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Osteoarthritis in Women living in Cape Town: prevalence, characteristics, and the effects of a non-pharmacological intervention

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DECLARATION

I, Candice Hendricks, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor 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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(Date)

ABSTRACT

Osteoarthritis in Women living in Cape Town: characteristics and the effects of a non-pharmacological intervention.

Osteoarthritis contributes to the burden of physical disabilities globally, as it is the most common cause of severe chronic pain impacting the function of millions of people. Osteoarthritis is more commonly reported by women who are obese and are physically inactive. These modifiable risk factors of obesity and lack of physical activity are also associated with other chronic diseases of lifestyle (CDL). A paucity of epidemiological data exists on the relationship between OA and CDL in women attending primary health care centres in Cape Town in South Africa, therefore, there was a need to further explore these inter-relationships to be able to plan and implement effective non-pharmacological management strategies to address the multidimensional health problem.

To inform the development and implementation of a contextually relevant non-pharmacological intervention for women with osteoarthritis at primary health care level, several studies were conducted. The primary aim of this research project was to develop, implement and evaluate an evidence-based non-pharmacological rehabilitation intervention, advocating a patient-centred self-management approach, for women with OA and CDL at primary health care centres in Cape Town. The literature review highlighted that a non-pharmacological intervention, consisting of self-management principles, health education and exercise would be an effective management strategy for women with both OA and CDL. However, there is a dearth of high-quality randomised controlled trials investigating the effects of such interventions on function and health outcomes in women with OA and comorbidities at primary health care level in a South African context.

Standardised outcome measures were selected and used to gather data for the different studies. The WHODAS 2 12-item questionnaire measured functional ability, EQ-5D-3L questionnaire measured health-related quality of life, Brief pain inventory (BPI) measured pain severity and pain interference, and Self-efficacy for Managing Chronic Disease 6-item Scale (SE-6) measured the level of confidence in managing chronic diseases were used and were available in English, Afrikaans, and isiXhosa languages. However, the COPCORD (survey about general health and osteoarthritis) and IPAQ (survey about physical activity levels) were not available in these languages and therefore needed cross-cultural adaptation and translation.

The translation of the COPCORD and IPAQ followed a rigorous process using language experts who contributed to the assurance that the translated questionnaires were of good quality and precise. After field testing, the translated Afrikaans and isiXhosa versions of the COPCORD and IPAQ showed acceptable validity and feasibility for use.

The epidemiological study (Phase I) was conducted at a local community health centre (CHC) and found that the typical woman (from a sample of 803 women) was of middle age (50 years), spoke isiXhosa, Afrikaans, or English, had low levels of formal education (grade 8), was married with children, was unemployed/a housewife and received government grants as an income. A high proportion of women suffered from chronic joint pain (45.3%; 95% CI: 41.9-48.8), of which 43.4% (158 of 364) had diagnosed OA. In addition, 50% had hypertension and 23% had diabetes mellitus type 2. Furthermore, these women experienced moderate pain severity (PSS=5.3, SD=1.45), and moderate pain interference with general activity (PIS=5.8, SD=2.83), normal work (PIS= 5.7, SD=3.09) and walking (PIS=5.4, SD=3.25). Most of these women were obese, had low levels of physical activity, had significantly lower health-related quality of life scores, and had lower WHODAS 2 scores indicating moderate difficulty with walking, standing, household responsibilities compared to women without these diseases. Women who attended this PHCC presented with multimorbidity that negatively impacted their health-related quality of life and physical functioning. These findings highlighted a need for Physiotherapists to implement a non-pharmacological intervention, consisting of self-management principles, education, and exercise in women with OA and comorbidities at primary health care level in Cape Town.

The specific information gathered from the above-mentioned studies were used to adapt and implement a six-week group-based non-pharmacological intervention (SmArt-Health) for women with OA and hypertension at the CHC where the Epidemiological study was conducted. The SmArt-Health intervention was a physiotherapist-led six-week workshop that comprised of “core treatment” (self-management, education, exercise) and the use of a supplementary workbook that included the content related to the core treatment to manage osteoarthritis and hypertension and relaxation techniques. The intervention aimed to reduce impairments (joint pain, hypertension, obesity) and improve activity and participation restrictions (health-related quality of life, physical activity levels, physical function in walking, climbing steps, sit-stand activities) in women with osteoarthritis and hypertension.

The physiotherapist-led intervention was tested in a single-blind, pragmatic randomised controlled trial (RCT) that used a pre-test-post-test design over a 12-week follow-up period. At the six-week testing, 71 participants (n=34-experimental group, n=37-control group) attended.

The main results of this study showed that women who participated in the SmArt-Health intervention had a significant improvement in the primary outcome of function and disability (WHODAS 2) and physical functional tests measured with ALF (Aggregated Locomotor functional test); in pain severity (PSS) and pain interference (PIS) (BPI); blood glucose levels (DM2), health-related quality of life (EQ-5D-3L) and self-efficacy (SE-6) compared to the women in the usual care control group. In addition, these women completed an acceptability questionnaire and provided positive feedback reporting that the intervention was appropriate and helpful and that they enjoyed being part of the group intervention. The findings and feedback suggest that the SmArt-Health intervention was well accepted and is an effective intervention for managing women with osteoarthritis and comorbidities in a primary health care centre in Cape Town.

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"Philippians 4:13 *I Can Do All Things Through Christ Who Strengthens Me."*

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"I learned that courage was not the absence of fear, but the triumph over it. The brave man (woman) is not he who does not feel afraid, but he who conquers that fear."

Nelson Mandela

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LIST OF ABBREVIATIONS

ACSM	American College of Sports Medicine
AIDS	Acquired immune deficiency syndrome
BMI	Body mass index
BP	Blood pressure
BPI	Brief Pain Inventory
CDL	Chronic diseases of lifestyle
CHC	Community Health Centre
COPCORD	Community Oriented Programme for the Control of Rheumatic Disease
COPD	Chronic obstructive pulmonary disease
CVA	Cerebral Vascular Accident
DALY's	Disability-adjusted life years
EQ-5D-3L	EuroQol Group 5-Dimension Self-Report Questionnaire
HIV	Human Immunodeficiency Virus
HRQoL	Health-related quality of life
IPAQ	International Physical Activity Questionnaire
MSD	Musculoskeletal disorder
NCD	Non-communicable diseases
OA	Osteoarthritis
QALY	Quality-adjusted life-year
RA	Rheumatoid Arthritis
TB	Tuberculosis
VAS	Visual Analogue Scale
WHO	World Health Organisation
WHODAS	World Health Organisation Disability Assessment Schedule
YLD	Years lived with disability
YLL	Years of life lost

1 CHAPTER 1: INTRODUCTION

1.1 Background and Nature of problem

There is currently a high prevalence of non-communicable diseases (NCDs) associated with severe disabilities in people around the world. The Global Burden of Disease study in 2010, stated that there is a shift in burden of disease (BOD) from communicable to non-communicable diseases and from high mortality rates to years lived with disability (YLD)[1]. A third of the global BOD was from non-communicable diseases (NCDs), for example chronic diseases of lifestyle (CDL) and musculoskeletal disorders (MSD). Furthermore, MSD contributed to 6.8% of total Disability-adjusted life years (DALY), with an increase of 2.1% in 10 years (from 4-7% in 1990). The Disability-adjusted life years (DALY) is the sum of years of life lost due to premature mortality (YLL) and years lived with disability (YLD). In other words, a DALY = YLL + YLD. The YLL is calculated as the number of deaths x the standard life expectancy at age of death. The YLD is calculated as the number of new cases of disease x a disability weight x the average time a person lives with the disease before remission or death [2].

Globally, YLDs in women contributed 50% of DALYs up until the age of 45 years and about 30% of DALYs over the age of 70[1]. Common chronic diseases that contributed to the global BOD were ischaemic heart disease, chronic lower respiratory infections, stroke (often caused by diabetes and hypertension), and musculoskeletal disorders. The shift in global BOD could possibly be due to the increased prevalence of chronic diseases of lifestyle in developing countries as a consequence of demographic and lifestyle changes associated with urbanisation[3]. This increase in prevalence of chronic diseases of lifestyle and MSD across the globe, creates new challenges for health care professionals and increases the burden for comprehensive health care and rehabilitation services.

Chronic diseases of lifestyle (CDL) is an umbrella term for a cluster of diseases that are caused by unhealthy lifestyle factors (modifiable risk factors) including obesity, smoking of cigarettes, the use of alcohol, stress and a lack of physical activity[3]. A lack of physical activity is a risk factor for obesity, cancer, osteoporosis, stress, depression, osteoarthritis, and other chronic diseases[3-5]. Common chronic conditions such as hyperlipidaemia, hypertension (HPT) and diabetes mellitus type II (DM2) are associated with CDL as well.

These conditions may contribute to long-term complications (stroke, ischaemic heart attack, cancer, cardiac failure, end-stage diabetes etc.) which frequently result in mortality or severe disability. These chronic diseases affect individuals predominantly living in poorer countries and are associated with disability leading to poor quality of life and premature death, which in turn result in increased economic challenges for families and communities[6].

Chronic musculoskeletal disorders (MSD), such as osteoarthritis (OA), contribute to the increased burden of physical disabilities globally. Osteoarthritis is the main cause of chronic pain, functional problems and physical disability in millions of people and contributes to 50% of all MSD globally[7-11]. The World Health Organisation (WHO) reported that OA was one of the top ten causes of non-fatal burden in in 2000, severely impacting the function of millions of people[12]. Osteoarthritis is characterised by joint dysfunction caused from changes in the synovium, subchondral bone, and articular cartilage. The continuous degeneration of the cartilage may lead to loss of cartilage tissue, eventually leaving the bony ends exposed with no protection. The degeneration to the articular cartilage and the formation of osteophytes on the bone may lead to joint stiffness, impaired mobility, and chronic pain, and symptoms may become worse with increased ageing[13-15].

Older people often complain of osteoarthritis (OA). A few studies found the presence of OA in people older than 50 years of age[16-20]. OA is more commonly reported by women, especially in those who are older and obese[21 22]. However, in Cape Town (South Africa), people as young as 45 years old were diagnosed with OA[23]. It seems that osteoarthritis does not affect older adults only, but are affecting younger people as well which could lead to further reduced functional activity and disability as they get older[23]. Perhaps exploring the various risk factors for OA could explain the possible reasons for this occurrence in younger populations.

The prevalence of OA increases as an individual age and is associated with obesity and a lack of physical activity[24, 25]. Adults with OA do not always participate in physical activities as they believe that being active will make their pain and symptoms worse[22], and the lack of physical activity could result in reduced function and disability. The increase in the number of older people throughout the world could increase the burden of disease and disability on society. For this reason, the United Nations and WHO endorsed the Bone and Joint Decade from 2000–2010[26].

These findings highlight that obesity and lack of physical activity are not only risk factors for osteoarthritis but are risk factors for chronic diseases of lifestyle (CDL) (heart disease, diabetes, high blood pressure) as well. Therefore, it could be assumed that a potential relationship between OA and CDL could exist[22] and that such a relationship could further impact on functional activities at work and home, and health-related quality of life in affected individuals.

A lack of robust epidemiological data on OA and comorbidities is available in the African context. However, a small study conducted at two Community Health Centres (CHCs) in Cape Town, South Africa found 36% (362 of 1005) of participants reporting musculoskeletal disorders (MSD) that were not due to injury. In addition, there were more women (63%, 635 of 1005) that participated in this study and more women (80%, 290 of 362) that were affected by these chronic MSD with an average age of 51.7 years (SD=15.3). Furthermore, a high prevalence of arthritis (76%), OA (10%), and rheumatoid arthritis (RA) (5%) was reported among participants with previously diagnosed conditions (15%)[27]. Chronic diseases of lifestyle such as hypertension (59%), diabetes mellitus type II (25%), and heart problems (19%) was found in this sample[27]. The possible associations between chronic MSD, gender, and age, were similar to another local study on arthritic joint pain conducted in Cape Town[23]. The findings from these two studies do not only highlight the high prevalence rates of arthritic conditions (such as OA) but also highlight the co-existence of CDL in women attending CHCs in Cape Town. Therefore, further investigation is needed to explore the possible relationship between OA and CDL in South African women to be able to plan effective management protocols to address the two-fold health problem of OA and CDL in disadvantaged communities. A theoretical framework is needed to explore the relationship between OA and CDL and the impact of these chronic diseases in affected individuals.

1.2 A theoretical framework to evaluate the impact of osteoarthritis and associated chronic diseases

Individuals with OA often complain about chronic pain and worsening symptoms as they get older. However, the impact of these symptoms of OA on these individuals, in terms of performing functional activities in the home and community, and their health-related quality of life, are not always reported or evaluated by health professionals and may be excluded as main outcomes for treatment strategies. It is, therefore, important to use a theoretical framework that can help describe the impact of OA on an individual's functional activity level and participation level in their community to understand the possible disability associated with OA.

The World Health Organisation (WHO) developed the International Classification of Functioning, Disability and Health (ICF) as a framework to describe health and health-related domains[28]. The ICF framework is designed to measure health and disability at an individual's and population level. WHO (2002, p.2) states that the ICF is "a universal classification of disability and health for use in health and health-related sectors"[29]. The new name, International Classification of Functioning, Disability and Health model (ICF), was changed from International Classification of Impairments, Disabilities and Handicaps (ICIDH) on 22 May 2001[28].

1.2.1 The ICF model of Disability

The ICF is constructed on the biopsychosocial model of disability, which integrates the medical model of disability and the social model of disability[29]. These separate models of disability had different interpretations of the term "disability". According to WHO (2002, p.8), the medical model interpreted "disability as a feature of an individual caused by a health problem or trauma which requires individual medical treatment by professionals" and medical treatment was aimed to "correct the problem with the individual"[29]. WHO (2002, p.9) reported that the social model of disability refers to "disability as a socially created problem and not at all an attribute of an individual"? According to this model, disability is caused by external factors such as attitudes of society, other characteristics of a social environment, and requires governmental bodies and constituencies to respond to the problem[29]. These two models are not comprehensive and holistic enough to use in the assessment and treatment of people suffering from disabilities.

The ICF model offers a better model of disability that incorporates both models into one, a biopsychosocial model that synthesises different domains of health by exploring the biological, individual, and social aspects relating to disability. Thus, the ICF is an integrated model that includes various factors such as biological, individual, and social factors of health and environmental factors together to classify an individual's level of functioning and disability[29].

The ICF is described according to WHO (2002, p.2) as "a classification of health and health-related domains that help us to describe changes in body function and structure, what a person with a health condition can do in a standard environment (their level of capacity), as well as what they actually do in their usual environment (their level of performance)"[29]. To understand the ICF theoretical framework better, an explanation of the concepts used within this framework is needed.

1.2.2 Concepts of functioning and disability

In Figure 1, the ICF disability and functioning framework diagram[30] is illustrated with interactions between health conditions (body function and structure), activities and participation, and contextual factors (personal and environmental). A greater understanding of contextual factors is necessary to adequately assess the ability of the individual in relation to the health condition. According to WHO (2002, p.10), there are external factors (environmental) like "social attitudes, architectural characteristics, legal and social structures, as well as climate, terrain and so forth; and internal personal factors, which include gender, age, coping styles, social background, education, profession, past and current experience, overall behaviour pattern, character and other factors that influence how disability is experienced by the individual"[29]. Furthermore, WHO (2013, p.3) reported that the ICF conceptualises functioning as "a dynamic interaction between a person's health condition, environmental factors, and personal factors"[31].

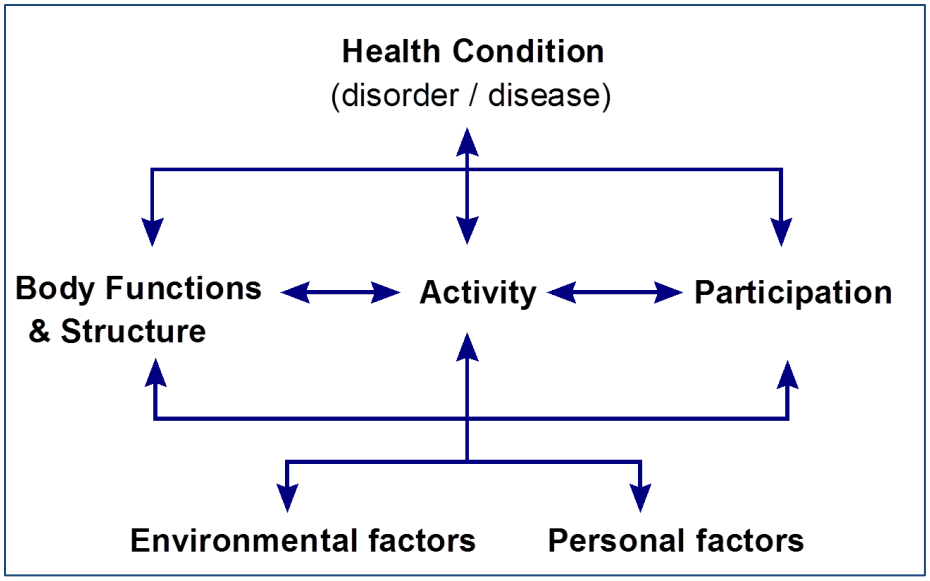


Figure 1: The ICF framework diagram

The ICF is currently used in different countries around the world and is being implemented in different contexts. The ICF is a versatile tool or instrument used for educational purposes, research, statistical, clinical and for non-medical purposes such as social, insurance, labour and policy development[31]. The ICF framework is a useful model in conceptualising the impact of OA, with regards to impairments, activity limitations, and participation restrictions in individuals and to establish the associated factors influencing possible treatment.

