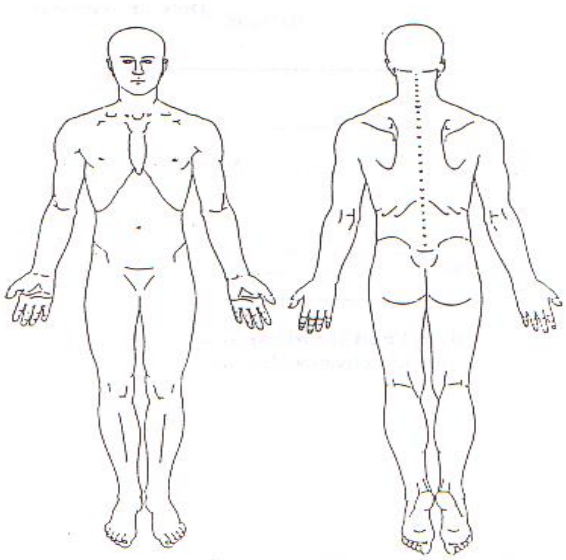
Appendix B: The Brief Pain Inventory

BRIEF PAIN INVENTORY

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains and toothaches). Have you had pain other than these everyday kinds of pain during the last week?

Yes No

2. On the diagram, shade in the areas where you feel pain. Put an **X** o the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its ***worst*** in the last week.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its ***least*** in the last week.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the ***average*.**

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have ***right now***.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

_____

_____

8. In the last week, how much ***relief*** have pain treatments or medications provided? Please circle the one percentage that most shows how much *relief* you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the one number that describes how much, during the past week, **pain** has ***interfered with*** your.

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Appendix C: The Western Ontario and McMaster Universities Osteoarthritis Index

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Name: _____ Date: _____

Instructions: Please rate the activities in each category according to the following scale of difficulty:

0=None, 1=Slight, 2=Moderate, 3=Very, 4=Extremely

Circle **one number** for each activity

Pain	1. Walking	0 1 2 3 4
	2. Stair Climbing	0 1 2 3 4
	3. Nocturnal	0 1 2 3 4
	4. Rest	0 1 2 3 4
	5. Weight bearing	0 1 2 3 4
Stiffness	1. Morning stiffness	0 1 2 3 4
	2. Stiffness occurring later in the day	0 1 2 3 4
Physical Function	1. Descending stairs	0 1 2 3 4
	2. Ascending stairs	0 1 2 3 4
	3. Rising from sitting	0 1 2 3 4
	4. Standing	0 1 2 3 4
	5. Bending to floor	0 1 2 3 4
	6. Walking on flat surface	0 1 2 3 4
	7. Getting in/out of car	0 1 2 3 4
	8. Going shopping	0 1 2 3 4
	9.Putting on socks	0 1 2 3 4
	10. Lying in bed	0 1 2 3 4
	11. Taking off socks	0 1 2 3 4
	12. Rising from bed	0 1 2 3 4
	13. Getting in/out of bath	0 1 2 3 4
	14. Sitting	0 1 2 3 4
	15. Getting on/off toilet	0 1 2 3 4
	16. Heavy domestic duties	0 1 2 3 4
	17. Light domestic duties	0 1 2 3 4

Total Score: _____/ 96 = _____%

Comments/Interpretation (to be completed by therapist only):

Appendix D: The EuroQol 5L (EQ-5D)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

We would like to know how good or bad your health is TODAY.

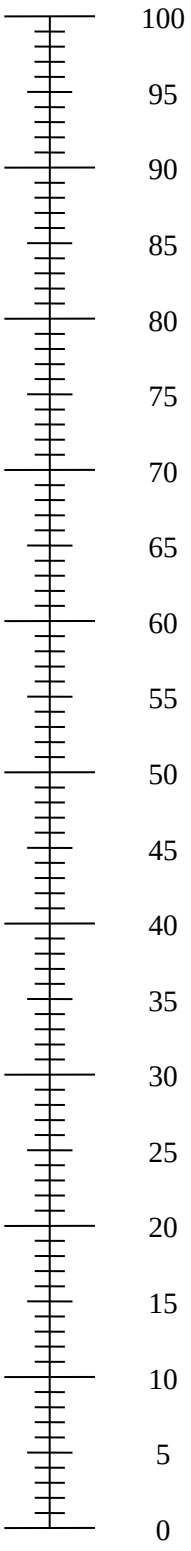
This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Appendix E: The Aggregated Locomotor Function Score

Aggregate Locomotor Function Test (Score sheet)

Code: _____ Date: _____

Flat, straight walk for 15.48m Time taken in seconds _____

Get up and go (15.48m) Time taken in seconds _____

Stairs Ascent (11 steps) Time taken in seconds _____

Stairs Descent (11 steps) Time taken in seconds _____

The tasks will be clearly set out for the participants, with the instruction being to do all activities as quickly as you possibly can.

The aggregate score for the above tasks will then be calculated, and this will be their test score.

Final score _____

Appendix F: The Tampa Scale of Kinesiophobia

TAMPA SCALE FOR KINESIOPHOBIA*

The purpose of this questionnaire is to find out what your feelings/thoughts are towards physical activity/exercises. There are 4 options for each question, which represent the extent to which you agree or disagree with each statement: **"I completely disagree"; "I don't completely disagree", "I agree to some extent"**; and **"I completely agree".** For each question, place an **X** in the block that matches **to which extent you AGREE or DISAGREE with the following statement**. Please only choose **ONE** block per question. Please ask the researcher/assistant if you are not sure what is being asked or what to do.