To fully comprehend the components of the ICF framework, the definitions of the components are provided in Box 1. All definitions are cited and extracted from the WHO (2002, p.10) ICF: Towards a Common Language for Functioning, Disability and Health document[29].

Box 1: Definitions of components of the ICF framework

- **Body Functions** are physiological functions of body systems (including psychological functions).
- **Body Structures** are anatomical parts of the body such as organs, limbs, and their components.
- **Impairments** are problems in body function or structure such as a significant deviation or loss.
- **Activity** is the execution of a task or action by an individual.
- **Participation** is involvement in a life situation.
- **Activity Limitations** are difficulties an individual may have in executing activities.
- **Participation Restrictions** are problems an individual may experience in involvement in life situations.
- **Environmental Factors** make up the physical, social, and attitudinal environment in which people live and conduct their lives.

The ICF framework has been used throughout this thesis as the theoretical framework to explore the impact of osteoarthritis (OA), possible associations with common chronic diseases of lifestyle and management strategies for people with OA. For this study, the assessment of individuals with OA was conducted to identify the impaired joints (body functions and structures), and common symptoms (chronic joint pain, joint stiffness, swelling), and an evaluation of activity limitations such as sit-to-stand activities, walking, climbing stairs, bending the affected joint, and other activities needed for self-care and for work. This information was used to inform the development of an appropriate intervention to target the individual's main functional problems.

1.3 Research setting: South African Health System

South Africa (SA) has a population of 55.7 million people recorded in the community census in 2016 [32]. There are more women (51%) than men recorded, with 36% of the population being classified as youth (15-34-year category). In the Western Cape, the total population was 6 279 730 whereby the majority (47.5%) of the population was classified as being of coloured race[32]. According to Erasmus (1999, p.169)[33] the term "coloured" in the apartheid era referred to: "South Africans loosely bound together for historical reasons such as slavery and a combination of oppressive and preferential treatment during apartheid, rather than by common ethnic identity"[33]. Furthermore, Ruiters (2009, p.109)[34] mentioned that "the state identified coloureds loosely as people who were neither white nor black. With forced removals, the state pushed together people who would not otherwise have lived in the same area or have mixed socially. This process led to a closer identification between neighbours and within neighbourhoods, cementing a closer sense of colouredness"[34]. Post-apartheid has removed this racist legislation for coloured people but unfortunately, the term has persisted due to the shared trauma of forced removals into coloured neighbourhoods during the apartheid period[34]. Along with apartheid engineering the group, it also engineered poverty with poor education, inadequate access to comprehensive health care, and inadequate access to work. Hence, being coloured is not only associated with a loss of identity and being part of an artificial social group but is also associated with contextual factors (personal and environmental) which will impact on the individual's health, as highlighted previously by the ICF in this chapter (section 1.2).

A General Housing Survey of 55 176 households was conducted in South Africa in 2016. Most households (82.6%) reported not having medical aid with 71.4% using public health care facilities as their first point of health care. In addition, only 24.7% of the participants in the Western Cape (n= 6362) reported having medical aid[35]. Although this survey had a small sample of individuals, it seems that a high proportion of households across the country are dependent on public health care institutions for assessment and treatment of their medical problems.

The first level of contact with the public health care system in the country are primary health care (PHC) clinics. The majority of consultations at these clinics were for women (66.6%)[36]. In the Western Cape, in Cape Town, these PHC clinics are called Community Health Centres (CHCs) which are multi-disciplinary clinics.

The CHCs offer a wide variety of services such as 24-hour emergency care, medical care, maternity care, pharmacy, mental health care, paediatric care, outpatient department, antiretroviral clinic, chronic diseases of lifestyle clinic and rehabilitation services including physiotherapy. Patients' who suffer from chronic diseases of lifestyle (CDL) (hypertension [HPT] and diabetes mellitus type 2 [DM2]), often receive their chronic medication and further rehabilitation at these CHCs. Some of these chronic patients may be recruited into chronic care clubs for further interventions. The chronic care clubs are managed by health promoters and nurses. The clubs provide group-based educational talks and health promotion for those with CDL. The chronic care clubs have a strong focus on education and little or no emphasis on exercise or physical activity [37].

The co-existence of OA and CDL in many women seeking care at the under-resourced primary health care facilities in South Africa creates an added burden on the facilities. Physiotherapy is usually recommended for the assessment and management of OA. Physiotherapy using moderate physical activity, education and encouraging the adoption of appropriate health behaviours are effective strategies for both OA and co-morbid CDL. Evidence-based self-management strategies that do not require many resources (staffing, medical services, and equipment) are needed for individuals suffering from these complex chronic diseases attending CHCs to help reduce the burden on the health care system and the affected individuals [38 39 40]. However, there seems to be a paucity of evidence-based, contextually appropriate, biopsychosocial interventions for middle to old-aged women with OA and associated CDL at primary health care facilities in South Africa. The next section will highlight and discuss evidence-based management strategies for OA.

1.3.1 Significance of the study

There is a need to develop and conduct evidence-based management strategies that are patient-centred for OA and CDL at primary health care clinics in South Africa[3]. Additionally, the South African Health system promotes a re-engineered Primary Health Care (PHC) approach which focuses on promotive and prevention services by improving health outcomes and strengthening interactions between service providers and patients with a focus on community re-integration[41]. Thus, physiotherapists managing patients with OA and CDL at primary health care clinics should integrate this PHC approach to educate and encourage affected individuals to become self-managers of their chronic diseases.

A non-pharmacological intervention that consists of self-management principles, education and exercise have been reported as an effective intervention strategy for people with OA attending primary health care centres in the Netherlands[42] and in London[43]. These studies reported significant improvements in functioning and in pain control. However, there is a dearth of clinical evidence on the efficacy of a non-pharmacological intervention in women with OA and comorbidities at CHCs in Cape Town. It is hypothesized that an intervention strategy including self-management principles, education and exercise might not only reduce the effect of OA on pain, function and HRQoL in women but could reduce the impact of CDLs as well. The goal of this project is to improve impaired function in daily activities and increase participation in community-based physical activity Programmes. Thus, an effective intervention has the potential to improve the overall health-related quality of life of economically disadvantaged women with OA and CDL in South Africa.

1.3.2 Problem statement and Research questions

It is clear from the information given above, that OA and CDL are prevalent in middle-aged women living in Cape Town and that these conditions have an impact on their physical functioning and HRQoL. There seems to be a lack of evidence-based non-pharmacological interventions for women with OA and common CDL attending local CHCs. Thus, there is a need for the development of effective patient-centred self-management interventions that use a biopsychosocial approach, and which include education, exercise and the principles of self-management and increasing self-efficacy for these affected women. Before an intervention can be developed and implemented for these women, it is important to first determine the contextual background by understanding the burden of the health problem and to describe the characteristics of the affected women. Therefore, the following research questions arise and need to be addressed.

1.3.3 Research questions

The research questions for this study are:

1. What are the characteristics, comorbidities, health-related quality of life, functional impact and contributing factors to OA in women with OA attending CHCs in Cape Town?

2. What would the components of a contextually relevant non-pharmacological intervention Programme be for women with OA and comorbidities in Cape Town?

3. How effective would this intervention Programme be in addressing the impairments, activity limitations and participation restrictions of these participants?

The main aim of the study is to develop, implement and evaluate a new model of care advocating a patient-centred self-management approach for women with OA and CDL at primary health care clinics in Cape Town. This will be done by adapting and implementing a non-pharmacological intervention Programme that was used previously in a local study for women with HIV/AIDS by Parker (2013) [44] which was based on exercise, education and self-management principles. The intervention for this study should be contextually relevant for women with OA receiving medical and rehabilitation services at a resource-constrained primary health care clinic in the Cape Town Metropole region.

Van Dijk (2006, p.163) described contextual relevance as:

> *"a sociocognitive account of context- that is not 'objective' or 'deterministic' constraints of society or culture at all, but subjective participant interpretations, constructions or definitions of such aspects of the social environment. In other words - what is now relevant for the participant"*[45].

Therefore, "contextual relevance" within this project refers to the development or adaptation of an appropriate intervention based on participant involvement.

1.3.4 Aims of the thesis

Aim 1: To determine the prevalence, characteristics, physical activity levels, health-related quality of life and function in women with osteoarthritis (OA) and comorbidities attending a Community Health Centre to establish the contextual background for the intervention.

Aim 2: To adapt and develop a contextually relevant non-pharmacological intervention Programme based on exercise, health education and self-management principles designed to educate, empower, improve functional status and health-related quality of life of women with OA and comorbidities.

Aim 3: To determine the effect of a non-pharmacological intervention Programme on impairments, activity, and participation restrictions in women with OA and comorbidities.

1.3.5 Objectives of the thesis

Aim 1: To determine the prevalence, characteristics, physical activity levels, health-related quality of life and function in women with OA and comorbidities attending a Community Health Centre to establish the contextual background for the intervention.

The **Objectives:**

- To ascertain the prevalence, characteristics and functional impact of OA and common comorbidities in women older than 18 years attending a CHC using an adapted version of COPCORD questionnaire and the WHODAS 2 questionnaire.
- To identify the clusters of chronic diseases of lifestyle (e.g. hypertension, diabetes, cardiovascular conditions etc.) which occur in women attending the health centre.
- To determine the body mass index, physical activity levels and health-related quality of life (HRQOL) in these women using clinical measurements, the International Physical Activity Questionnaire (IPAQ) and EQ-5D-3L, respectively.
- To establish whether possible relationships between OA, common comorbidities, and other factors (age, obesity, lack of physical activity) exist.

Aim 2: To adapt and develop a contextually relevant non-pharmacological intervention Programme based on exercise, health education and self-management principles designed to educate, empower, improve functional status and health-related quality of life of women with OA and comorbidities.

The **objectives**:

1. To conduct a review to determine the evidence for effective interventions that include exercise and education based on self-management principles for people with osteoarthritis.

2. To determine which topics are relevant to the participants to incorporate in the educational component of the intervention by extracting the results from Aim 1.

3. To ensure contextual relevance and compliance to the intervention by including the participants in the decision making regarding the preferences, nature, and content of the intervention Programme through surveys.

Aim 3: To determine the effects of the non-pharmacological intervention programme on impairments, activity, and participation restrictions in women with OA and comorbidities.

The **objective**:

1. To establish whether the intervention had a significant effect on functional ability, pain, health-related quality of life, obesity, physical activity, blood pressure, blood glucose and self-efficacy by evaluating the primary and secondary outcomes post-intervention.

The effectiveness of the intervention was determined by improvements in the following outcomes:

1. Functional limitations (WHODASII, Aggregated Locomotor Functional test)
2. Impairments (Pain, BMI, blood pressure and blood glucose levels)
3. Physical activity (IPAQ questionnaire)
4. Health-related quality of life (EQ-5D-3L)
5. Self-efficacy for Chronic diseases management (Self- efficacy).

1.3.6 Main outcome of study:

The development and implementation of a non-pharmacological intervention, which is contextually relevant, effective, and acceptable for women with OA and comorbidities presenting to primary health care facilities in the Cape Metropole Region in the Western Cape, South Africa.

1.4 Outline of this thesis

This thesis will present the findings of a series of studies conducted to determine the functional impact of a non-pharmacological and contextually relevant intervention for osteoarthritis in women with associated comorbidities presenting to a community health centre in Cape Town.

Chapter 2: Causes and impact of osteoarthritis: literature review

A literature review describing the burden of osteoarthritis, the epidemiology and pathophysiology of osteoarthritis; and the risk factors associated with the condition. It further describes the prevalence of osteoarthritis and comorbidities and the impact of these conditions on affected individuals. Lastly, it provides an overview of evidence-based management strategies for osteoarthritis.

Chapter 3: The use, selection, translation, and validation of instruments

This chapter describes the selection of reliable and valid outcome measures relevant for use in studies of chronic musculoskeletal disorders. Secondly, the translation process that was used for two instruments will be presented. Thereafter, the feasibility of the use of the translated instruments in a local community and the process of validation of translated instruments will be discussed.

Chapter 4: The prevalence, characteristics and functional impact of chronic musculoskeletal disease and comorbidities in women attending a community health centre in Cape Town

In this chapter, the findings of the epidemiological study describing the profile and characteristics of women with chronic joint pain (MSD) and associated comorbidities attending a local community health centre in a poorly resourced area of Cape Town are presented. This chapter presents the prevalence of disease, the medical and physiotherapy management received for their conditions and the possible risk factors associated to MSD. This chapter provides the framework for the development and implementation of the intervention Programme which will be discussed in detail in the next few chapters.

Chapter 5: The development of a contextually relevant intervention for osteoarthritis

This chapter presents information pertaining to the development of the intervention to be implemented in the randomised controlled trial.

Chapter 6: The effect of a six-week non-pharmacological intervention Programme on function and health outcomes in women with osteoarthritis and hypertension: randomised controlled trial

In this chapter, the findings of the randomised controlled trial are presented. The aim of the intervention was to determine the effect of exercise, health education and self-management on physical function and other health outcomes in women with osteoarthritis and comorbidities.

Chapter 7: Conclusion and Recommendations

In the last chapter of the thesis, a summary of the main findings of the chapters is presented. Finally, the chapter concludes with recommendations for clinical practice, especially for health professionals at community health centres in Cape Town and highlights the application of the findings for future research.

2 CHAPTER 2: CAUSES AND IMPACT OF OSTEOARTHRITIS: A NARRATIVE LITERATURE REVIEW

2.1 Introduction

This chapter provides an overview of the literature on the prevalence of osteoarthritis (OA); the pathology of OA; the risk factors associated with OA; the possible interactions with common chronic diseases of lifestyle (CDL) and the impact of these chronic diseases on the affected individual's physical function, health, and well-being. This chapter highlights the need to conduct epidemiological studies in OA in South Africa and summarises the scientific evidence for effective management strategies for OA.

A literature search was conducted using Pubmed, PeDro, CINAHL, Cochrane library, EBSCOhost, Africa wide via EBSCOhost and Google Scholar with a date range from 1950 to 2020. However, studies older than 20 years were only used if there was no recent literature available to substantiate claims or theories. The keywords used were: "osteoarthritis", "prevalence of osteoarthritis", "risk factors of osteoarthritis", "pathology OR pathogenesis of osteoarthritis", "chronic diseases of lifestyle AND osteoarthritis" and "treatment interventions for osteoarthritis".

2.2 Epidemiology of Osteoarthritis

2.2.1 Osteoarthritis – Part of the Global Burden of disease

Globally, understanding of the burden of disease has shifted from using measures of mortality and premature deaths to measuring the impact of illness on participation using years lived with disability (YLD). An increase in YLD from 537.6 million in 1990 to 764.8 million in 2013 for both men and women were reported in the 2013 Global Burden of Disease study (GBD 2013). An increase in total disability-adjusted life years (DALYs) was recorded from 21.1% in 1990 to 31.1% in 2013[46]. In the GBD 2016 study, musculoskeletal disorders (MSD) (17.1%) and other non-communicable diseases (NCD) (18.6%) had contributed to nearly half of the YLDs, increasing the non-fatal burden of disease. This increase in the prevalence of NCDs and MSD led to a substantial increase in YLDs and DALYs. Furthermore, the increase in the prevalence of NCDs and MSD may be a consequence of ageing, population growth and epidemiological changes[47]. Even though the global mortality rates have reduced, the burden of NCDs and MSD, specifically osteoarthritis (OA), have increased substantially leading to higher numbers of people being affected by disabling chronic diseases[1 46 48]. Therefore, diseases with non-fatal outcomes such as OA, are important outcomes to consider when evaluating this burden of disease.

The GBD studies have highlighted a greater need for the assessment of causes of disability. Osteoarthritis (OA) was reported as one of the top ten causes of non-fatal burden globally, causing severe disabilities and functional impairments in millions of people[48]. OA was reported as one of the ten leading causes of YLDs in countries such as Canada, Denmark, Germany, and in other Eastern and Central European, East Asian and sub-Saharan African countries[48]. These findings highlight that OA is a disabling chronic condition that affects people living in developed and developing countries. Further research on OA to determine the prevalence, causes, risk factors, associated conditions and how this disease impacts on an individual's life, in terms of physical functioning and overall wellbeing, is needed. This information will be beneficial for various health systems across the world to provide evidence-based prevention and chronic care management strategies for the ageing population[1 46 48].

2.2.2 Prevalence of Osteoarthritis: Global and in Africa

There is an increase in the demand for health care services for the management of osteoarthritis associated with an increase in the prevalence of the condition across the globe. In developed countries, studies report an OA prevalence ranging from 14.2% in adults older than 30 years (n=207 610; in Canada)[9]; 26.6% in adults older than 45 years (n=531 254, in Sweden)[49]; and 66% (spine), 60% (hand) and 38% (knee) in 696 patients older than 65 years in South Korea[19].

A similar trend in the prevalence of OA was reported in some developing countries. In Iran, 2001 participants were evaluated with OA being the most commonly reported condition (18.6%) followed by low back pain (17.7%) and rheumatoid arthritis (RA) (0.9%)[50]. In Mexico, a 25.5% prevalence of MSD was recorded (n=19 213), with OA being the most common MSD with a prevalence of 10.5%[51]. Furthermore, a prevalence of 28.7% (n=4909) of OA was reported in India[52].

There is a scarcity of epidemiological data on OA in the African context. The data that are available are from relatively small studies. In Cameroon, an OA prevalence of 9.9% (n=1496 individuals) was reported[53]. In Congo, a low prevalence of 1.5% (n=13,041) of knee OA was found[54]. The possible reasons for the low prevalence (or under-estimated prevalence) in these two African countries could be attributed to methodological issues with recruitment and stringent exclusion criteria. In the Cameroon study, participants with a diagnosis of knee OA were recruited from two rheumatology clinics and had to report mechanical knee pain for three months, had radiological features of knee OA on x-rays fulfilling the American College of Rheumatology (1986) criteria for knee OA. Participants were excluded if they had previous history or recent knee trauma, infection of the knee or other inflammatory joint diseases. The study conducted in Congo, recruited participants through reviewing medical folders and from consultations at rheumatology clinics. If the participant reported mechanical knee pain, it needed to be confirmed as knee OA with x-rays using the Kellgren and Lawrence criteria. Other possible reasons could be attributed to environmental, domestic, or socio-economic demands that could have affected the sample's health status and inadequate access to the hospitals introducing a recruitment bias.

In South Africa (SA), there seems to be a dearth of prevalence data on OA, however, some small studies have been conducted in arthritis.

The WHO endorsed the SAGE study (study on global ageing and adult health) and collected data from 4006 households and 4221 individuals from each province in SA between January 2007 and November 2008. Nearly a quarter (24%, n=918) of the adults self-reported a diagnosis of arthritis[55]. A systematic review on the prevalence of arthritis in Africa by Usenbo (2015)[17] summarised data from 27 studies (from 11 countries). Most of the studies (n=12) were from South Africa. The prevalence of OA in South Africa was 55% in urban areas. In rural areas, the prevalence ranged from 29.5% to 82.7% in individuals older than 65 years of age[17].

The studies mentioned above included prevalence of arthritis, which is an umbrella term that refers to more than 100 different types of arthritic conditions that may lead to chronic pain[56]. The use of an umbrella term such as arthritis may be problematic as a potential bias can be introduced due to the uncertainty about the specific type of arthritis and could possibly influence the prevalence data. Participants often self-diagnose arthritis, which may lead to misdiagnosis and under-estimation of the true prevalence of the condition. It could be assumed that the prevalence of arthritis reported in several studies would include a diagnosis of OA as it is "associated with chronic pain". This assumption is supported by the literature reporting that osteoarthritis (OA) is the most common type of arthritis[57-60]. Since Usenbo (2015)[17] reported a high prevalence of arthritis in older people, it could be further assumed that the prevalence reflects a type of arthritis that is related to ageing. The most common arthritis related to ageing is osteoarthritis[61 62]. Even though some research has been done to determine the extent of arthritis or OA in South Africa, the relationship between OA and comorbidities has not been elucidated.

There are few studies reporting on the prevalence of common non-communicable diseases (NCD), specifically, multimorbidity, in South Africa. In 2010, a national study evaluated patients with multimorbidity NCD in South African primary health care clinics (PHC)[36]. Previous data related to a morbidity survey included data from 18 856 consultations with 24 561 diagnoses were used in this report. The data represented patient consultations from different provinces in SA (Limpopo: 6 678 consultations, the Northern Cape: 1 504, North West: 5 082 and the Western Cape: 5 592) with most consultations being for women (66.6%). The most common NCD recorded in PHC was hypertension (13%), followed by diabetes mellitus type 2 (3.9%), osteoarthritis (2.2%), asthma (2%), epilepsy (1.9%) and COPD (0.6%). In addition, nearly 50% of the sample (N=18 856) had these comorbidities and 14.4% had two or more NCD (multimorbidity) with COPD (36.4%) and OA (23.7%) being the most common comorbidities[36].

A local study conducted at two primary health care clinics in Cape Town assessed 1005 individuals for chronic MSD[27]. A high prevalence (36%) of MSD was found with joint problems being mostly reported (60%), of which 10% were OA. Comorbidities such as hypertension (59.1%), diabetes mellitus type 2 (24.8%) and heart problems (18.9%) were the most common comorbidities reported in this sample[27]. This study highlighted the prevalence of non-traumatic MSD which could relate to OA in patients attending these clinics. However, the prevalence data of this study did not include clinically diagnosed MSD or OA and may not represent the true prevalence or burden of OA in this sample at these clinics. This highlights a need for up-to-date data on the prevalence of diagnosed OA in primary health care clinics in Cape Town.

2.2.3 Characteristics of individuals affected by Osteoarthritis

It is important to describe the characteristics of individuals affected by osteoarthritis to be able to develop and implement contextualised patient-centred management strategies. An increased prevalence of osteoarthritis in the studies summarised above was reported mostly by older individuals. Higher prevalence of OA (range: 26% to 82.7%) was reported by individuals older than 35 years of age in both developed and developing countries, including South Africa[49 19 52 17]. Women reported a higher prevalence of OA than men in developed and developing countries[9 19 63 52 17]. Therefore, older women have a higher prevalence of osteoarthritis and may present with specific characteristics and risk factors.

According to Cho et al., (2015)[19], knee and hand OA was significantly associated with being female. A similar association between OA and being female was found in Congo[64] and in South Africa[17]. In addition, knee OA was significantly associated with obesity[52 53 64]. Apart from being obese, a higher prevalence of OA was found in individuals who did not engage in exercise (83%) compared to those who regularly participated in exercise (36%)[52]. Therefore, older women, who are obese and who do not exercise, are at higher risk for developing OA, specifically at the knee, than men.

As older, obese women are affected by OA, it is important to identify the presence of any associated comorbidities to be able to manage these affected women comprehensively. Studies from both developed and developing countries report that OA was significantly associated with comorbidities such as hypertension (HPT), diabetes mellitus type 2, depression and chronic obstructive pulmonary disease (COPD)[9 53 64].

These findings are similar to South African studies, where hypertension (13%), diabetes mellitus type 2 (3.9%), asthma (2%) and COPD (0.6%) were reported in PHC[36] and similar comorbidities have been reported in other CHCs in Cape Town[27].

There are similarities in the findings of studies from developed and developing countries, with a higher prevalence of OA reported by older women compared to men. Similarly, OA is associated with female gender, obesity, sedentary lifestyles, and comorbidities (hypertension, diabetes mellitus type 2 and COPD) in both developed and developing countries. All these studies have highlighted that the prevalence of OA increases as the population ages, thus increasing the burden of disability and demand for appropriate health care for this vulnerable group of individuals utilising the primary health care system globally[9 19 63 17].

In summary, a widespread of prevalence of OA (10% to 66%) has been recorded in studies from developed and developing countries. Studies from high and middle-income countries reported that OA was the most common type of arthritis and MSD. Furthermore, all the studies reported a high prevalence of OA in various contexts such as communities, hospitals, and primary health care clinics. Osteoarthritis is more common in middle and older-aged women compared to men globally. These global findings are reflected in the high prevalence rates of OA and the co-morbid CDL in middle-aged women recorded in the smaller studies conducted at local clinics in Cape Town.

This two-fold health problem of OA and CDL in middle-aged women has the potential to contribute to chronic pain, functional limitations and disability and may become a burden to the country, especially in the over-burdened public health care system, and to society. Unfortunately, there is limited evidence available on the relationships between OA and co-morbid CDL in middle-aged women attending CHCs in Cape Town, which in turn, creates a challenge for determining best management strategies for these affected women. Before such management strategies can be discussed, we need to first explore the biological processes and causes of osteoarthritis and its related symptoms to be able to understand the disease. Thus, a discussion of the pathophysiology of OA will be presented next.

2.3 Pathophysiology of Osteoarthritis

The definition of osteoarthritis (OA) can be based on the symptoms experienced by the patient or on the biological mechanisms (pathology) that lead to the disease[65]. The symptom-based definition of OA is a degenerative disease that is characterised by chronic joint pain, joint stiffness, tenderness, crepitus, local inflammation, occasional effusion and problems with mobility[66]. The pathology-based definition of OA involves the destruction of the synovial joint that is caused by inflammation and deterioration of the articular cartilage with associated osteophyte formation and subchondral bone sclerosis. Damage of the surrounding soft tissue structures (synovium, ligaments and muscles) are evident by the disease[65 67]. However, the use of a symptom-based approach or a pathology-based approach will be problematic because people may have evidence of pathology without symptoms and may have symptoms without evidence of severe pathology. Therefore, clinically to make a diagnosis of OA, a combination approach is pragmatic[65].

Osteoarthritis is a complex multi-factorial disease. The pathophysiology of OA includes biomechanics, biochemistry and biopsychosocial factors with treatment approaches ranging from conventional pharmacological, surgical to non-pharmacological (exercise and education) interventions[65]. Due to the chronic nature and complexity of the disease, a shift in treatment approaches from medical to a biopsychosocial approach (including non-pharmacological treatment) is needed to manage patients effectively[65 67]. A thorough understanding of the pathology (changes in bone leading to joint damage) and symptoms of OA are needed to accurately diagnose and treat the condition.

2.3.1 Pathogenesis of Joint damage

Osteoarthritis affects the synovial joint with damage to the articular cartilage, subchondral bone, inflammation to the joint capsule, synovitis and the formation of osteophytes[68]. Furthermore, damage to the articular cartilage (due to proteolytic degradation of the cartilage matrix) results in cartilage surface fibrillation, cleft formation and reduced cartilage volume[69 68]. Subchondral bone changes may further contribute to the pathogenesis of joint damage as bone has the ability to repair, adapt and change the joint, whereas articular cartilage does not have the same ability [70]. However, it is uncertain whether the damage to the bone and cartilage occurs simultaneously or whether the changes to the bone lead to early damage to the cartilage[68]. These changes to the bone structure can be evaluated with radiography.

Osteoarthritis can be diagnosed by using various imaging modalities with radiography being the most used modality to assess the bony structures of the joint[71]. According to Kellgren and Lawrence (1957)[72], the following features could be seen on a radiograph of a patient with osteoarthritis: osteophytes on the joint margins; periarticular ossicles; narrowed joint cartilage and sclerosis of subchondral bone; small pseudocystic areas; and altered shape of the bony ends[72]. Kellgren and Lawrence (1957)[72] graded these radiological features from no osteoarthritis (grade 0) to severe osteoarthritis (grade 4) using the following grading system: grade 0=none (no features); grade 1=doubtful (doubtful joint space narrowing and possible osteophyte formation); grade 2=minimal (definite osteophyte with possible joint space narrowing); grade 3=moderate (definite osteophytes with joint space narrowing, some sclerosis of subchondral bone and possible bone deformity); and grade 4=severe (large osteophytes, joint space greatly impaired with marked sclerosis of subchondral bone and deformity of bony ends)[72]. Even though this grading system has been widely used in research and clinical settings, it has several limitations. The grading system has been mostly criticised for the use in monitoring the progression of osteoarthritis, not being sensitive to change, and for not recognising patellofemoral arthritis as a radiographic feature. It is, therefore, recommended that the Kellgren and Lawrence grading system should be used together with a comprehensive clinical evaluation of an individual presenting with osteoarthritis[73].

Radiographs can only provide an outline of skeletal damage to the joint and do not reveal early damage or pathological changes to the joint[74]. Therefore, it is recommended to use magnetic resonance imaging (MRI) to show early joint damage related to OA[75] but this is not always easy or feasible to use in population-based research. The radiographic evidence of the advanced stage of osteoarthritis (joint space narrowing, osteophyte formation and sclerosis of subchondral bone)[76] could suggest that the affected individual may suffer from severe joint pain as well[68]. However, there are weak associations between radiographic changes and symptoms such as joint pain[77]. Thus, the question of whether a relationship between joint damage and joint pain exists or not remains unclear. It is important to understand the mechanisms contributing to pain in people with osteoarthritis.

2.3.2 Pain in people with osteoarthritis

2.3.2.1 Definition of pain

Pain is the most commonly reported symptom related to osteoarthritis[66] [65] [78] [79] [8]. The International Association for the Study of Pain (IASP) has recently defined pain as *"an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage"*[80]. The IASP defined pain as a subjective experience; it considers both sensory and neurobiological; it relates to a noxious stimulus or threat of tissue damage; it confirms that pain may be associated with potential tissue damage and that an individual who is unable to communicate can still experience pain and needs to be treated with appropriate pain management strategies[81]. Recently, IASP further expanded the definition of pain and added the following key notes [80]:

- *Pain is always a personal experience that is influenced to varying degrees by biological, psychological, and social factors.*
- *Pain and nociception are different phenomena. Pain cannot be inferred solely from activity in sensory neurons.*
- *Through their life experiences, individuals learn the concept of pain.*
- *A person's report of an experience as pain should be respected.*
- *Although pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being.*
- *Verbal description is only one of several behaviours to express pain; inability to communicate does not negate the possibility that a human or a nonhuman animal experiences pain*

This definition highlights that pain is related to multiple factors (personal and environmental) and that pain can impact an individual's ability to do functional and physical activities, and to participate in their community and environment. In addition, this definition emphasises the biopsychosocial experience of pain, as illustrated by the ICF framework discussed earlier in Chapter 1, and that each individual's perception of pain is unique[82, 83].

Pain can be classified, into three classes namely: nociceptive pain, neuropathic pain and nociplastic pain[84]. The three classes of pain are described according to IASP[85]:

1) Nociceptive pain which refers to *"pain that arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors"*.

2) Neuropathic pain which is "*pain caused by a lesion or disease of the somatosensory nervous system*".

3) Nociplastic pain which *"arises from altered nociception despite no clear evidence of actual or threatened tissue damage causing the activation of peripheral nociceptors or evidence for disease or lesion of the somatosensory system causing the pain"*[85].

2.3.2.2 Pain in osteoarthritis

It is important to understand the type of pain experienced by individuals with OA as this will assist in selecting the most appropriate pain management strategies. Pain related to OA was classified previously as nociceptive pain, as clinicians assumed it was correlated to the severity of joint damage leading to the activation of peripheral nociceptors[86]. In addition, people with OA often complain about pain when moving the affected joint during weight-bearing functional activities, which is indicative of nociceptive pain[87]. Since OA is degenerative in nature, the pain would often become worse over time leading to chronic pain at rest and at night[87]. However, studies reporting on the lack of correlation between the presence or severity of pain and tissue damage in people with OA has led to an understanding that the pain associated with OA may not be purely nociceptive but also chronic and nociplastic.

Chronic non-malignant pain, refers to pain that persists for three or more months and is distinct from acute pain[88 89]. Chronic pain is the type of pain that is constant and has persisted beyond the normal time frame of tissue healing[90]. In people with OA, there may be ongoing nociceptive pain, but the chronicity of the condition with persistent tissue damage results in alterations in nociception with changes in peripheral and central processes. These alterations in the nociceptive system result in nociplastic pain [86].

Nociplastic pain is associated with functional and structural changes in the nervous system (both central nervous and peripheral nervous system). The brain includes neural systems that generate an image of "self" which identifies the body as a unit. This built-in network of neurons is often referred to as a neuromatrix[91]. The neuromatrix of self is affected by sensory stimuli such as persistent tissue damage. Persistent nociceptive stimuli can lead to functional and structural changes in the central nervous system (CNS) at both the spinal cord and cortical levels. Changes may also occur in the psychoneuroimmune stress regulation systems which lead to chronic nociplastic pain[92]. In other words, the changes or "plasticity" in the CNS extends the individual's experience of pain[93].

Evidence for plastic changes in the CNS in people with OA is wide ranging.

Individuals with OA have reduced connectivity of the medial prefrontal cortex (MPC), which is an important part of the brain that contributes to the generation of pain[94 95]. The MPC has a dual role in pain, providing anti-nociceptive effects during acute nociceptive stimuli or contributing to the induction of chronic nociplastic pain. One of the mechanisms by which chronic nociplastic pain may be induced is through a reduction in dopamine activation via the ventral tegmental area (VTA) in the mid-brain[95]. Multiple other structural and functional changes have been recorded in the CNS of people with painful OA. Therefore, individuals with OA may experience a combination of nociceptive and nociplastic pain or "mixed" pain[93 96] at the same time. When the affected individual experiences acute pain whilst suffering from chronic pain, it is referred to as a "flare up" of symptoms[97].

In addition to considering the mechanisms of pain in people with OA, it is worth considering the classification of pain in people with OA. Individuals with chronic pain related to OA might be classified differently based on the pathophysiology of their disease. Recently, the updated IASP classification of chronic pain for the International Classification of Diseases-11 (ICD-11) had classified chronic pain related to OA as chronic secondary musculoskeletal pain associated with structural changes of the joint[98]. With literature highlighting that pain is a complex, high order, somatosensory experience created by the brain and not a simple measure of tissue damage, painful OA must be appropriately assessed. This includes assessment of multiple biopsychosocial variables contributing to the development of OA to facilitate the effective and comprehensive management of the person with OA [99].