		Place an X in appropriate block			
Number	Feelings/thoughts	Strongly disagree	Disagree	Agree	Strongly agree
1	I am afraid that I will injure myself when I exercise.	1	2	3	4
2	I feel that if I try to overcome it, my pain will increase.	1	2	3	4
3	My body is telling me that there is something dangerously wrong.	1	2	3	4
4	My pain would probably be relieved if I were to exercise.	1	2	3	4
5	People do not take my condition seriously.	1	2	3	4
6	My condition has put my body at risk for the rest of my life.	1	2	3	4
7	Pain always means that I have injured myself.	1	2	3	4
8	Just because something increases my pain, does not mean that it is bad.	1	2	3	4
9	I am afraid that I will injure myself by accident.	1	2	3	4
10	The safest thing for me is to not do anything that will increase my pain.	1	2	3	4
11	I have this much pain because there is something dangerously wrong with me.	1	2	3	4
12	Although I am in pain, I will be better off if I exercise.	1	2	3	4
13	Pain tells me that I must stop exercising so that I d not injure myself.	1	2	3	4
14	It is really not safe for someone like me, who has fibromyalgia, to exercise.	1	2	3	4
15	I can't do things that normal people do because of my pain.	1	2	3	4
16	Although I have pain, I don't think that it is dangerous.	1	2	3	4
17	No one should have to exercise if they are in pain.	1	2	3	4

Morris L. Virtual reality exposure therapy as treatment for pain catastrophizing in Fibromyalgia patients: Proof-of-concept study (PhD dissertation) N10/05/184 Stellenbosch University, South Africa 2013

Appendix G: Study information

(To be explained over the phone and given to participants at the initial contact session. Informed consent will be obtained along with this.)

The effects of a six-week pre-operative, physiotherapy led exercise and education intervention on post-operative recovery, in terms of pain and function, in patients with osteoarthritis, undergoing total knee replacement in the Western Cape.

Good day. I am a qualified physiotherapist completing my master's in physiotherapy at the University of Cape Town. I am planning to work with the physiotherapy department at Tygerberg Hospital to do a study on people with arthritis in their knees.

Why are we doing this study?

I am interested in finding out if taking part in a six week course for people with arthritis will make a difference to your recovery following your knee replacement. The aim of the course is to increase your knowledge about arthritis, and to teach you some light exercises and relaxation techniques. To find out if the course actually makes a difference, we would like to interview people with arthritis, and invite them to take part in a six-week exercise and education course.

Why did we contact you?

You are currently on the waiting list for a knee replacement at Tygerberg Hospital, and are due to have your surgery soon, so this makes you a potential candidate for this study.

What will you have to do?

- If you would like to take part in the study, you will be asked to come to the hospital for the first visit. At this visit we will ask you a few questions which will help us to check if it is safe for you to take part in exercise. If it is not safe, you will not be asked to continue.
- We will tell you all about the study and any questions that you may have will be answered at this visit.
- We will help you to complete four short questionnaires (in English, Afrikaans or isiXhosa) which ask general questions about you and your health.
- We will then ask you to do four short tasks which will show us how well you can do daily activities. One test will simply require you to walk along a straight path. The second test will check your ability to get up out of a chair and walk as quickly as you can along a straight path. The third test will look at how quickly you can climb up 11 stairs, and the fourth test will look at how quickly you can go down those stairs. All these tests will be timed so that we can figure out how easy or difficult it is for you to manage these tasks.

This whole session should take about one hour. We know that this is quite a long time but we need to try and get as much information as we possibly can to see how well you are managing with your condition.

- We will then put you into one of two groups. One group will take part in the programme, the other group won't. You have the same chance of being put into either group.
- One group will be asked to come back to the Tygerberg Physiotherapy department at the hospital once a week for the next six weeks, to take part in the course which will happen once a week for 2 hours. This group will consist of 12 people, who all have arthritis and are waiting for joint replacements, just like you. The group sessions will take place on either Wednesdays or Thursdays from 12:00-14:00.
- The other group will continue to receive their normal care which their doctors have prescribed. We will still ask them to return to fill out the questionnaires and perform the tasks again after six weeks, immediately before surgery, on discharge from hospital after surgery, at the 6 week follow up and 3 months after surgery. The participation of people in this group is very important, and will give us the information we need to compare normal care to the six week programme.

Will you be paid for taking part?

We will not provide payment for taking part in the study. We will give R30 to cover the costs of transport for hospital visits so that it does not cost you to participate.

How does this benefit you?

We hope that this course will help you to learn more about arthritis and how to cope better with it. We hope that we can show you the importance of exercise and how it may help you by making you fitter and stronger and making it easier to do some daily activities. We also hope that you can learn about goal-setting and how to achieve your goals, so that you can believe more in your abilities.

What are the risks to you?

We want to minimise any risk to you as much as possible. Our exercise sessions will be led by a qualified physiotherapist, who will check beforehand if it is safe for you to exercise. We know that exercise can cause some stiffness or a mild ache in the muscles for the day or even two days after exercising, especially if it is new to you. We will try to minimise this by checking what you can do at the start and then starting slowly. Each week you should get more used to exercising, and as you do, the physiotherapist will give you a bit more exercise to do. If, during the study, you experience a big increase in pain, we will make sure that you are assessed and we will act as necessary, either advising you to do a bit less exercise or to stop and we will refer you to the appropriate doctor for management.

How will we use these results?

The information (but of course not your personal details) we get from this study will be provided to local authorities, the local institutions helping people living with arthritis, to the scientific community, and to provincial and central government. It can't be guaranteed, but we would like for the information we provide to

lead to changes in the treatment of patients with arthritis. We can also not say for sure that participation in the study will provide any direct benefit to you or your family.

Will anyone know what answers you've given to the questions?

At the start of the study you will be given a code which we will use instead of your name when storing all information. All the answers will be put together and no-one will know who gave which answer except for the researchers and members of the ethics committee. We will not give your name to anyone and your name will not be linked to any results.