2.4 Risk factors for Osteoarthritis

The risk factors associated with OA can be divided into non-modifiable (systemic) and modifiable risk factors[62]. The most common predisposing non-modifiable factors for OA are age, female gender, genetics, and ethnicity. Unfortunately, these systemic factors cannot be altered to help reduce the risk of OA. However, a focus should be placed on exploring common local risk factors (modifiable risk factors) associated with OA to be able to target these factors with appropriate management strategies.

Literature highlighted that obesity is a modifiable risk factor for OA in diverse populations across developed and developing countries[100 24 62 101 102 53]. Furthermore, obesity is associated with an increased risk of chronic diseases of lifestyle (CDL) such as hypertension, diabetes mellitus type 2 and ischaemic stroke in more women than men in low and middle-income countries[103 104 105]. The possible mechanism behind why obesity is a risk factor for all these chronic diseases could be due to the changes in adipokines and cytokines that contribute to the low-grade inflammation (pro-inflammation) in adipose tissue that is associated to the development of these chronic diseases[106-108]. Obese individuals are usually reluctant to engage in physical activity or exercise and this lack of physical activity can lead to further metabolic imbalances and low-grade inflammation, placing the individual at higher risk of developing multiple chronic diseases (multimorbidity)[108 109].

A lack of physical activity has been found to be a risk factor for OA[110]. Sedentary work, as a form of lack of physical activity, is an associated risk factor for OA[52]. A lack of physical activity is a major contributor to common CDL[111] and is associated with obesity, breast cancer, colon cancer, osteoporosis, stress, anxiety and depression[3 5 112 113]. Although a lack of physical activity is associated with OA, participation in some sports such as soccer, elite-level long-distance running, weightlifting and wrestling may increase the prevalence of secondary OA (OA that develops from previous injury or damage)[114]. Therefore, other risk factors such as previous injury to the joint, repetitive bending, occupational activities, joint malalignment, and muscle strength play a vital role in the development of OA. Although it is not an easy task to change these risk factors, it is important to recognise these factors and address them in treatment plans to prevent future disabling conditions[62 67 52].

There seems to be some controversy about how much physical activity is required to improve health and disease states, as both doing too little or doing too much physical activity may increase the risk of OA.

Therefore, a recommendation of moderate levels (moderate-intensity) of physical activity seems to be an appropriate strategy to reduce the high prevalence of OA and associated comorbidities[115 116].

In summary, obesity and the lack of physical activity are risk factors for OA and for common CDL (hypertension and diabetes mellitus type 2). This suggests that a possible relationship could exist between OA and CDL. If this is true, the burden of multimorbidity would increase the health challenges of affected women with multiple impacts on physical functioning resulting in poorer quality of life and more severe disability. Furthermore, women with multimorbidity are likely to require a more comprehensive health care approach increasing patient costs and the workload of health care professionals. Multimorbid patients are complex to manage and increase the burden on an overstretched health system in South Africa. This highlights a need for research to determine whether a relationship between OA and common CDL do exist in women to be able to develop innovative comprehensive models of care for women with multimorbidity.

2.5 Osteoarthritis related functional impacts and participation restrictions in women

Osteoarthritis (OA) is a degenerative disease often reported by older people as OA usually affects people between the ages of 55 to 74[16]. Women play a pivotal role in South African communities as nearly half (42%) of all African homes are being led by women, more specifically by grandmothers[117 118]. The high prevalence rates of OA in middle-aged and older women represent a huge health and economic challenge for our country.

In the absence of husbands, these lone mothers experience poverty whether they are unemployed or in low-skilled and poorly paid employment[119]. Many of these women, who have been traditionally marginalised from attaining high levels of education or professional careers during the apartheid system in South Africa, are now highly dependent on their physical and functional abilities to work to earn an income. If these women suffer from OA, not only will they experience chronic pain, joint stiffness, and other symptoms, but they could suffer from other CDL and experience difficulties with daily functional activities. These lone mothers and women with OA tend to rely heavily on public primary health care services for management of their OA in the hope to recover and get back to their physical functioning level needed for their financial security, caregiving, and access to public transport. Even though international literature postulates that women are more at risk to develop OA and CDL, it is an important theory to investigate in our context, particularly in the primary health care setting.

The burden of chronic diseases has a serious impact on low and middle-income countries such as South Africa, as it hinders development and economic growth[6]. Slow economic growth and productivity could eventually affect the countries' labour force by depleting the quality and number of employees and reduce the countries' income[120]. Women living with chronic diseases, such as OA and CDL, are deprived of good health and struggle to perform optimally at work which in turn affects their potential to earn an income and to pay for the medical management of their diseases[120]. Unfortunately, the burden of chronic diseases leads to a series of negative events impacting the individual, family, and country. The presence of chronic diseases can influence the affected individual's health negatively as a lack of physical activity in individuals with OA (due to a forced sedentary lifestyle caused by chronic pain, joint stiffness and limited function) could lead to secondary complications such as obesity, hypertension, diabetes mellitus-type 2 and thus experience a poor quality of life[22]. Therefore, it is the assumption that, if the primary medical problem, OA, is not managed effectively, a cycle of secondary chronic diseases of lifestyle could occur (Figure 2).

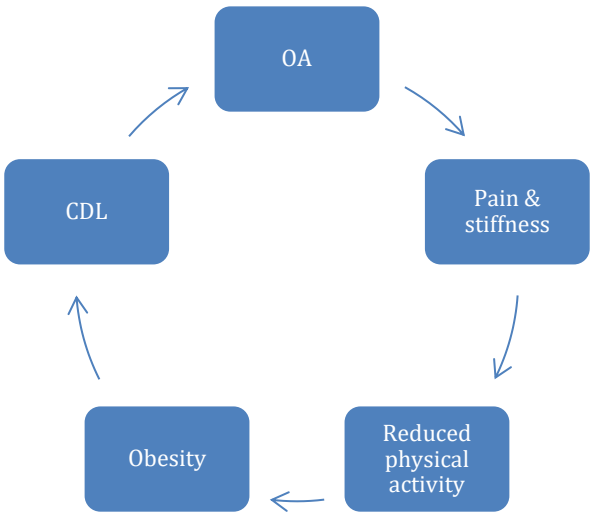


Figure 2: The hypothesised interactions of osteoarthritis and chronic diseases of lifestyle

The ICF framework, discussed in Chapter 1, is used to analyse the possible functional impact of OA in individuals and is an important framework for planning an assessment for individuals with OA. Individuals with OA (health problem) have impaired body functions and structures with the joint that is damaged, causing chronic joint pain, joint stiffness and muscle weakness in the surrounding muscles supporting the affected joint.

In addition, the impairments could lead to activity limitations with daily activities such as walking, bending the affected joint, and other activities needed for self-care. These activity limitations can lead to participation restrictions in the workplace and the wider community. Individuals with OA might have difficulty in driving a car or with climbing stairs at work. Furthermore, other factors (environmental and personal) may also influence women affected by OA. Environmental factors could be related to the physical space and environment around the home of the individual and personal factors could be related to the lifestyle and social habits of the individual. These factors could act as facilitators for recovery and healing or barriers that might delay healing.

The following patient example of a women with knee osteoarthritis is presented to describe the impact of OA using the ICF model.

“Mrs B, a single 55-year-old woman, has been diagnosed with bilateral knee OA since the age of 45. Mrs B complains of chronic pain, joint stiffness, specifically in the morning that interferes with her normal activities at home such as bending her knees to make up the beds in her home and walking her two young children to primary school. Mrs B loved to work in her garden daily but struggles to climb the stairs to tend to her garden on ground floor as she lives in an apartment on the 3rd floor. Mrs B is also struggling to drive her manual car as the pain worsens while changing gears. She has become depressed about her inability to tend her garden and to drive her and is sitting most of the time watching television. Due to this, she has gained extra weight and seems to be having more challenges with cleaning and moving around in the house. Mrs B smokes cigarettes for the past 20 years and is not planning to quit soon” (

Figure **3**).

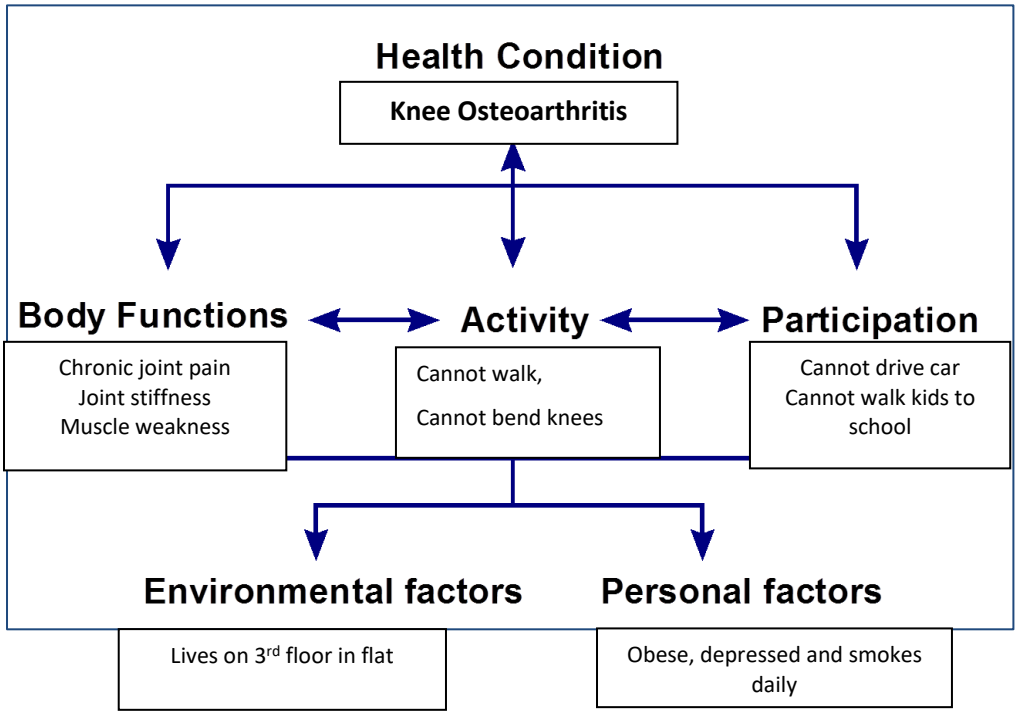


Figure 3: The functional impact of osteoarthritis in women using the ICF

Unfortunately, this analysis shows that the functional impact of OA is significant on individuals and could be worsened with the added burden of CDL, highlighting the need for comprehensive evidence-based management strategies.

2.6 Management strategies for Osteoarthritis

Evidence-based recommendations on managing OA have been formulated into clinical guidelines as an aid for health professionals to improve the quality of health care. Field (1990, p.8)[121] has defined a practice guideline as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"[121]. Clinical or practice guidelines are commonly developed by guideline development groups including researchers, professional societies in medicine, public sector agencies, and health care organisations[121].

2.6.1 Assessment of individuals with osteoarthritis

Guidelines recommend that individuals with osteoarthritis should receive comprehensive assessment and management of the symptoms related to the condition. This means that the assessment should focus on all aspects of the individual's life, following a biopsychosocial approach as described in the ICF framework discussed in Chapter 1 rather than assessing the symptoms of the condition only. According to the National Institute for Health and Care Excellence[38], the assessment should include a holistic approach by including aspects such as pain assessment, functional abilities, other musculoskeletal pain, health beliefs and knowledge of OA, the influence of comorbidities, occupation, social support network, mood, quality of sleep, and attitude to exercise. The guideline emphasises that not all the aspects of the assessment may be necessary or relevant for everyone with OA and it is the responsibility of the health professional to include essential elements[38].

Apart from following a biopsychosocial approach with the assessment, the health professional should share the decision-making of the treatment plan with the affected person by including their opinions and recommendations in the plan. The management plan should include the possible effects of associated comorbidities and offer appropriate treatment to address these comorbidities. Any possible benefits or risks associated with the planned treatment strategies should be discussed with the patient. The goal for the planned management strategy for OA should be to reduce disability, improve joint movement and function, and reduce pain. The planned management strategy must be holistic and should include education about the disease and therapeutic techniques[122 38].

2.6.2 Management strategies for osteoarthritis at the primary health care level

Conservative management is usually recommended for patients with mild to moderate OA. This management includes both pharmacological and non-pharmacological interventions. The following section will describe the pharmacological treatment for osteoarthritis. Thereafter, evidence for non-pharmacological management strategies for OA will be discussed. Based on current knowledge, treatment strategies are focused on addressing the symptoms of OA as altering the disease (joint changes) does not seem feasible. Therefore, it would be beneficial to improve the affected individual's quality of life by reducing disability, enhancing joint movement and function, and managing their pain.

2.6.2.1 Pharmacological treatment for osteoarthritis

Common symptoms related to osteoarthritis, such as pain, have been treated with traditional medication like analgesics and non-steroidal anti-inflammatory drugs (NSAIDS), either specific or non-specific for inhibition of cyclo-oxygenase-2 (COX-2)[123] [124]. However, these pharmacological agents could have inadequate efficacy on pain control and may cause adverse effects to the gastrointestinal, renal, and cardiovascular systems[125] [126]. Since OA is a progressive degenerative disease, the analgesic effects of these medications often become less effective in symptom management over time and other treatments such as intra-articular injections or corticosteroid may then be administered. However, the effect of intra-articular corticosteroids on outcomes such as pain and physical function in patients with OA is short-lived (6 weeks) and the quality of the evidence is poor[127].

In the past, opioid medication was recommended for OA when first-line analgesics failed. However, due to their poor side effect profile[128] and lack of efficacy compared with mild opioids and NSAIDS[129], opioid prescription is no longer supported for pain related to hip or knee OA[129]. In the event of persistent symptoms following the unsuccessful use of the various medications highlighted above, the patient would usually be referred for a total joint replacement (TJR) as the last medical treatment option for OA[130]. Various factors need to be considered when deciding to have a TJR including the severity of bone changes on radiographs, the severity of symptoms and the type of pain (nociceptive vs nociplastic). Furthermore, the presence of comorbidities in individuals with OA might delay surgery, pose a risk for post-operation complications, or recovery. It would seem that traditional pharmacological treatment is not effective to manage the symptoms related to OA, highlighting the need for non-pharmacological treatment strategies to help manage pain and associated functional problems with OA[131].

2.6.2.2 Evidence for non-pharmacological management strategies for osteoarthritis

The primary aim for the management of OA includes pain reduction, improved range motion in diseased joints, and improvement in functional activities. For this reason, non-pharmacological management should include using self-management strategies targeting pain control, education, weight-loss and exercise[132 133 131].

A review of clinical guidelines on non-pharmacological interventions for osteoarthritis was performed using the following databases: PubMed (which includes Medline), Scopus (which indexes Embase); Africa-wide: CINAHL; PsychARTICLES; PSYCINFO; PSYCHIATRYONLINE; ScienceDirect and Web of Science, Cochrane library and PEDro. For this study, clinical guidelines on the management of lower limb (hip and knee) osteoarthritis that was published between 2007 and 2019 were included in this review. The search identified clinical guidelines for the management of OA from NICE, OARSI and EULAR. The following section will highlight the interventions recommended in these clinical guidelines that were graded as strong with high (grade A) quality of evidence[134].

A. NICE – National clinical guideline on care and management in adults with osteoarthritis

The National Institute for Health and Clinical Excellence (NICE) is a public organisation in the United Kingdom (UK) that develops public health guidance to promote healthier lifestyles through prevention strategies. In 2008, NICE released national guidelines on the care and management of osteoarthritis in adults. These guidelines were updated in 2014[122 38]. The updated guidelines aimed to review up-to-date evidence and provide recommendations on the use of pharmacological treatment for OA, specifically, the effectiveness of paracetamol in the management of OA. However, only the non-pharmacological treatments will be highlighted in this review. The clinical guideline formulated “core treatments” for osteoarthritis. The following Box 2 highlights these core treatments.

Box 2: NICE core treatments for osteoarthritis

Education, Advice and Access to appropriate information:

Oral and written information should be provided to the affected person to increase their knowledge and understanding of the condition and how it impacts their life. Individual self-management strategies should be formulated with the person with osteoarthritis to adopt positive and healthy behavioural changes, such as exercise, weight loss and the use of suitable footwear or bracing, if appropriate for the person's condition.

Activity and exercise:

Provide appropriate advice about engaging in exercise as part of treatment for osteoarthritis, irrespective of their age, chronicity of pain or presence of comorbidity. The exercises should include local muscle strengthening and general aerobic fitness.

Interventions to achieve weight-loss:

If the affected person is overweight or obese, appropriate advice and management should be provided.

If additional non-pharmacological treatment is needed after the core treatments, the following adjunct treatments should be considered, see Figure 4[122 135].

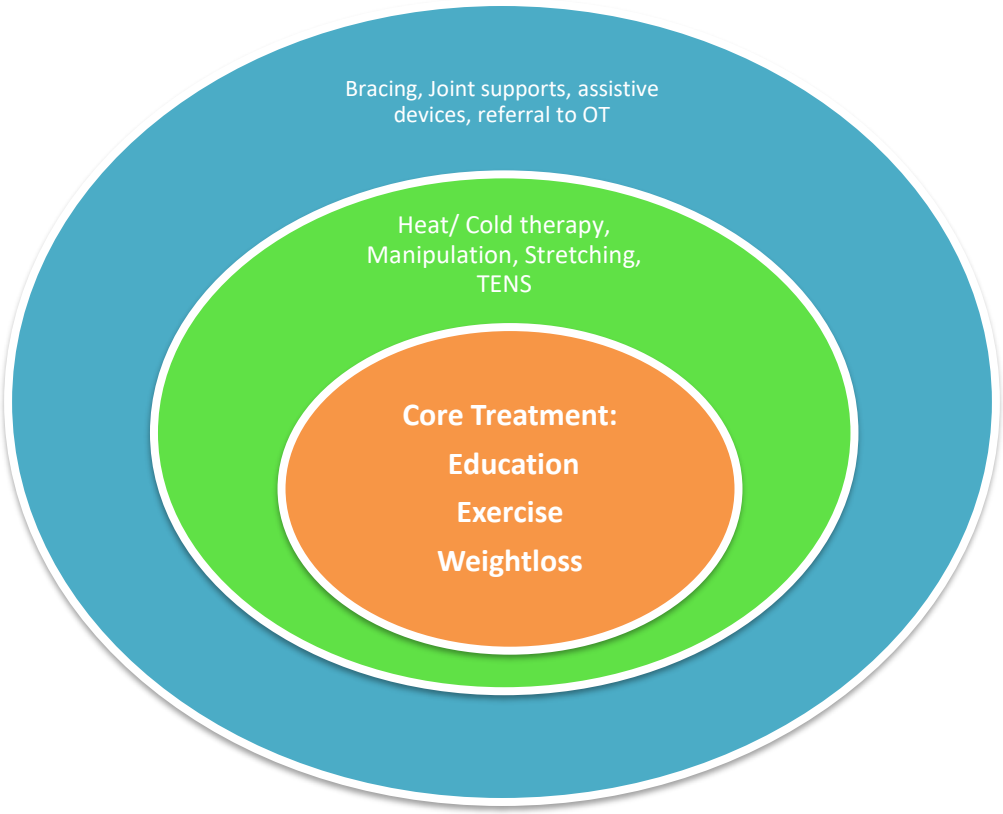


Figure 4: NICE Non-pharmacological CORE treatments for OA

Based on the National Institute for Health and Clinical Excellence (NICE) osteoarthritis treatment recommendations (Conaghan et al., 2008)

B. OARSI recommendations for the management of hip and knee osteoarthritis

The Osteoarthritis Research Society International (OARSI) has developed a committee of international experts to review the evidence and provide expert recommendations for treating hip and knee OA. The OARSI treatment guidelines committee had critically reviewed published guidelines and a systematic review from 2002 to January 2006[136]. Thereafter, evidence-based expert consensus recommendations for the management of hip and knee OA was published in 2008[123]. This followed a systematic review of published guidelines between 1945 and January 2006 using the Appraisal of guidelines research and evaluation (AGREE) instrument to recommend a core set of management treatments for hip and knee OA[123]. Since then, the updated 2009 OARSI guideline summarised the evidence for the management of hip and knee OA from 2006 to January 2009[137]. In 2014, OARSI provided updated guidelines with literature published between 2009 and March 2013.

The 2014 guidelines provided relevant treatment recommendations for four clinical sub-groups namely, people with knee OA and no comorbidities, knee OA with comorbidities, multi-joint OA and no comorbidities and multi-joint OA with comorbidities. The reason for stratifying into these clinical sub-groups was that OA in multiple joints and associated comorbidities might affect treatment choices[39].

In the 2014 guideline, the OARSI team ranked the appropriateness of each treatment recommendation based on the number of votes for agreement or disagreement of appropriateness on a scale from 1 to 9, whereby 1 to 3 was deemed "inappropriate", 4 to 6 was "uncertain" and 7 to 9 was considered "appropriate". The interpretation of the "uncertain" proposition was not to disqualify or exclude the treatment recommendation but rather to suggest that the evidence could be misleading, or the unclear appropriateness could be due to limited effectiveness[39].

The 2014 guideline highlighted three categories of recommendations for each treatment modality. The appropriate treatment modalities for knee OA were self-management and education, land-based and water-based exercise, strength training and weight management. These treatments are still considered "core" treatment modalities that were proposed in the 2008 and 2010 guidelines. Other treatment modalities such as acupuncture, crutches, transcutaneous electrical nerve stimulation, and ultrasound were recommended as "uncertain". Electrotherapy (neuromuscular electrical stimulation) was voted "not appropriate" for treatment of knee OA. These unclear recommendations could be due to the lack of strong evidence about the efficacy of outcomes in patients with knee OA. Thus, more high quality and level of research is needed to investigate the efficacy of these treatment modalities in outcomes such as pain and physical function.

More recently in 2019, OARSI published updated clinical guidelines on the non-surgical management of hip, knee and polyarticular osteoarthritis[138]. This updated guideline was more comprehensive than the other guidelines as it was patient-centred and it provided recommendations for four subgroups of people with OA and gastrointestinal comorbidities, OA and cardiovascular comorbidities, OA and frailty and OA with widespread pain and/or depression. This guideline provided a treatment pathway to assist clinicians to decide on the best treatment for patients with OA and comorbidities. Furthermore, treatments were rated according to level 1A as "strong" or level 1B as "conditional" recommendations in favour (>75% of votes by panel) or against (<25% of votes by panel).

Thus, the core treatment recommendations for OA were rated as level 1A "strong recommendation" (>75% in favour and >50% strong)[138].

The 2019 guideline had strongly recommended that the "core treatment" (education, land-based exercise, and weight-loss interventions for obese people) is appropriate and safe for people with knee, hip or polyarticular OA with comorbidities. Water-based exercise, walking aids and self-management Programmes were deemed as level 1B "conditional recommendation" (>75% in favour and > 50% conditional) for knee OA and comorbidities. However, some treatments were not recommended for certain comorbidities. Water-based exercise was conditionally recommended (level 1B) for knee OA due to possible problems with finance, accessibility, and uptake. Even though there is some evidence available for the effectiveness of water-based exercises on pain and function, it was not recommended for people with knee OA and frailty, due to the high possibility of injury[138].

For hip and polyarticular OA, the 2019 guideline strongly recommended (level 1A) land-based exercise and OA education as core treatment, but no strong recommendation was given for people with hip or polyarticular OA and comorbidities, due to the lack of high-quality evidence available. However, Tai Chi or Yoga (mind-body exercises), self-management Programmes, and walking aids were conditionally recommended (level 1B) for hip and polyarticular OA with all comorbidity subgroups. In addition, weight-loss interventions were conditionally recommended for polyarticular OA with all comorbidity subgroups, except for those with frailty[138]. Furthermore, no recommendations were given in this guideline for adjunct treatments that were mentioned in the previous OARSI guidelines.

C. EULAR recommendations for the management of knee osteoarthritis

The European League Against Rheumatism (EULAR) is a non-profit educational and scientific organisation which represents both health professionals in rheumatology and people affected by arthritis or rheumatism. EULAR provides up-to-date evidence in treatment and rehabilitation of musculoskeletal diseases such as OA to help alleviate the high burden of rheumatic diseases. EULAR appointed a steering committee in 1998 that was endorsed by the International Clinical Studies Including Therapeutic Trials (ESCISIT), and consisted of 21 experts in rheumatology (rheumatologists and orthopaedic surgeons) from different countries in Europe[139].

A comprehensive list of relevant treatments for knee OA was compiled to assist the review process and agreement of 10 important questions related to treating knee OA was done. Using the list as a guide, a systematic search for relevant publications (systematic reviews, meta-analyses, RCTs, controlled trials and observational studies), from January 1966 to January 1999 was performed. Only studies related to the management of knee OA were selected and included in the review[139]. The EULAR 2000 treatment recommendations comprised of a list of 10 propositions, of which three recommendations were related to non-pharmacological treatment. An optimal management plan for patients with knee OA should firstly follow a holistic approach by considering all the factors affecting the patient (age, comorbidity, symptoms, personal attitude, and knowledge). Thereafter, other treatments relevant to the patient's health profile were necessary to be implemented. Common non-pharmacological treatment recommendations, such as patient education, aerobic and quadriceps strengthening exercise, walking sticks, insoles, and weight reduction were advocated as effective interventions for knee OA.

The updated EULAR 2013 clinical guideline on non-pharmacological management for hip and knee provided the latest evidence with more details about the recommendations stated in previous guidelines[40]. The updated guideline provided more information related to patient education, the frequency and delivery of exercise, weight reduction and combination of interventions. Furthermore, additional information about the long-term effect of interventions for OA on adherence was included.

The following Table 1 has been compiled to provide a comparison of similar interventions recommended by NICE, OARSI and EULAR clinical guidelines available at the time of this review. All three clinical guidelines agreed on the "core" non-pharmacological management approach for adults with OA: education about osteoarthritis, exercise, self-management principles and interventions to achieve weight-loss. All three guidelines agreed that the education component should provide both verbal and written information about the disease process and the management of the condition. The exercise Programme (whether on land, water-based or home-based) should include safe exercises for local muscle strengthening, general aerobic fitness, and range of motion. If a weight-loss component is added, it should include information about meal plans with a focus on reducing calories, fat, sugar, and portion size. For the self-management component, strategies to promote positive behavioural changes through goal setting and action plans to start and maintain an exercise or weight loss Programme with feedback on progress should be included.

Furthermore, if adults are having difficulties with their activities of daily living, the guidelines recommended using assistive devices as part of the “core treatment”.

Other adjunct treatment interventions were recommended, but not by all the guidelines. These included: appropriate footwear (NICE and EULAR); bracing or joint support and insoles (NICE and OARSI); and heat therapy or cryotherapy (NICE). Although TENS and manual therapy were recommended as adjuncts in the NICE guidelines, the OARSI guidelines (2014) indicated there was insufficient evidence and the EULAR guidelines had no recommendations for these treatments. Therefore, no clear recommendations can be provided about these adjunct treatments for OA. The use and effect of acupuncture and ultrasound are questionable, as none of the guidelines recommended these treatments based on a lack of evidence.

Table 1: Comparison of recommendations from clinical guidelines on non-pharmacological management for OA of the hip and knee

INTERVENTION	RECOMMENDATION FROM CLINICAL GUIDELINE	NICE[38]	OARSI[39 138]	EULAR[40]
Core Treatment	Appropriate information about osteoarthritis and self-management, exercise, and weight-loss interventions if the person is overweight or obese.	Recommended	Recommended	Recommended
Exercise	Incorporate exercise as part of core treatment, irrespective of age, comorbidity, pain severity or disability. Exercise (land, water-based home-based) should include muscle strengthening, general aerobic fitness and range of motion exercises.	Recommended	Recommended	Recommended
Education	Provide verbal and written information about OA (disease processes and management). Ensure that information sharing is an ongoing component of the management plan rather than a single event at the beginning of the management Programme. Discuss and agree with the affected person on a suitable plan for managing their osteoarthritis by using principles of shared decision making.	Recommended	Recommended	Recommended
Self-management	Provide self-management (SM) strategies to promote positive behavioural changes (exercise, weight-loss, footwear, pacing). The SM should aim to teach and encourage behavioural change strategies through goal setting, action plans to maintain changes and regular follow-up to re-evaluate and discuss goals and action plans. Factors such as person's exercise goals, feedback on progress made towards the goals, problem solving, reinforcements of maintaining exercise (exercise plans and logbooks, written information in booklets, audiotape, videotape, and booster sessions) should be considered in the SM Programme to improve adherence to new behaviours.	Recommended	Recommended	Recommended

INTERVENTION	RECOMMENDATION FROM CLINICAL GUIDELINE	NICE[38]	OARSI[39 138]	EULAR[40]
	The self-management Programmes should emphasise the recommended core treatments.			
Weight-loss	Provide weight-loss interventions as part of the core treatment for people with OA and who are obese or overweight. The interventions should include strategies to reduce calorie intake by meal plans, reducing fat and sugar, reducing portion size, meal replacements, self-monitoring, weight-loss goals and maintaining body weight in participants who had reached their goals.	Recommended	Recommended	Recommended
Assistive devices	Assistive devices (walking sticks) should be considered as adjunct to core treatments for people with problems with activities of daily living.	Recommended	Recommended	Recommended
Footwear	Provide advice on appropriate footwear as part of core treatment for osteoarthritis.	Recommended	No recommendation available	Recommended
External protection	People with OA with biomechanical joint pain or instability should be assessed for possible bracing/joint supports/insoles as an adjunct to core treatments.	Recommended	Recommended but weak evidence	No recommendation available
Heat and Cryotherapy	Heat or cold compresses should be considered as an adjunct to core treatments.	Recommended	No recommendation available	No recommendation available
TENS	Transcutaneous electrical nerve stimulation (TENS) should be considered as an adjunct to core treatments for pain relief.	Recommended	Uncertain: insufficient evidence	No recommendation available
Manual therapy	Manipulation and stretching should be considered as an adjunct to core treatments.	Recommended	No recommendation available	No recommendation available

INTERVENTION	RECOMMENDATION FROM CLINICAL GUIDELINE	NICE[38]	OARSI[39 138]	EULAR[40]
Acupuncture	Provide acupuncture for the management of osteoarthritis.	Not Recommended	Uncertain: insufficient evidence	No recommendation available
Ultrasound	Use ultrasound for the management of osteoarthritis.	No recommendation available	Uncertain: insufficient evidence	No recommendation available

Note: Interventions in red are core intervention strategies

In summary, as clinical guidelines are a valuable resource in identifying appropriate interventions for OA, this review highlights that the top three guidelines provided strong evidence for incorporating health education, principles of self-management, exercise, and weight loss interventions as effective and affordable non-pharmacological management interventions for adults with lower limb OA. This evidence serves as a guideline for best practice for OA and is extremely beneficial to physiotherapists managing adults with OA particularly working in under-resourced primary health care facilities in Cape Town, South Africa.

D. Evidence of the effectiveness of the combination of education and exercise interventions for osteoarthritis from randomised controlled trials

All the above clinical guidelines advocated using a biopsychosocial approach in managing osteoarthritis by including the "core" components of exercise, education about the condition and pain management, and weight-loss if necessary, as the first level of treatment for adults with OA[122 38 39 40]. Even though these recommendations were first made 20 years ago, there is still clear under-utilisation of these "core" treatment approaches[140]. Despite the known benefits of participating in physical activities and weight-loss strategies for people with OA, these strategies are not always being prioritised by health professionals, with an increasing number of adults with OA being obese and physically inactive [141 140]. In addition, health professionals do not appear to be providing education about behavioural strategies (physical activity and weight loss) equally across sex, age, disability, and formal education levels, resulting in poorer quality of management for some people with OA [142].

Apart from incorporating these "core" treatment components as management for OA, these treatments must be cost-effective for treatments to be sustainable. Self-management education strategies and exercise were both found to be cost-effective[143]. These self-management strategies with a focus on coping with pain and exercise have been advocated as appropriate interventions to reduce pain, disability and improve quality of life in people with chronic pain[144-146]. Evidence has been generated to support the non-pharmacological interventions based on these "core" components through randomised controlled trials (RCT) in people with OA in various countries. These trials have evaluated whether a combination intervention was more beneficial in improving outcomes (pain, health-related quality of life and function etc.) compared to usual treatment or individual treatments. Table 2 highlights randomised controlled trials evaluating the effectiveness of exercise versus education, or a combination of exercise and education versus usual care in health outcomes in adults with OA.

Table 2: Summary of RCT tested interventions that used education, exercise, and self-management strategies for osteoarthritis

Author, year of publication	Title of article	Aim	Outcome measures	Methods	Interventions	Results
Maurer, B.T., Stern, A.G., Kinossian, B., Cook, K.D., and Schumacher, H.R.J. (1999)	Osteoarthritis of the Knee: Isokinetic Quadriceps Exercise Versus an Educational Intervention	To evaluate the effects of a patient education Programme versus isokinetic exercise on pain and function in older participants with knee osteoarthritis	Adapted Baltimore Hip replacement study questionnaire Arthritis Impact Scale version 2 (AIMS2) Western Ontario McMaster's Arthritis Index (WOMAC) Short Form 36 of the Medical Outcome Study (SF-36 MOS) Walking (50 feet) Stair climbing ROM of knee-goniometer Muscle strength of knee extensors-dynamometer	A randomised, comparative clinical trial that conducted an 8-week intervention and had follow-up evaluation at 12 weeks. A total of 113 male and female participants were randomly allocated to complete an 8-week isokinetic knee exercise Programme or to complete an OA education and self-management Programme. Follow-up testing were done at week 0, week 8 and at week 12.	The Isokinetic exercise group did knee extensor muscle strengthening exercises (3 sets of 3 extensions at different velocities). 3 x per week for 8 weeks. A total of 27 repetitions were performed and the velocity in between the sets were adjusted. The education group had 4 classes of education about 1) the disease process of OA, 2) a video discussing joint protection and other OA self-management techniques, 3) a session on nutrition guidelines and 4) a session on coping with pain and disability.	Both exercise and education groups had significant improvements in muscle strength ($p<0.05$). In addition, there were no differences in ROM between groups, however, a decrease in ROM occurred in both groups over the treatment period. The Exercise group had significantly improved in the WOMAC-pain scores, walking and stair-climbing scores. The education group had improved WOMAC-pain and MOS scores. There was a difference between groups for “pain change” ($p=0.007$) and “stairs pain” ($p=0.02$) at week 8 in the exercise group. In conclusion, the study showed that isokinetic strengthening reduced pain in OA patients. However, it seemed that combined interventions consisting of exercise and education could provide substantial benefits to patients with early OA.