Taking part in the study will not interrupt your normal care at all. Taking part is completely up to you and nothing bad will happen to you if you choose not to participate. If you do choose to take part, you are allowed to pull out at any time and you may choose not to answer certain questions if you don't want to answer them. If you choose to stop coming, it will not affect your normal care at all. Your chances of getting a knee replacement and position on the waiting list will in no way be affected by your decision to participate or not. You may continue to ask questions at any point during the study and you are welcome to contact either myself or my supervisor for any necessary information that you may need. Should you choose not to participate, and you are not receiving physiotherapy but would like to, we will refer you to the physiotherapist at your nearest clinic to be treated there. We would really appreciate your participation in this project should you choose to join us.

What if something goes wrong?

The University of Cape Town (UCT) has insurance cover for the event that research-related injury or harm results from you participation in the trial. The insurer will pay all reasonable medical expenses in accordance with the South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI) in the event of an injury or side effect resulting directly from your participation in the trial. You will not be required to prove fault on the part of the university.

The University **will not be liable** for any loss, injuries and/or harm that you may sustain where the loss is caused by

- The use of unauthorised medicine or substances during the study
- Any injury that results from you not following the protocol requirements or the instructions that the study doctor may give you
- Any injury that arises from inadequate action or lack of action to deal adequately with a side effect or reaction to the study medication
- An injury that results from negligence on your part

An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study doctor immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications.

Appendix H: Questions to include or exclude patients telephonically

(Using ACSM guidelines for pre-participation screening)

To make sure that the information we get from you is useful for us, we need to make sure that we use a group of people who are similar to each other. This means similar in age, language and health status. I need to start by asking you some questions to make sure you fit into this group before we can have you as participate in the study.

1. How old are you?
2. Do you have osteoarthritis in one knee only?
3. Do you have problems in any other joints in your legs?
4. Do you have any other problems with your back or legs which give you pain?
5. Have you had any accidents/ previous surgery for problems in your legs before?
6. Can you read, write and understand either English or Afrikaans or isiXhosa?
7. Do you have any condition which affects your ability to understand concepts?
8. Have you participated in any self-management programme for arthritis before?

As we have discussed, this study involves participation in an exercise programme. We need to make sure that it will be safe for you to take part in these exercises. To do this, I'm going to ask you a few more questions.

Do you have or have you had any of the following? (Category 1 – immediate exclusion. Yes to any of these, stop the interview and thank them for their time. They are not eligible for the study)

___ A heart attack

___ Heart surgery

___ Cardiac catheterization

___ Coronary angioplasty (PTCA)

___ Pacemaker/implantable cardiac defibrillator/rhythm disturbance

___ Heart valve disease

___ Heart failure

___ Heart transplantation

___ Congenital heart disease

a. Screening question (see specific responses)

- Do you have diabetes?

  IF YES, Is it controlled by medication?

Yes – OK; No – end interview, thank you but not eligible

- Do you have asthma other lung disease?

  IF YES, Is it controlled by medication?

Yes – OK; No – end interview, thank you but not eligible

YES to 2 or more of these 4 following questions not eligible, end interview, thank you for your time. Yes to one of these, perform exercise assessment.

1. ___ Do you have burning or cramping in your lower legs when walking short distances.
2. ___ Do You experience chest discomfort with exertion.
3. ___ Do You experience unreasonable breathlessness.
4. ___ Do You experience dizziness, fainting, blackouts.
5. ___ Are you pregnant?

Appendix I: Informed consent

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6401 Fax: +27 (0) 21 406 6323

Dear participant

Please read the attached information sheet for the study titled: The effects of a six-week pre-operative, physiotherapy led exercise and education intervention on post-operative recovery, in terms of pain and function, in patients with osteoarthritis, undergoing total knee replacement in the Western Cape.

Our hope is that this study will help health professionals to better understand whether a six-week course for arthritis, which includes exercise and education, helps people to cope with their condition more easily. All records will be kept confidential and all information given in questionnaires will remain anonymous.

You may contact Sara Warren (investigator) on 0727844298, Dr. Romy Parker (supervisor) on (021) 4066431 or the UCT FHS Human Research Ethics Committee on (021) 406 6338 with any questions regarding your rights and welfare as research subjects on the study. Your decision to participate is voluntary and choosing not to participate or withdrawing at any time will not result in any change to your normal care or prevent you from receiving any services to which you are entitled.

I,_____ have read and understand the above information sheet.* All my questions have been answered and I understand what will be asked of me for this study. Knowing this, I have chosen to participate in the study. I am aware that my normal care will continue with no interruption or change and that I may withdraw from this study at any point without experiencing any unfair treatment or change to my normal care as a result. I also know that I do not have to answer any question which I feel I do not want to. I give permission for the researchers to contact me to interview me. I commit to attending the six (6) week course if I am placed in the course group and I understand that although the researchers will do their best to make sure that anything said in the intervention group remains confidential, they cannot guarantee this because it rests on the group itself. I agree to come to the hospital and participate in the study from now until three (3) months following my surgery.

_____ _____

Participant Date

_____ _____

Witness Date

_____ _____

Researcher Date

* By agreeing to participate in this study, you do not give up your right to claim compensation for injury where you can prove negligence, in separate litigation. In particular, your right to pursue such a claim in a South African court in terms of South African law must be ensured. Note, however, that you will usually be requested to accept that payment made by the University under the SA GCP guideline 4.11 is in full settlement of the claim relating to the medical expenses.

An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study doctor immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications.

UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions you were given while you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.