Author, year of publication	Title of article	Aim	Outcome measures	Methods	Interventions	Results
Heuts, P., de Bie, R., Drietelaar, M., Aretz, K., Hopman-Rock, M., Bastiaenen, C., Metsemakers, J., van Weel, C., & Schayck, O. (2005).	Self-management in osteoarthritis of hip or knee: a randomised clinical trial in a primary health care setting	To assess in a primary health care setting the efficacy of a self-management Programme in middle-aged patients with osteoarthritis (OA).	Pain-VAS WOMAC: stiffness and physical function scales Main outcome measures: pain severity in hips and knees, other significant complaints, and functional limitations.	A randomised controlled trial in 273 patients (63 women and 110 men) with OA of the hip and/or knee. Participants were randomly allocated to a self-management intervention group (n=132) and a usual-care control group (n-141). Testing and follow-up measurements were done at baseline, 3 months and 21 months.	The self-management (SM) group completed 6 sessions (2 hours each) that was led by physiotherapists. The SM Programmed included exercise, education and counselling. The SM group was informed how to manage their personal health, functioning, how to set goals and to reward themselves once achieved, and self-relaxation techniques for pain control. The control group received usual care from the family doctor.	The SM group had significant improvements in VAS-scores for knee pain (score 0.67; SD 2.10) and in the WOMAC (score 2.46; SD 9.49) at 3 months. The control group showed stable VAS knee pain (0.01; SD 2.00) and had deteriorated in the WOMAC (-0.53; SD 9.47). There was a difference in VAS pain of the knee between groups, favoring the SM group (VAS pain knee: p values -0.023 at 3 months to 0.004 at 21 months; WOMAC: p values from 0.030 to 0.022). The SM intervention consisting of exercise and education seemed to benefit people with OA, in terms of pain control and improved functioning.
Hurley, M., Walsh, N., Mitchell, H., Pimm, T., Patel, A., Williamson, E., Jone, R., Dieppe, P., Reeves, B. (2007).	Clinical Effectiveness of a Rehabilitation Programme Integrating Exercise, Self-Management, and Active Coping Strategies for Chronic Knee Pain: A Cluster Randomised Trial	To compare the effectiveness of a rehabilitation Programme integrating exercise, self-management, and active coping strategies (Enabling Self-	WOMAC: Self-reported functioning and pain scales Aggregate Functional Performance Time: 50 feet timed walk, get up and go test, stairs ascent and stairs descent	A single-blind, pragmatic, cluster randomised controlled trial was conducted in 418 participants with knee pain for >6 months (OA) recruited from primary care practices. Testing was done at baseline, immediately after the intervention	Primary care practices were randomised to continue with usual primary care only; or to continue with usual primary care and the rehabilitation Programme for individual participants, or usual primary care and rehabilitation for groups of 8 participants.	An improvement in functioning was seen at 6 weeks (usual care 25.9, 95% CI 23.4, 28.3; rehabilitation 20.0, 95% CI 18.3, 21.7; Individual-rehab 19.8, 95% CI 17.6, 22.0; Group-rehab 20.2, 95% CI 17.6, 22.9). Some of these improvements had been lost at 6 months, but WOMAC-function was significantly different across the 3 interventions (joint Wald's test, p=0.04).

Author, year of publication	Title of article	Aim	Outcome measures	Methods	Interventions	Results
		management and Coping with Arthritic Knee Pain through Exercise [ESCAPE knee pain]) with usual primary care in improving functioning in persons with chronic knee pain.	Exercise health beliefs and self-efficacy questionnaire Anxiety and depression (Hospital Anxiety and Depression Scale (HADS) General Health status (EQ-5D-3L) McMaster Toronto Arthritis quality of life (MACTAR) Quadriceps strength	or at recruitment to the usual primary care arm (6-week assessment), and at 6 months after intervention or 7.5 months after recruitment to the usual care arm. The effect of the intervention at the 6-week testing on functioning was used for comparison with other studies.	The format and the content used for the rehabilitation groups were the same for the Individual-rehab and Group-rehab. The rehab consisted of 12 supervised sessions (2 sessions per week for 6 weeks). There rehab had an education and an exercise component: 1) education: information about OA, pain, coping with pain and how to self-manage their health problems. 2) exercise: a progressive exercise Programme that was tailored to everyone's needs and abilities. The same physiotherapist supervised all participants in all sessions.	WOMAC-function was significantly better in the rehabilitation group compared to the usual care group (difference in WOMAC-function -3.33, 95% CI -5.88, -0.78, p=0.01; effect size 0.29, 95% CI 0.07, 0.52; ICC 0.04) Mean WOMAC-functioning scores of both rehab groups were significantly different from usual care (difference in WOMAC-function: Individual-rehab -3.53, 95% CI-6.52, -0.55, p=0.04; Group-rehab -3.16, 95% CI -6.55, -0.12, p= 0.04) but not from each other (Individual-rehab 21.5, 95% CI 19.3, 23.6; Group-rehab 21.8, 95% CI 19.6, 24.0). Providing a personalised rehabilitation Programme consisting of exercise, education, and active coping strategies (ESCAPE-knee pain) with usual primary care delivered to individuals or groups of people with knee OA had significantly improved functioning for up to 6 months after the intervention.

Author, year of publication	Title of article	Aim	Outcome measures	Methods	Interventions	Results
McKnight, P.E., Kalse, S., Going, S., Villanueva, I., Cornette, M., Faar, J., Wright, J., Streeter, C. & Zautra, A. (2010).	A Comparison of Strength Training, Self-Management, and the Combination for Early Osteoarthritis of the Knee	To assess the relative effectiveness of combining self-management and strength training for improving functional outcomes in patients with early knee OA	Leg press Functional range of motion ERGOS work simulator Get up and go Stair climbing Pain: VAS SF-36 WOMAC Arthritis severity: VAS	An unblinded randomised controlled trial was done to compare the effects of 3 interventions: strength training, self-management and a combined strength training and self-management Programme in 273 participants over a 24-month period. Participants were randomly allocated to one of three intervention groups. The participants had knee pain for less than 5 years	*Strength training intervention:* Participants engaged in 2 phases. Phase 1: 9-month intervention of stretching and balance, range of motion, flexibility, and isotonic muscle strengthening. Participants completed 3 sessions per week for 60-65 minutes that was led physical trainers. Phase 2: 15-month intervention focused on self-directed long-term exercising habits. Trainers encouraged the participants to meet every quarter for booster sessions. *Self-management intervention:* The 9-month phase 1 consisted of 12 weekly 90-minute classroom sessions facilitated by the Programme manager and local health professionals. The 2-phase self-management	All the outcome measures had a significant improvement over time, regardless of treatment intervention. There were no differences over time, nor were there pooled differences between the treatment groups. Most of the participants in all the groups had clinically relevant improvements in WOMAC disability (26% criterion) and pain (40% criterion). The results showed that strength training and self-management, produced improvements in pain, function, and physical performance in people with knee OA. Therefore, a combination of strength training and self-management may be beneficial for patients with OA. Health care providers may confidently recommend self-management and strength training for their OA patients.

Author, year of publication	Title of article	Aim	Outcome measures	Methods	Interventions	Results
					intervention targeted coping and self-efficacy skills. A well-balanced exercise Programme that included strength, flexibility, and aerobic conditioning was done. Participants received list of exercise resources to start their own exercise regimen with no instructions on exercises *Combined treatment:* The combined group participated in both the strength training and self-management courses.	
Bezalel, T., Carmeli, E., Katz-Leurer, M. (2010).	The effect of a group education Programme on pain and function through knowledge acquisition and home-based exercise among patients with knee osteoarthritis: A parallel randomised single-blind clinical trial.	To assess the effect of a group education Programme on pain and function through knowledge acquisition and a home-based exercise Programme.	WOMAC The repeated sit-to-stand test The get-up-and-go test.	A parallel randomised single-blind controlled trial in participants with knee osteoarthritis were conducted. Participants were randomly allocated to an intervention group (n=25) and a control group (n=25). Testing were done at baseline, after the intervention (4 weeks) and again 8 weeks later.	The intervention group completed an education Programme once a week for 4 weeks, followed by a self-executed home-based exercise Programme. The control group were given a short course in short-wave diathermy treatment for OA.	There was a significant improvement in both groups in all outcomes, except for the WOMAC stiffness score immediately after the intervention. The WOMAC total score was reduced by a mean of 9.5 points [95% confidence interval (CI) −12.3 to −6.7]. At 8 weeks, the intervention group had continued improvement in the get-up-and-go test and the WOMAC pain and disability scores. No further improvements were noted in control group.

Author, year of publication	Title of article	Aim	Outcome measures	Methods	Interventions	Results
						A group education and exercise Programme for patients with knee OA had improved functional abilities and reduced pain.
Coleman, S., Briffa, N., Carroll, G., Inderjeeth, C., Cook, N., McQuade, J. (2012).	A randomised controlled trial of a self-management education Programme for osteoarthritis of the knee delivered by health care professionals	To determine if a disease-specific self-management Programme for patients with osteoarthritis (OA) of the knee (the Osteoarthritis of the Knee Self-Management Programme (OAK)) led by health care professionals would achieve and maintain clinically meaningful improvements in health-related outcomes compared with a control group.	WOMAC SF-36 VAS Timed Up and Go test Quadriceps and hamstrings muscle strength test ROM of knee flexion and extension	A randomised, controlled trial with 146 participants were conducted. Participants were randomly allocated to the control group (n=75) or the intervention group-OAK (n=74). Testing was done at baseline, week 8 and at 6 months.	The OAK was a 6-week self-management Programme led by a health care professional, for 2.5-hours each week. Each session consisted of an education on OA, self-management skills (goal-setting, problem-solving, modelling, positive thinking and improving self-efficacy), medication, pain management strategies (cognitive and pharmacologic), exercise (strength, flexibility, aerobic and balance) with active demonstration and instruction of exercises in group, joint protection, nutrition and weight control, fall prevention (balance and proprioception), and coping with negative emotions.	WOMAC scores for pain and function improved significantly in the OAK group compared to the control group. In the OAK group, VAS pain decreased 30% during the 8-week intervention (mean: 5.21 (0.30) to 3.65 (0.29), $p \leq 0.001$). There were improvements in the Physical Function, Role Physical, Body Pain, Vitality and Social Function scales of the SF-36 in the OAK group compared to the control group and this was maintained at 6 months. The TUG results showed significant improvements in the OAK group compared to the control group at 8 weeks and at 6 months. The hamstrings muscle strength and ROM in knee joint showed improvements in the OAK group compared to control group at 6 months.

Author, year of publication	Title of article	Aim	Outcome measures	Methods	Interventions	Results
					In addition, patients received a booklet with all the information discussed each week. The control group was given usual care at the day hospital.	There were statistically significant improvements evident in the OAK group after engaging in a 6-week self-management education and exercise Programme in pain, quality of life and function.
Saw, M; Kruger-Jakins, T., Edries, N., Parker, R. (2016)	The effects of a six-week physiotherapist-led exercise and education intervention in patients with osteoarthritis, awaiting an arthroplasty, in South Africa: a randomised controlled trial	To explore the effects of a six-week physiotherapist-led exercise and education intervention in patients waiting for joint replacement surgery.	Brief pain inventory: pain severity and pain interference scores Physical performance task battery Health Assessment Questionnaire (HAQ) EQ-5D-3L Self-efficacy for managing chronic disease 6-item scale	A single blinded randomised controlled trial of 74 participants with hip or knee OA awaiting arthroplasty was conducted. Participants were randomly allocated to an experimental group (n=35) and a control group (n=39). Testing was done at 6 weeks, 12 weeks and six months.	The intervention group completed a six-week physiotherapist-led education and exercise Programme. The intervention consisted of education, (neuroscience education), self-management strategies and an active exercise component. The intervention session was a 2-hour session each week and participants were allocated in small groups of 12. Each session had an educational component, an exercise component of 30-minutes and a relaxation session. Important topics such as self-management strategies, goal setting, coping mechanisms, stress management,	The experimental group had significant improvements in pain severity [current effect: F(3, 216)= 8.904, p<0.01], seen at 6 weeks between groups (p<0.01, ES=0.94, 95% CI: 0.45-1.41) and at 6 months (p=0.02, ES=0.74, 95% CI: 0.26-1.2) The experimental group had significant improvements in pain interference [current effect: F(3, 216)= 6.85, p<0.01], seen at 6 weeks (p<0.01, ES=1.2, 95% CI=0.7-169) and week 12 (p=0.04, ES=0.68, 95% CI=0.2-1.14) and at 6 months (p<0.01, ES=0.98, 95% CI 0.49-1.45) The experimental group had significant improvements in self-efficacy [current effect: F(3, 216)= 4.37, p<0.01], between groups seen at 6 weeks (p=0.03, ES=0.76, 95% CI=0.28-1.22) The experimental group had significant improvements in HRQoL [current effect: F(3, 216)= 4.45, p<0.01], between groups seen at 12

Author, year of publication	Title of article	Aim	Outcome measures	Methods	Interventions	Results
					pacing, nutrition, medication was discussed. Each participant received a "Living with Osteoarthritis" booklet with content of each session and had tasks for each participant to complete. Participants had to record weekly goals that they would like to achieve. The exercise component consisted of stretching, aerobic exercise and different lower limb strengthening exercises. The control group continued to receive usual care.	weeks (p=0.03, ES=0.71, 95% CI=0.24-1.18). No significant differences were seen in the Disability index, HAQ pain VAS or in the Physical performance task battery between groups. The experimental group had significant long-term improvements in pain severity and pain interference when compared to the control group. Therefore, this six-week physiotherapist-led exercise and education Programme was a successful intervention for patients with hip and knee OA, awaiting a joint replacement.

In Table 2, a total of seven RCT studies are highlighted. The studies compared individual interventions to each other (exercise or education)[147], or individual versus combination[148], or combined exercise and education strategies with either usual care alone[42, 149-151], or in addition to usual care[43]. The duration of the interventions ranged from four weeks to 24-months, with five of the studies conducting the intervention over a six-week period. Regarding the samples, most of the studies (n=5) recruited males and females from the ages of 40 years[147 42 43 149] and two studies recruited adults older than 18 years[150 151], and 35 years [148] respectively.

The most utilised outcome measures were the Western Ontario McMaster's Arthritis Index (WOMAC) which was used to assess pain, stiffness, and function; the Visual analogue scale (VAS) for pain; the Short Form 36 (SF-36) for general quality of life; and the EuroQol (EQ-5D-3L) for general health-related quality of life. In the South African study by Saw et al. (2016)[151], the Brief Pain Inventory (BPI) was used to assess pain severity and pain interference with function. The Health assessment questionnaire (HAQ) was used to assess pain and functional ability, instead of the WOMAC. Saw and colleagues justified selecting these tools and not those mentioned above because both tools had been translated and validated in the South African context[151]. Apart from these self-reported outcome measures, common functional performance outcome measures such as walking, stair climbing, up-and-go test, and sit-to-stand were utilised in the RCTs reviewed[151 150 149 148 43 147]. Muscle strength of the quadriceps and hamstring muscles[150 147 152], and range of motion of the knee joint [150 147] were also used in some studies. Only two studies reported the use of self-efficacy tools to evaluate the self-management component of the interventions[43 151]. These were the Exercise health beliefs and self-efficacy questionnaire and the Self-efficacy for managing chronic disease 6-item scale.

A range of different types of exercises was used in the studies, including strengthening, stretching and balance, flexibility and range of motion, isotonic and aerobic exercises. These exercises targeted the lower limb anatomical structures (muscles and joints). The exercise Programmes ranged from 20 to 60 minutes per session across the studies. The exercises were executed once a week for four of the studies,[42, 149, 150 153], twice weekly for one study [43], and three times per week for two studies [147 148].

All the studies used an education component which included various topics such as the disease processes of osteoarthritis (OA), chronic pain mechanisms and coping with pain and disability.

Furthermore, self-management techniques (goal setting, problem-solving, self-efficacy, how to manage personal health and diseases, self-relaxation), joint protection, nutrition and advice on weight loss, stress management and medication for OA. However, only two studies[150 151], provided participants with work booklets containing this information for the participants.

The shortest intervention for the combined intervention was 4-weeks[149]. Despite such a short time, this study found significant improvements in the WOMAC overall, and in the pain and function sub-scores, as well as in the get-up-and-go test immediately post-intervention. However, McKnight (2010)[148], had the longest study intervention of 24-months (phase I=9 months and phase II=15 months) and found significant changes over time in all of the outcomes. The Osteoarthritis of the knee self-management Programme (OAK) study by Coleman (2012)[150], ran for six weeks. Participants in the intervention had improvements at 8-weeks which lasted until 6-months in WOMAC scores for pain and function, VAS-pain, TUG and in the SF-36 general quality of life instrument, particularly in the physical function, role limitations, bodily pain, vitality and emotional well-being and social function domains[150].

Lastly, Saw et al (2016)[151] had reported on the effects of a 6-week intervention with a follow-up for 6 months. They reported similar results to those of Coleman (2012) with significant improvements in pain, specifically pain severity and pain interference with function on the BPI which were maintained at 6 months. The significant results of their combined exercise and education intervention suggest that this type of intervention may be more effective than pharmacological treatment for pain in people with OA waiting for arthroplasty[123].

The consistency of these findings on the effectiveness of combined exercise and education interventions is remarkable. Although the seven studies had apparent differences in the duration of the intervention (4-weeks to 24-months), types of exercises, educational content delivered, provision of work booklets and the dosage of intervention (once a week vs three times a week), the results support the use of combination interventions for treating people with OA. The interventions appear to be effective when they include exercise, self-management education targeting pain and function, and other related outcomes for adults with OA. These interventions appear to have both short-and-long-term benefits lasting several months in patients with OA.

Similar management strategies, including chronic disease self-management principles, have also been shown to be effective to help change unhealthy behaviours in individuals suffering from chronic diseases of lifestyle[154].

A randomised controlled trial of a 7-week, small-group chronic disease self-management Programme in a "real world" setting based on the principles of self-management and self-efficacy, similar to the above-mentioned studies in OA, reported statistically significant and clinically meaningful improvements in self-efficacy, health behaviours, and health status in participants[154]. These results were sustained at 1 year[154]. Therefore, chronic disease management Programmes with a focus on self-management appear to be appropriate interventions to improve health behaviours and health outcomes in people with CDL. However, few studies have been conducted in South Africa using this management approach in individuals with chronic diseases of lifestyle.

The only South African study found in the literature review explored the effects of a community-based health and wellness club in Khayelitsha, Cape Town[155]. This club was led by residential Community Health Workers (CHW), who were trained to educate affected individuals on methods to reduce hypertension amongst adults. This study found that the health club was a sustainable and culturally appropriate intervention to facilitate positive health behaviours and lifestyle changes when facilitated by CHW for local people[155]. However, it is not clear whether this Programme included any educational components based on the principles of self-management and self-efficacy or whether the education was didactic. Without this information, further research is indicated to explore the effect of self-management education in combination with chronic disease management strategies in people suffering from CDL in South African populations.

Effective health care for CDL requires that patients are empowered to become actively involved in taking care of their own health in order to be compliant with the medical treatment of their long term diseases[3]. Therefore, patient-centred management approaches are needed for resource-scarce primary health care centres in the public sector of South Africa[3]. In response to this need, WHO (2009)[156] endorsed the Intervention of Diet and Physical activity report which recommended that interventions for chronic diseases should be implemented at the primary health care level. This report highlighted that the demand for health services should be reduced through the delivery of interventions aimed at maintaining the health and functional capacity of middle to older populations.

In addition, the literature reviewed highlighted a need to develop and implement patient-centred management strategies for South African individuals with chronic diseases such as OA and CDL (hypertension and diabetes mellitus type 2). The dearth of high-quality experimental studies investigating the effects of non-pharmacological interventions for OA and CDL in women in a South African context highlights the need for further work in this area.

In summary, the prevalence of OA and CDL in middle-aged women places a high burden on primary health care institutions in South Africa. With the steady rise in aged populations globally, this burden will likely be increased with a rising prevalence of OA and CDL[1]. Thus, the rising burden of OA and CDL will probably impose new challenges on the current health systems. Effective evidence-based management strategies for women with both OA and CDL are needed to reduce this burden on both the individual and on society. To be effective and sustainable, these management strategies should be sufficiently adapted to the cultural context and involve community members[156].

3 CHAPTER 3: INSTRUMENTATION – THE USE, SELECTION, TRANSLATION AND VALIDATION OF INSTRUMENTS

3.1 Introduction

One reason of many reasons, for conducting clinical research in health sciences is to determine the outcome of health care or services for individuals. Clinicians and researchers are recommended to select and use appropriate instruments that are valid and reliable to effectively measure outcomes. This form of research, better known as "outcomes research", usually provides the scientific evidence to be able to make informed decisions for change and policymaking in health care. According to Clancy (1998, p.245), outcomes research is defined as the *"study of the end results of health services that takes patient's experiences, preferences and values into account"*[157]. Thus, the purpose of outcomes research is to be able to accurately measure outcomes experienced and valued by patients[158].

In this chapter, a description of the outcome measures selected for the two main studies related to this thesis will be done. The information is presented in three sections: 1) the selection of appropriate instruments for research in osteoarthritis (OA); 2) the translation of selected instruments for this study; and 3) the validation and feasibility of the translated instruments.

3.2 Outcome measures in osteoarthritis research

Various outcome measures have been used for musculoskeletal and osteoarthritis research. Due to the complexity of these chronic musculoskeletal conditions, different self-report measures, in the form of generic or condition-specific instruments were developed. Generic measures usually identify the health condition in a holistic manner whereas the condition-specific measures are tailored for specific anatomical sites of the body or specific pathologies (i.e. knee osteoarthritis). Generic measurements are used to evaluate the health and wellbeing of an individual and include numerous domains such as social, physical function, emotional and cognitive concepts and, might not always provide comprehensive information specific to one component, such as physical function. For this reason, some researchers prefer to use condition-specific outcome measures that focus on one component[159].

Physiotherapists and other health professionals frequently uses patient self-report outcome measures (PROMs) as these measures provide patient-centred information about the impact of health conditions on their life[160]. The use of PROMs in measuring the health status of patients may assist clinicians, managers and even policymakers in better decision-making about quality assessment and treatment of health conditions[161].

Other advantages in using PROMs in research is that they are easy to use, inexpensive, evaluate a variety of functional tasks and determine the patient's opinion of any changes[162]. However, possible changes in function may be inaccurate or invalid due to other factors such as low education levels, impaired cognition, memory and pain severity[163] [162] [164]. Another limitation of using PROMs is recall bias. Depending on the period of recall (last 24 hours, last seven days, last month etc.), patients may be subjected to forgetfulness and biases that could undermine the validity of the information captured which could lead to measurement error and problems with assessing treatment effectiveness in clinical trials. Ultimately, the inherent risk of recall bias will increase as the recall period increases. In other words, it is preferable to have a shorter recall period that is closer to the period of the actual event or experience to help minimise the risk of bias [165].

Physical performance outcome measures (PPOMs) are specific physical tests or tasks that are performed by the patient which serve as a baseline measurement and a marker to evaluate change in performance tasks with follow-up testing[162]. The difference between physical performance outcome measures and PROMs, is that PPOMs assess the skills and capabilities of patients objectively, and PROMs assess the patient's opinion about their health status[164]. Therefore, researchers are encouraged to use physical performance outcome measures in addition to PROMs to provide a comprehensive assessment.

There are several standardised measurement instruments that are valid and reliable for use in research about chronic musculoskeletal disorders, such as OA. The selection of appropriate and valid measurement instruments for research, specifically in the health and rehabilitation sciences, is vitally important to determine significant results in outcome studies which have the potential to affect the lives of people suffering from health conditions[166]. Furthermore, selecting the most appropriate measurement instrument for clinical or outcome studies, depends on issues other than reliability and validity of instruments. Consideration about how the selected measurement instrument compliments the understanding of what the researcher expects to change; to what extent the outcome will possibly change; to what period of time is needed for this change to occur and the best way to identify the change in outcome, is needed[166]. A set of guidelines have been established to assist researchers on how to select the best measurement instruments to ensure future studies are optimally developed to obtain valuable results from interventions to advance the lives of affected people.

According to Coster (2013)[166], the following guidelines can be used by researchers to select appropriate outcome measures:

- An evaluation of the psychometric properties (whether an instrument is valid and reliable) of a specific measurement instrument that is appropriate for the outcomes of the study should be done.
- Researchers should consider that different instruments can describe different features such as function or participation and may have potential item bias as the instrument may not be valid across cultures.
- The researcher should ensure there is a "good match" between the selected measurement instrument and the overall aim of the researcher to determine change in outcomes to obtain good and valid results of outcomes.

The following section will highlight and describe the selected outcome measures that were used for the studies in this thesis. The ICF was used as a framework to identify and describe appropriate outcome measures for research in OA. Various standardised outcome measures will be described according to the following ICF components: Functioning and Disability (body functions and structures; activity and participation) and Contextual Factors (environmental and personal factors)[28] as discussed in Chapter 1.

3.2.1 Outcome measures according to the ICF component of Functioning and Disability

3.2.1.1 Body functions and structures - Health condition and impairments

Prevalence of Osteoarthritis – COPCORD (PROM)

The Community Oriented Programme for Control of Rheumatic Diseases (COPCORD) is a tool designed to gather information in developing countries about musculoskeletal disorders (MSD) such as osteoarthritis[167]. COPCORD was a joint initiative by the International League of Associations for Rheumatology (ILAR) and WHO and was launched in the early 1980's[168]. Since its launch, the tool has undergone several improvements to facilitate standardisation of diagnosis in population-based studies, improving estimates of prevalence of rheumatological conditions[167]. The COPCORD consists of different stages whereby population data is gathered in three phases. Phase 1 uses a population-based survey (house to house survey) that identifies cases with current or past pain or both, tenderness, swelling or stiffness in bones, muscles and joints, or all three[167 169].

In Phase 1, sociodemographic and medical history are collected. In Phase II, information pertaining to current pain and the impact of disability is gathered[167]. There are four main sections in this phase namely: (a) joint pain, soft tissue pain, swelling and stiffness, (b) impact of functional ability, (c) difficulty performing specific tasks, and (d) treatment. Phase III is an in-depth medical evaluation by a doctor or rheumatologist. This phase aims to gather specific health and functional information. In addition, further laboratory and radiological investigations are conducted to confirm medical diagnosis[167].

Many researchers have adapted the original COPCORD questionnaire and translated it for cultural and contextual relevance. Furthermore, various studies have investigated the validity of these translated COPCORD questionnaires. The COPCORD questionnaire was evaluated thoroughly, in terms of validity, sensitivity and specificity, in Latin American populations in different countries (Brazil, Chile, Mexico, Venezuela and Argentina). These studies reported that the translated COPCORD questionnaires (in the respective native languages) exhibited good sensitivity and specificity and were valid in the detection of rheumatic diseases such as OA in South American participants[170-172]. There are some similarities between Latin American countries and South Africa. Most of these countries, excluding Chile, are categorised as upper middle-income countries[173].

Most of the population living in South Africa and other upper middle-income countries are dependent on the state's public health care systems for free or affordable health care[174-176]. Therefore, the COPCORD questionnaire could be an appropriate outcome measure to use in South Africa as the profiles of these upper middle-income countries are so similar.

The COPCORD questionnaire has been used reliably before in South African studies. These studies aimed to determine the prevalence of joint pain in people at primary health care centres in Cape Town[27] and in Bloemfontein[177]. This outcome measure was found to be valid and reliable in these local settings and in the international studies reported.

It is for this reason, that the COPCORD questionnaire (Phases I and II) was selected to determine the prevalence of osteoarthritis in this study. However, to ensure cultural compatibility and acceptability for the population in Cape Town, additional questions were added. The process of adaptation and validity of the COPCORD questionnaire will be described later in this chapter.

Pain assessment - Brief pain inventory (PROM)

The use of standardised, reliable and valid outcome measures to assess pain is important for clinical research studies and to measure the effectiveness of pain management strategies[178]. The assessment of acute pain may consist of pain intensity at rest, pain on movement (dynamic pain), location of pain and other aspects of pain, which are important to evaluate the effects of treatment of the health condition[178]. Chronic pain assessment requires multidimensional outcome measures and health-related quality of life tools for more holistic and reliable assessment. There are numerous multidimensional outcome measures designed for different conditions, including OA. Some of these tools include the McGill Pain Questionnaire[179] and the Short-form McGill Pain Questionnaire[180], the Chronic Pain Grade Scale[181], the Short-form 36 Bodily pain scale (SF-36 BPS)[182] and the Brief Pain Inventory[183]. For this study, all the above-mentioned outcomes were considered, however, the Brief Pain Inventory was selected and will be discussed next.

The Brief Pain Inventory (BPI) is one of the most used outcome measures in the assessment of pain and its impact on function. The pre-cursor to the BPI was the Wisconsin Brief Pain Questionnaire (WBPQ)[184]. These outcome measures were endorsed by The Pain Research Group at the University of Wisconsin Medical School-Madison, spearheaded by Dr Cleeland, and were originally developed to measure pain in patients with cancer. The BPI short form consists of 11 questions in total, with four pain severity item descriptors “worst”, “least”, “average” and “present” pain. This form retains the body diagram to indicate the location of the worst pain. For scoring, the four pain severity scores ranging from 0 – 10 are averaged to generate a Pain Severity Score (PSS). The remaining seven questions assess the participant’s pain interference with general activity, mood, walking ability, normal work, relations with other people, sleeps and enjoyment of life. The seven pain interference scores are averaged to generate a Pain Interference score (PIS)[183 184].

To detect a minimal clinically important difference in scores, at least 2 points (on a scale from 0-10) should be evident between pre- and-post measurement scores[185]. The BPI short form is commonly referred to as the BPI and is currently used in both clinical and research settings[184].

In terms of test-retest reliability, the BPI was examined in patients with osteoarthritis. Mendoza (2006)[186] found a high correlation ranging from 0.83 to 0.88 between consecutive daily administration of the pain severity items for a week. Furthermore, high correlations ranging from 0.83 to 0.93 were reported for pain interference items. The high correlation indicates good test-retest reliability of the BPI. Kapstad (2010)[187] assessed the psychometric properties of the BPI among patients with osteoarthritis undergoing total hip replacement surgery. The BPI, WOMAC and SF-36 were used in 250 patients at baseline and at 1-year post-surgical intervention. In the assessment of pain severity and interference, the BPI had satisfactory reliability for internal consistency (Cronbach's coefficient alphas >0.80).

In terms of construct validity, correlation coefficients between BPI, WOMAC and SF-36 scores were assessed with high correlations between the pain scales of all three outcomes. The physical function scale on the WOMAC was highly correlated to the pain severity index of the BPI (r=0.57). Moderate to high correlations were found between the bodily pain and physical functioning scales of the SF-36. Thus, higher correlations (r>0.4) between subscales assessing similar constructs in the WOMAC and SF-36 support the construct validity of the BPI[187].

The BPI is available in Afrikaans[188] and isiXhosa[189] and has been validated in several South African populations[44 190 151 191]. The BPI-Xhosa have good internal reliability and good concurrent validity for pain severity (Cronbach alphas: 0.77) and for pain interference (Cronbach alphas: 0.83) in amaXhosa women with HIV/AIDS[44 189]. Therefore, the BPI-Xhosa version was a valid outcome measure for pain severity and interference in this population[189]. Furthermore, the translated BPI was successfully used to determine baseline measurements to monitor effectiveness of pain treatment strategies in intervention studies related to chronic musculoskeletal conditions in Bloemfontein[190], patients with end-stage OA on a waiting list for joint replacement surgery in the Western Cape and in Gauteng[151] and related to HIV/AIDS in the Western Cape[191]. In summary, the BPI was selected for this study as it is reliable, valid, and culturally responsive in the South African context.

Measuring obesity - Body mass index

According to the WHO global estimates of obesity in 2014, more than 1.9 billion adults were overweight and 600 million of these adults were obese. Furthermore, the global prevalence of obesity had doubled in number between 1980 and 2014[192]. These statistics reflect the high burden of obesity in the world.

Body mass index (BMI) has been endorsed by the WHO (2000) [193] as the population-level outcome measure for the assessment of overweight and obesity. BMI is an index for adults which classify weight-for-height according to the categories of underweight, normal, overweight, and obese. It is calculated by using the weight of a person (kilograms) divided by the square of height in metres (kg/m^2)[193].

WHO (2000) classifies the BMI categories as: underweight (BMI of <18.5), normal weight (BMI of 18.5 to 24.99), overweight (BMI of 25 to 30), and obese (BMI of 30 and more). Obesity is further categorised into grades or classes with grade 1 obesity (BMI of 30 to <35 [34.99]), grade 2 obesity (BMI of 35 to 39.99) and grade 3 obesity with BMI of ≥40[193].

The BMI classification of overweight and obesity is useful to recognise populations at risk of morbidity and mortality for planning and implementing appropriate interventions for groups; for comparisons of weight status across different populations and for evaluating interventions[193 194]. Thus, the weight and height of participants in this study was measured and the BMI was used as an outcome measure.

Evaluation of Blood pressure and Blood glucose

According to the WHO-SAGE population survey, a high prevalence of 43% of hypertension was found in South African adults with 33% using hypertensive medication and 18% had controlled hypertension (BP < 140/90 mmHg). In addition to this, increased waist-to-hip ratio (>0.5) and diabetes mellitus type 2 were associated risk factors for hypertension[195]. Veronese (2018)[196] found that knee OA was associated with hypertension as people with knee OA had a higher risk of developing hypertension compared to people without the condition[196]. Another study found associations between OA and diabetes mellitus type 2(DM2) as well as there was a higher OA prevalence in people with DM2 compared to people without DM2[197].