Appendix J: ACSM pre-participation screening

History (mark all true statements)

You have had:

___ a heart attack

___ heart surgery

___ cardiac catheterisation

___ coronary angioplasty (PTCA)

___ pacemaker/implantable cardiac

___ defibrillator/rhythm disturbances

___ heart valve disease

___ heart failure

___ heart transplantation

___ congenital heart disease

Symptoms

___ You experience chest discomfort with exertion.

___ You experience unreasonable breathlessness.

___ You experience dizziness, fainting or blackouts.

___You take heart medications.

Other health issues

___ You have diabetes.

___ You have asthma or other lung disease.

___ You have burning or cramping sensation in your lower legs when walking short distances.

___ You have musculoskeletal problems that limit your physical activity.

___ You have concerns about the safety of exercise.

___ You take prescription medication(s).

___You are pregnant.

If you marked any of the statements in this section, consult your physician or other appropriate healthcare provider before engaging in exercise. You may need to use a facility with a medically qualified staff.

Cardiovascular risk factors

___ You are a man older than 45 years.

___ You are a woman older than 55 years, have had hysterectomy or are post-menopausal.

___ You smoke or quit smoking within the previous six months.

___ Your blood pressure is >140/90 mm Hg.

___ You do not know your blood pressure.

___ You take blood pressure medication.

___ Your blood cholesterol level is >200 mg/dL.

___ You do not know your cholesterol level.

___ You have a close blood relative who had a heart attack or heart surgery before age 55 (father or brother) or age 65 (mother or sister).

___ You are physically inactive (i.e. you get <30 minutes of physical activity on at least 3 days per week).

___ You are >20 pounds overweight

If you marked two or more of the statements in this section, consult your physician or other appropriate healthcare provider before engaging in exercise. You may need to use a facility with a professionally qualified exercise staff to guide your exercise programme.

___ none of the above

You should be able to exercise safely without consulting your physician or other appropriate healthcare provider in a self-guided programme or almost any facility that meets your exercise programme needs.

Appendix K: Ethical approval from the UCT Health Sciences HREC

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

28 September 2015

HREC REF: 651/2015

A/Prof R Parker
Physiotherapy Division
F-45
OMB

Dear A/Prof Parker

PROJECT TITLE: THE EFFECTS OF A SIX-WEEK PRE-OPERATIVE, PHYSIOTHERAPY-LED EXERCISE AND EDUCATION INTERVENTION ON POST-OPERATIVE RECOVERY, IN TERMS OF PAIN AND FUNCTION, IN PATIENTS WITH OSTEOARTHRITIS, UNDERGOING TOTAL KNEE REPLACEMENT IN THE WESTERN CAPE (Masters Candidate – Ms S Warren) Sub-study linked to 378/2013

Thank you for your response dated 22 September 2015, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has formally approved the above-mentioned study.

Approval is granted for one year until the 30th September 2016.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the following student:-Sara Warren is also involved in this project.

Please quote the HREC reference no in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

hrec/ref:651/2015

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☒ Approved	Annual progress report	Approved until/next renewal date	30.8.2017
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	30/8/2016

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	29 August 2016		
HREC REF Number	651/2015	Current Ethics Approval was granted until	30 September 2016
Protocol title	The effects of a six-week pre-operative, physiotherapy-led exercise and education intervention on post-operative recovery, in terms of pain and function, in patients with osteoarthritis, undergoing total knee Replacement in the Western Cape.		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes ✓ No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	A/Prof. Romy Parker		
Department / Office Internal Mail Address	Physiotherapy Department Romy.parker@uct.ac.za		

1.1 Does this protocol receive US Federal funding?	☐ Yes	✓ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	✓ No
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	☐ Yes	✓ No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Appendix L: Letter of Approval from Tygerberg Hospital

Western Cape Government
Health

TYGERBERG HOSPITAL
REFERENCE: **Research Projects**
ENQUIRIES: **Dr GG Marinus**
TELEPHONE:**021 938 6267**

Ethics Reference: 651/2015

TITLE: **The Effects of a six- week pre - operative, physiotherapy - led exercise and education intervention on post - operative recovery, in terms of pain and function, in patients with osteoarthritis, undergoing total knee replacement in the Western Cape (Masters Candidate - Ms Warren) Sub- study linked to 378/2013**

Dear Prof Parker

PERMISION TO CONDUCT YOUR RESEARCH AT TYGERBERG HOSPITAL.

In accordance with the Provincial Research Policy and Tygerberg Hospital Notice No 40/2009, permission is hereby granted for you to conduct the above-mentioned research here at Tygerberg Hospital.

DR D ERASMUS
CHIEF EXECUTIVE OFFICE

Date: 10 November 2015

Administration Building, Francie van Zijl Avenue, Parow, 7500 Private Bag X3, Tygerberg, 7505
tel: +27 21 938-6267 fax: +27 21 938-4890 www.capegateway.gov.za

TYGERBERG HOSPITAL

ETHICS REFERENCE: 651/2015

TITLE: The Effects of a six- week pre - operative, physiotherapy - led exercise and education intervention on post - operative recovery, in terms of pain and function, in patients with osteoarthritis, undergoing total knee replacement in the western cape(Masters Candidate - Ms Warren) Sub- study linked to 378/2013

BY _____

An authorized representative of Tygerberg Hospital

NAME Dr DS Erasmus

TITLE CEO

DATE 10 November 2015

Appendix M: Approval of study amendments by the UCT HREC

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)		
☒ Approved	☐ Type of review: Expedited	☐ Full committee
This serves as notification that all changes and documentation described below are approved.		
Signature Chairperson of the HREC		Date: 30/8/16

Note: All major amendments must include a local PI synopsis justifying the changes for the amendment. Please note that incomplete amendment submissions will not be reviewed.

Comments from the HREC to the Principal Investigator:
Note: The approval of this protocol amendment does not grant annual approval. Please complete the FHS016 / FHS017 form for annual approval at least one month before study expiration.

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	29 August 2016		
HREC REF Number	651/2015		
Protocol title	The effects of a six-week pre-operative, physiotherapy-led exercise and education intervention on post-operative recovery, in terms of pain and function, in patients with osteoarthritis, undergoing total knee replacement in the Western Cape.		
Protocol number (if applicable)			
Principal Investigator	A/Prof. Romy Parker		
Department / Office Internal Mail Address	Physiotherapy Department Romy.parker@uct.ac.za		
1.1 Is this a major or a minor amendment? (see FHS006hlp) Major (tick box) Minor (tick box)		☐ Major	X Minor
1.2 Does this protocol receive US Federal funding?		☐ Yes	X No
1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval?		☐ Yes	X No

Appendix N: Other relevant data and analysis

Table 6: Least pain scores and differences between groups from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Participants (n=27)	Experimental (n=14)	Control (n=13)	Statistical analysis
Least pain				
Recruitment	4 (0-10)	4.5 (0-10)	4 (2-8)	U=85; p=0.79
Post-intervention	5 (3-10)	7 (4-10)	5 (3-7)	U=33; p=0.01*
Post-op	6 (0-9)	6 (2-9)	5 (0-8)	U=36; p=0.077
6 weeks post-op	3 (0-9)	4.5 (0-9)	1 (0-4)	U=19.5; p=0.01*
3 months post-op	3 (0-9)	5 (1-7)	2 (0-9)	U=32.5; p=0.07

* indicates significance

Table 7: Least pain score within group changes for both groups from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Experimental – p=0.03*		Control – p=0.02*	
Least pain	**Median**	**Range**	**Median**	**Range**
Recruitment	4.5 (0-10)	10	4 (2-8)	6
Post-intervention	7 (4-10)	6	5 (3-7)	4
Post-op	6 (2-9)	7	5 (0-8)	8
6 weeks post-op	4.5 (0-9)	9	1 (0-4)	4
3 months post-op	5 (1-7)	6	2 (0-9)	9

* indicates significance

Table 8: Pain right now scores and differences between groups from recruitment to three-months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Participants (n=27)	Experimental (n=14)	Control (n=13)	Statistical analysis
Pain right now				
Recruitment	5 (0-10)	5 (0-10)	3 (0-9)	U=70.5; p=0.33
Post-intervention	6.5 (0-10)	7 (4-10)	6 (0-9)	U=33.5; p=0.01*
Post-op	6 (2-10)	8 (2-10)	5 (3-9)	U=43; p=0.18
6 weeks post-op	3 (0-9)	4 (0-9)	0.5 (0-4)	U=20.5; p=0.01*
3 months post-op	3 (0-9)	5 (1-9)	2 (0-8)	U=25.5; p=0.02*

* indicates significance

Table 9: Pain right now score within group changes for both groups from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Experimental – p=0.03*		Control – p=0.03*	
Pain right now	**Median**	**Range**	**Median**	**Range**
Recruitment	5 (0-10)	10	3 (0-9)	9
Post-intervention	7 (4-10)	6	6 (0-9)	9
Post-op	8 (2-10)	8	5 (3-9)	6
6 weeks post-op	4 (0-9)	9	0.5 (0-4)	4
3 months post-op	5 (1-9)	8	2 (0-8)	8

* indicates significance

Table 10: Differences between groups on the individual items of the PIS from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Participants (n=27)	Experimental (n=14)	Control (n=13)	Statistical analysis
Interference with general activity				
Recruitment	6 (2-10)	7 (2-10)	5 (2-10)	U=72; p=0.37
Post-intervention	7 (2-10)	7 (4-10)	6 (2-10)	U=71; p=0.5
Post-op	8 (4-10)	8 (5-10)	7.5 (4-9)	U=40.5; p=0.21
6 weeks post-op	4 (0-9)	6 (0-9)	2 (0-7)	U=28; p=0.04*
3 months post-op	4.5 (0-8)	5 (2-7)	3 (0-8)	U=40.5; p=0.2
Interference with mood				
Recruitment	5 (0-9)	6.5 (0-9)	4 (0-8)	U=57; p=0.1
Post-intervention	5.5 (0-10)	6 (0-10)	5 (0-9)	U=77.5; p=0.74
Post-op	5.5 (2-9)	6 (4-9)	5 (2-9)	U=49; p=0.49
6 weeks post-op	3 (0-10)	4 (0-9)	1 (0-10)	U=36.5; p=0.13
3 months post-op	3 (0-9)	5 (0-9)	1 (0-8)	U=43; p=0.26
Interference with walking ability				
Recruitment	6 (0-9)	6.5 (0-9)	5 (0-8)	U=63; p=0.18
Post-intervention	6 (2-10)	8 (3-10)	6 (2-10)	U=48; p=0.07
Post-op	7.5 (4-10)	8.5 (4-10)	7 (4-9)	U=35; p=0.11
6 weeks post-op	4 (0-10)	4.5 (1-10)	1.5 (0-7)	U=22.5; p=0.02*
3 months post-op	4 (0-9)	5 (0-9)	4 (0-8)	U=40.5; p=0.2
Interference with normal work				
Recruitment	6 (0-9)	6 (1-9)	5 (0-9)	U=74.5; p=0.44
Post-intervention	6.5 (2-10)	8 (5-10)	5 (2-10)	U=44.5; p=0.04*
Post-op	8 (1-10)	8.5 (7-10)	6 (1-10)	U=27.5; p=0.04*
6 weeks post-op	4(1-10)	6 (2-10)	2 (1-4)	U=15; p=0.01*
3 months post-op	5 (0-9)	6 (1-9)	4 (0-7)	U=43.5; p=0.28
Interference with relations with others				
Recruitment	2 (0-10)	5 (0-9)	1 (0-10)	U=67.5; p=0.26
Post-intervention	4 (0-10)	5 (0-10)	4 (0-10)	U=55; p=0.14
Post-op	6 (0-10)	6.5 (0-10)	5.5 (0-9)	U=50; p=0.53
6 weeks post-op	2 (0-10)	3 (0-7)	0 (0-10)	U=21; p=0.01*
3 months post-op	3 (0-10)	5 (0-10)	2 (0-10)	U=44.5; p=0.31
Interference with sleep				
Recruitment	5 (0-10)	6 (0-10)	3 (0-9)	U=60.5; p=0.15
Post-intervention	6 (3-10)	7 (3-10)	5 (3-10)	U=62; p=0.26
Post-op	7 (4-10)	7.5 (4-10)	7 (4-9)	U=44.5; p=0.32
6 weeks post-op	4 (0-9)	6 (1-9)	1.5 (0-5)	U=19; p=0.01*
3 months post-op	3 (0-9)	5 (1-9)	2 (0-8)	U=35.5; p=0.11
Interference with enjoyment of life				
Recruitment	5 (0-9)	6.5 (0-9)	3 (0-8)	U=63.5; p=0.19
Post-intervention	6.5 (2-10)	7 (4-10)	5 (2-10)	U=45.5; p=0.048*
Post-op	7.5 (0-10)	8 (0-10)	5.5 (1-9)	U=34.5; p=0.1
6 weeks post-op	4 (0-8)	5 (0-8)	1.5 (0-8)	U=32; p=0.07
3 months post-op	4.5 (0-10)	5 (0-10)	4 (0-8)	U=43.5; p=0.28

* indicates significance

Table 11: PIS individual item within group changes for both groups from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Experimental – p=0.04*		**Control – p=0.01***	
Interference with general activity	**Median**	**Range**	**Median**	**Range**
Recruitment	7	8	5	8
Post-intervention	7	6	6	8
Post-op	8	5	7.5	5
6 weeks post-op	6	9	2	7
3 months post-op	5	5	3	8
Interference with mood	**Experimental – p=0.46**		**Control – p=0.13**	
Recruitment	6.5	9	4	8
Post-intervention	6	10	5	9
Post-op	6	5	5	7
6 weeks post-op	4	9	1	10
3 months post-op	5	9	1	8
Interference with walking ability	**Experimental – p=0.046***		**Control – p=0.035***	
Recruitment	6.5	9	5	8
Post-intervention	8	7	6	8
Post-op	8.5	6	7	5
6 weeks post-op	4.5	9	1.5	7
3 months post-op	5	9	4	8
Interference with normal work	**Experimental – p=0.03***		**Control – p=0.09**	
Recruitment	6	8	5	9
Post-intervention	8	5	5	8
Post-op	8.5	3	6	9
6 weeks post-op	6	8	2	3
3 months post-op	6	8	4	7
Interference with relations with others	**Experimental – p=0.29**		**Control – p=0.04***	
Recruitment	5	9	1	10
Post-intervention	5	10	4	10
Post-op	6.5	10	5.5	9
6 weeks post-op	3	7	0	10
3 months post-op	5	10	2	10
Interference with sleep	**Experimental – p=0.21**		**Control – p=0.04***	
Recruitment	6	10	3	9
Post-intervention	7	7	5	7
Post-op	7.5	6	7	5
6 weeks post-op	6	8	1.5	5
3 months post-op	5	8	2	8
Interference with enjoyment of life	**Experimental – p=0.1**		**Control – p=0.13**	
Recruitment	6.5	9	3	8
Post-intervention	7	6	5	8
Post-op	8	10	5.5	8
6 weeks post-op	5	8	1.5	8
3 months post-op	5	10	4	8

* indicates significance

Table 12: WOMAC Pain sub-scores and differences between groups from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Participants (N=27)	**Experimental (n=14)**	**Control (n=13)**	**Statistical analysis**
Pain subscore				
Recruitment	14 (4-20)	14.5 (10-20)	12 (4-19)	U=45; p=0.03*
Post intervention	14 (6-19)	16 (6-19)	14 (10-18)	U=68.5; p=0.43
Post-op	14 (4-19)	14 (10-19)	13.5 (4-17)	U=49.5; p=0.35
6 weeks post-op	9 (0-17)	11.5 (1-17)	8.5 (0-14)	U=38.5; p=0.17
3 months post-op	10.5 (3-17)	12 (4-17)	6 (3-14)	U=35.5; p=0.11

* indicates significance

Table 13: WOMAC Pain sub-score within group changes for both groups from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

	Experimental – p=0.08		**Control – p=0.05***	
Pain subscore	**Median**	**Range**	**Median**	**Range**
Recruitment	14.5 (10-20)	10	12 (4-19)	15
Post intervention	16 (6-19)	13	14 (10-18)	8
Post-op	14 (10-19)	9	13.5 (4-17)	13
6 weeks post-op	11.5 (1-17)	16	8.5 (0-14)	14
3 months post-op	12 (4-17)	13	6 (3-14)	11

* indicates significance

Table 14: Self-care scores for both groups from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

Self-care	Experimental	Control	Total
Recruitment			
None	8	10	18
Slight	3	2	5
Moderate	1	1	2
Severe	2	0	2
Unable	0	0	0
Missing	0	0	0
Post-intervention			
None	5	5	10
Slight	3	3	6
Moderate	3	5	8
Severe	2	0	2
Unable	0	0	0
Missing	1	0	1
Post-op			
None	3	3	6
Slight	5	5	10
Moderate	4	2	6
Severe	1	0	1
Unable	0	0	0
Missing	1	3	4
6 weeks post-op			
None	8	8	16
Slight	3	2	5
Moderate	1	0	1
Severe	0	0	0
Unable	0	0	0
Missing	2	3	5
3 months post-op			
None	9	9	18
Slight	1	1	2
Moderate	1	0	1
Severe	0	1	1
Unable	0	0	0
Missing	3	2	5

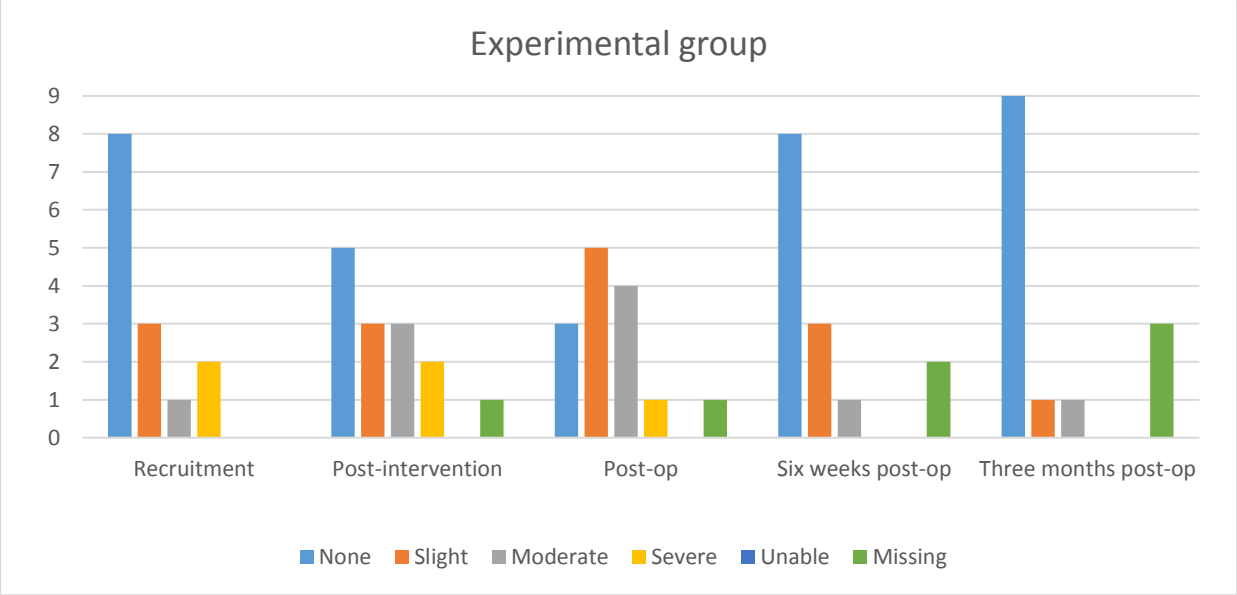


Figure 19:Self-care scores for the experimental group from recruitment to three months post-operative follow-up

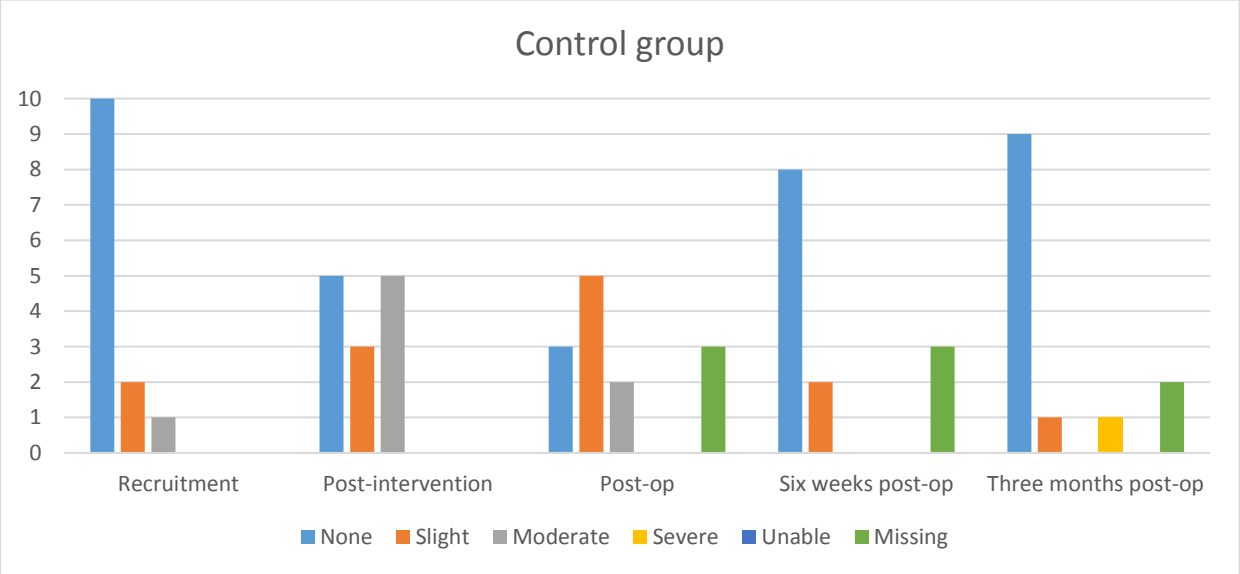


Figure 20: Self-care scores for the control group from recruitment to three months post-operative follow-up

Table 15: Anxiety/depression scores for both groups from recruitment to three months post-operative follow-up (median and range used as measures of central tendency and dispersion)

Anxiety/depression	Experimental	Control	Total
Recruitment			
None	6	10	16
Slight	3	1	4
Moderate	1	2	3
Severe	4	0	4
Extreme	0	0	0
Missing	0	0	0
Post-intervention			
None	3	3	6
Slight	3	6	9
Moderate	4	3	7
Severe	2	0	2
Extreme	1	1	2
Missing	1	0	1
Post-op			
None	4	3	7
Slight	5	5	10
Moderate	2	2	4
Severe	2	0	2
Extreme	0	0	0
Missing	1	3	4
6 weeks post-op			
None	6	8	14
Slight	6	1	7
Moderate	0	1	1
Severe	0	0	0
Extreme	0	0	0
Missing	2	3	5
3 months post-op			
None	7	7	14
Slight	4	3	7
Moderate	0	1	1
Severe	0	0	0
Extreme	0	0	0
Missing	3	2	5

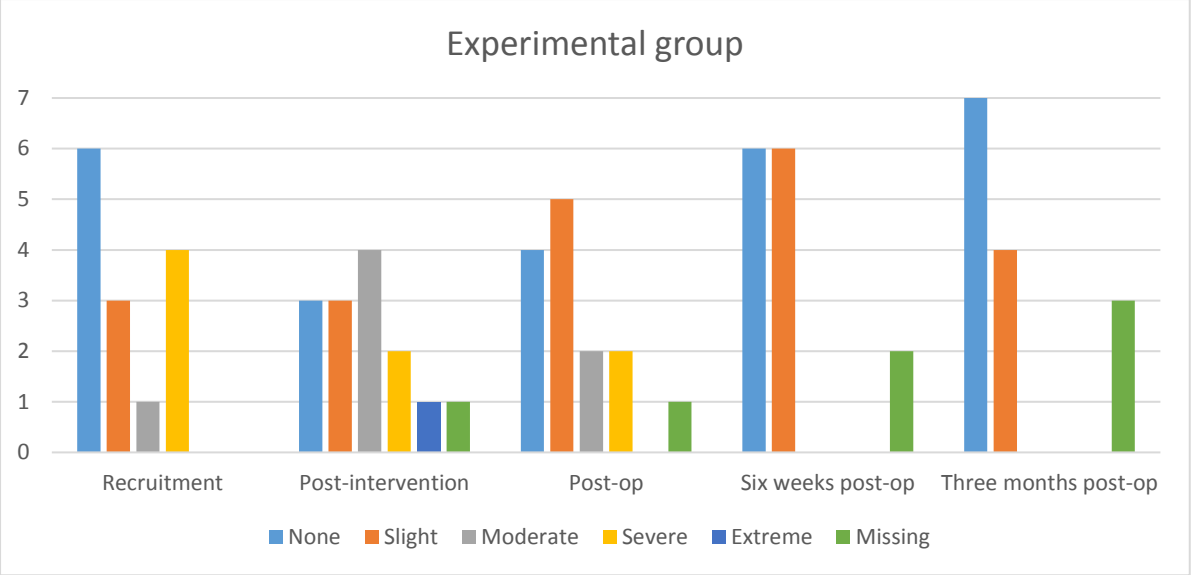


Figure 21: Anxiety/depression scores for the experimental group from recruitment to three months post-operative follow-up

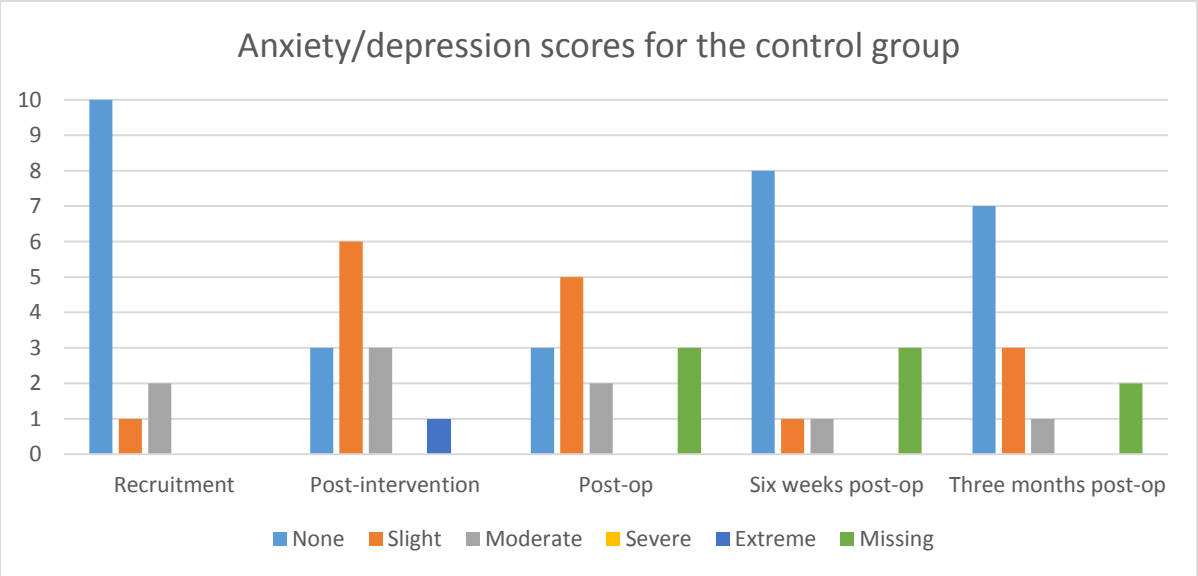


Figure 22: Anxiety/depression scores for the control group from recruitment to three months post-operative follow-up

Appendix O: Demographic questionnaire

Code: _____ Date: _____

Group allocation: _____

Home language: _____

Date of birth: _____

Gender: _____

Contact details:

Telephone number: _____

Cellphone number: _____

Which area do you live in? _____

When were you added to the waiting list? _____

Do you use an assistive device? _____

If so, what do you use? _____

Do you have any other medical conditions? If so, please name them:

_____

_____

_____

Do you take any medications? If so, what do you take and how much?

_____

_____

_____

_____

_____

What is your highest level of education? _____

Are you currently employed? If so, what do you do? _____

Any other useful information gathered from the patient's folder:

_____

_____

_____

_____

_____

_____

_____

_____