It is possible that the commonly shared risk factors such as obesity and age could contribute to the co-existence of chronic diseases of lifestyle (hypertension and diabetes mellitus type 2) and OA[197 105 103].

It is important to include monitoring systems for blood pressure and blood glucose levels in people with OA to prescribe appropriate and comprehensive interventions to combat the cumulative impact of these chronic diseases on the affected individual[196] [197].

Blood pressure measurement

It is for this reason that blood pressure and blood glucose levels were included as outcomes for this study. Blood pressure was measured using the Rossmax upper arm automatic digital blood pressure monitor (model-CF155F) to confirm the diagnosis of hypertension and to record the blood pressure values for monitoring possible improvements. This blood pressure digital monitor passed all the requirements set by the European Society of Hypertension and was found to be clinically accurate [198]. Furthermore, this digital monitor complies with the standard requirements of the Association for the Advancement of Medical Instrumentation (AAMI)[199] and is a valid tool to use for blood pressure monitoring. Hypertension is defined as having a systolic blood pressure of 140 mmHg or higher and/or a diastolic pressure of 90 mmHg or higher[200].

Blood glucose measurement

Blood glucose levels were measured with the Accu-Chek Active (Model GU) glucometer. A random sample of fasting blood was obtained through skin puncture using the Accu-Chek Safe-T-Pro lancing devices by the health professional at the clinic. The Accu-Chek Active glucometer has been assessed and fulfilled the accuracy requirements and standards of DIN EN ISO 15 197[201] and is a valid tool to use for blood glucose monitoring. According to Wild et al., (2005), WHO defines diabetes mellitus type 2 as having a venous blood glucose concentration of >11,1 mmol/l[202].

3.2.1.2 Activity limitations and Participation restrictions

Assessing physical function and disability - WHODAS (PROM)

The World Health Organisation (WHO) has developed a tool for measuring disability - an important aspect in measuring the burden of disease[203] [204]. The World Health Organisation Disability Assessment Schedule 2.0 (WHODAS 2) is the second version of the WHODAS developed as a standardised cross-cultural measurement tool to assess health, functioning and disability. The conceptual framework for this measuring instrument is based on the International Classification of Functioning, Disability and Health (ICF) and describes the individual's functioning in six major life domains[203] [204]. The domains explored in the WHODAS 2 questionnaire include: cognition, mobility, self-care, getting along with people, life activities and participation in the community.

During the administration of the WHODAS 2 questionnaire, participants are asked a number of questions to indicate how much difficulty they experience in performing a functional activity or a task in the last 30 days, with the use of an assistive device, according to the following scale: “None”, “Mild”, “Moderate”, “Severe” and “Extreme or cannot do”[204]. The WHODAS 2 12-item questionnaire uses a simple scoring protocol whereby a score is assigned to each item: “none” (0), “mild” (1) “moderate” (2), “severe” (3) and “extreme” (4) and the scores are added to obtain a summary score. This score is used to provide a description of the degree of functional limitations[205] [204].

The WHODAS 2 was developed through reviewing existing measurement instruments of functioning and disability. Field testing was done across different countries to assess the health status in different cultures and to obtain feedback on how well the participants understood the questions and the reliability of the instrument[203]. The WHODAS 2 performed well in different cultures in people with various physical and mental health problems.

The instrument was found to be meaningful and relevant, and the interview time for the 12-item version was five minutes and for the 36-item version was 20 minutes. In reference to the recall times, the participants reported that the 30-day time frame was more appropriate to recall disability than other time frames offered[203].

Three versions were developed for the WHODAS 2 namely: a 36-item, 12-item, and a 12+24 item version. All versions consist of the six domains highlighted above with a recall period of 30 days. Users can generate an overall functioning score by calculating the scores for the six domains. The 36-item version can be self-administered or interviewer or proxy- administered and can be completed within 20 minutes. The 12-item version is a shorter version of the WHODAS 2 and is useful for health-outcome studies which have time constraints for longer questionnaires. The 12-item questionnaire can be self-administered, interview or proxy-administered and can be completed within five minutes. The 12+24-item version is a combination of the 12 and 36-item versions. The first 12 items are used for screening of problems with functioning across the six domains. Following positive responses to these 12 items, an additional 24 questions are given to the respondents to capture all 36 items, avoiding negative responses. This version takes approximately 20 minutes to complete[203].

In terms of internal consistency of items, the correlation between items for the WHODAS 2 36-item questionnaire is very good (0.96).

For test-retest reliability, the correlations ranged from 0.69 to 0.89 for items, 0.93 to 0.96 for domains and 0.98 in overall, indicating that the instrument showed good reliability in repeated applications[203]. Furthermore, concurrent validity of WHODAS 2 was tested by comparing the results to the WHO Quality of life measure[206], the London Handicap scale (LHS)[207], the Functional Independent Measure (FIM)[208] and the Short Form Health Survey (SF)[209 210]. The results showed the highest correlation of 0.78 between WHODAS 2 and FIM mobility domains. In addition, correlations between 0.45 and 0.65 indicate that the WHODAS 2 and other instruments have similar constructs. Overall, the WHODAS 2 was highly correlated to the LHS (0.75), WHOQOL (0.68) and the FIM (0.68). The results showed that the domains of the WHODAS 2 correlate highly with the scores of the FIM motor scale (0.67) and the SF-36 physical component (0.66). These correlations reflect that the WHODAS 2 is a valid measuring instrument for day-to-day functioning across activity domains[203].

Scant research was available on the use of the WHODAS 2 in people with OA internationally and during the time of this study, no South African studies were conducted using this tool. However, Kutlay, Küçükdeveci, Elhan, Oztuna, Koç & Tennant (2011)[211] investigated the reliability and validity of the WHODAS 2 in patients with osteoarthritis in Turkey using Rasch analysis. This study assessed 225 patients with a mean age of 58 years (SD=11) and with the majority being female (81%).

In terms of reliability, the six domains of the WHODAS 2 were analysed using the Cronbach's alpha, intra-class correlation coefficient (ICC) and test-retest by ICC and found values of 0.71 and 0.94, 0.71 and 0.94, 0.89 and 0.97 for the six domains, respectively. The reliability for the three domains: "understanding and communicating", "getting around" and "life activities" were high in comparison to the other three domains that had adequate reliability. The reliability values for activities and participation domains of the WHODAS 2 were also high (above 0.85)[211].

In terms of construct validity, adequate moderate correlations were found when the WHODAS 2 was compared to domains of the WOMAC. The items in "life activities" and "getting around" domains showed high residual correlations, indicating that many items are simply near replications of each other and could possibly give an inaccurate result of the reliability of the tool. However, the total score for the six domains of the WHODAS 2 was reliable and valid. Thus the WHODAS 2 instrument was found to be a good and reliable measurement of health status and disability in people with osteoarthritis in Turkey[211]. Since there was no South African study available that used the WHODAS 2 reliably in OA, the findings of Kutlay (2011) were used to substantiate the use of this tool in this study.

The WHODAS has been translated into the isi-Xhosa and Afrikaans languages and been used within a large-scale community-based survey in Cape Town, South Africa[212]. Thereafter, the internal consistency and reliability, construct validity and concurrent validity of both versions were examined. The internal consistency for the total scale was high (0.95) and correlations ranged from 0.81 to 0.95 for all domains, showing a good correlation within domains. The Cronbach's alpha in the "Getting along" domain was lower in the Afrikaans version (0.78) compared to the isiXhosa version (0.82). However, the internal consistency was above 0.75 in all domains in both languages and indicates acceptable consistency[212]. Confirmatory factor analysis for both versions was used to determine the construct validity of the translated WHODAS 2 with construct validity supported in this context[212].

Concurrent validity of the translated versions of the WHODAS 2 was established by comparison with the WHOQOL and EQ-5D-3L index. The correlations between the three instruments were highly significant, showing a high correlation between functioning and quality of life (Qol). These results suggest that the WHODAS 2 is a valid instrument in assessing overall health and well-being in a South African context.

In terms of responsiveness, the WHODAS 2 was found to be at least as sensitive to change compared to other functioning instruments with effect sizes ranging from 0.44 to 1.07. Thus, the WHODAS 2 has good reliability and good concurrent validity compared with other instruments and can be used to assess function and disability in individuals in different countries and contexts. It can be used in the general population with different health conditions and in clinical research to determine the effectiveness of interventions to reduce the impact of disability by establishing differences between groups in interventions[203]. The WHODAS 2 show that the items included for constructs of functioning are appropriate and that the high internal consistency scores indicate that it is a reliable tool in a South African context[212]. Even though the WHODAS 2 tool was not used in a people with OA in the study highlighted above, the tool seemed to be an appropriate and reliable tool to measure function and disability in South African people and context. It is for this reason that the WHODAS 2 was selected as a suitable tool to measure function and disability in people with OA in this study.

Assessing lower limb physical function - Aggregated Locomotor Functional test (PPOM)

Performance-based outcome measures are important to use in both clinical and research practice as it provides an objective measurement for monitoring and evaluation. The Aggregated Locomotor Functioning score (ALF) is a tool used to evaluate physical function in people with knee and hip osteoarthritis. The ALF determines a final score by adding the mean timed scores in seconds of three functional tests namely; walking, climbing stairs and transferring in and out of a chair[213].

The ALF is a simple 10-minute functional test. It includes walking across a marked floor of 8 meters three times with times recorded on a hand-held stopwatch. The average time of the three distances is recorded as the mean walking time. The second test involves climbing up and down seven steps (ascending four steps of 15cm and descending three steps of 20cm) with patients instructed to climb at their own pace and to make use of the bannisters, if necessary. The test is repeated four times and the time for each repetition is recorded by stopwatch. The mean climbing time is used for the ALF score. The last test is transferring in and out of a chair. The patients are instructed to walk two meters to a chair, to sit down, stand up and immediately walk back to the starting point. The patient is timed when they approach and leave the chair and does three repetitions. The mean transfer time is recorded to use to calculate the ALF score.

The outcome score is determined by the summation of the mean timed scores in seconds from all activities (walking, stair-climbing and transferring in and out of a chair). This outcome measure has demonstrated excellent intra-rater reliability and intra-class correlation coefficient statistics ($ICC_{2,k}$ 0.99; IC 0.98-0.99). Criterion-related validity with physical function domains of WOMAC and SF-36 was good with correlation coefficients of 0.59 and 0.53 respectively[213]. The standardised response means were higher for the ALF (0.49) compared to WOMAC (0.39) and SF-36 (0.12). This outcome measure is a reliable, valid and responsive outcome measure and can be used successfully for evaluating change in physical function in patients with knee osteoarthritis[213]. In addition, all the activities in the ALF are culturally appropriate in South Africa too. It is for this reason that the ALF was selected as an outcome measure for this study.

Assessment of Health-related quality of life: EQ-5D-3L (PROM)

The EuroQol instrument was developed through a series of meetings held by the EuroQol group, over a time period from 1987 to 1990[214]. The 5-dimension EuroQol (EQ-5D-3L) instrument was thus developed in the year 1990, as a generic instrument that describes and measures the health-related quality of life in people with disease living in diverse contexts[214].

The EQ-5D-3L is a self-administered questionnaire consisting of four components: a description of the participant's current health state using the EuroQol classification; rating of own health using a thermometer with "0" indicating worst health state and "100" as best imaginable health state; valuation of health states according to the EuroQol classification and sociodemographic information such as age, gender, education, occupation, experience of illness and smoking[215].

The first component of the EQ-5D-3L instrument consists of five dimensions: 1) mobility; 2) self-care; 3) usual activities which include study, work, housework, family, or leisure; 4) pain or discomfort and lastly 5) depression or anxiety. Each dimension has been subdivided into three levels of responses (no problem, moderate problem, and extreme problem) for participants to review. This classification generates 243 potential health states and two more health states (unconscious and dead) were added to generate a total of 245 health states. Participants are usually asked to rate the EQ-5D-3L health states according to their current health condition[216 217].

The second component of the EQ-5D-3L instrument consists of the EQ-VAS, a 20 cm vertical visual analogue scale that asks participants to self-rate their health status according to a scale from 0 (worst imaginable health state) to 100 (best imaginable health state). The EQ-5D-3L is commonly used in various research studies such as health surveys, observational and clinical trials[217].

In terms of practicality, the EQ-5D-3L questionnaire is used to gather information on 1) the health status of patients; 2) to assess the severity of diseases; 3) to evaluate the effectiveness of medical interventions or processes; 4) to provide information about resources for economic studies, and 5) to determine local and international levels of population health status[216]. Furthermore, the EQ-5D-3L is commonly used for research, specifically in both clinical observational and randomised controlled trials.

Test-retest reliability for the EQ-5D-3L was established in a British population with a mean Intraclass correlation coefficient (ICC) of 0.78 for the VAS, indicating that the instrument is an acceptable and reliable tool in this population. High reliability scores were associated with better health status[218]. Another study evaluated the reliability and the stability of instrument scores in 233 patients with rheumatoid arthritis over three months and a smaller sample of 31 participants over a 2 week period [219]. The results for the retest (n=31) showed that the EQ-5D-3L performed moderately well over the 3-month period with ICC of 0.70 (CI: 0.60-0.80) for EQ-5D-3L VAS and ICC of 0.73 (CI: 0.63-0.83) for EQ-5D-3L utility. For the two-week period, the correlations for EQ-5D-3L VAS and EQ-5D-3L utility improved slightly. Thus, the EQ-5D-3L is a reliable tool for measuring changes in self-reported health status[219].

The EQ-5D-3L has been validated in the same study described above[220]. Construct validity was determined by examining correlations between EQ-5D-3L and disease-specific measures and demographics of participants. The instrument had moderate to high correlations with the Health Assessment Questionnaire (HAQ) (Spearman $r = 0.61$; $p < 0.05$) and high correlations with EQ-5D-3L utility measures (Spearman $r= 0.78$; $p <0.05$).

Similar correlations were found between the Pain-VAS of the American College of Rheumatology (ACR) disease activity core set and EQ-5D-3L Vas (r=0.63) and EQ-5D-3L utility measures (r=0.73). The results indicate that the EQ-5D-3L is a valid outcome measure of health-related quality of life as it is highly correlated with the participants' perception of their disabilities highlighted in the HAQ scores[220].

The EQ-5D-3L has been culturally adapted and translated into both IsiXhosa and Afrikaans for research in South Africa. A local study by Jelsma et al., (2004)[221] examined the reliability and validity of the isiXhosa version of the EQ-5D-3L in an urban Xhosa speaking population. Test-retest reliability was assessed and found ICC coefficients ranging from 0.39 to 0.75 across the domains between the two interviews and the ICC for the EQ-5D-3L VAS was 0.63. In addition, concurrent validity was examined by comparing the mobility domain scores with gait velocity. Thus, the EQ-5D-3L is both a reliable and valid tool for use to evaluate health-related quality of life in Xhosa speaking people[221].

The EQ-5D-3L is a well-constructed, short, and easy to administer questionnaire to assess the health-related quality of life in people both with and without disease. The fact that validated versions of the instrument are available in isiXhosa and Afrikaans and that it has been used in other South African studies related to children[222], to patients with critical illness in ICU[223], to patients with stroke[224], to patients with chronic pain in HIV[44 225] and in osteoarthritis[226] demonstrates that it is an appropriate tool to use for populations in South Africa. Therefore, the EQ-5D-3L was selected as an outcome measure for this study.

Assessing physical activity levels - The International Physical Activity Questionnaire (PROM)

The international physical activity questionnaire (IPAQ) was developed by an International Consensus Group at the World Health Organisation headquarters in Geneva in 1998. The aim of the group was to develop a self-reported instrument to measure physical activity in various populations for cross country comparisons and for physical activity surveillance[227 228]. There were two forms of the IPAQ developed through this meeting, the short and long format.

The IPAQ short form consists of seven items related to domains of physical activity. The questions are related to the number of days and time in minutes engaging in vigorous activities, moderate activities and walking during the last week. The last question is about the time spent on sitting on a weekday[227 229].

The IPAQ long form is more complicated than the short form and consists of 27 items across five activity domains that measure specific physical activity domains. The five activity domains are related to work-related physical activity; transportation; housework, house maintenance and caring for the family; recreation, sport and leisure-time physical activity; and time spent sitting. The questions related to the activity domains are about the number of days and time in minutes engaging in vigorous and moderate activities, walking and sitting[227 229].

Both the IPAQ short and long forms have specific scoring protocols as defined in the guidelines for data processing and analysis[230]. Both forms are used to calculate the total weekly physical activity levels as a continuous measure established in METs to generate a score in MET-minutes. Therefore, METs can be defined as multiples of the resting metabolic rate and a MET-minute is calculated by multiplying the MET score of an activity by the time (in minutes) performing the activity. The total scores can also be reported as a categorical measure and classified according to low, moderate, and high physical activity levels. The method used to classify participants' physical activity scores into the categories mentioned above is reported in the scoring protocol document[230].

The validity and reliability of both the short and long forms of the IPAQ have been assessed in 12 different countries[227]. There was good test-retest reliability for both the long form (Spearman's r= 0.8; CI: 0.79–0.82) and the short form (Spearman's r= 0.76; CI: 0.73–0.77). In terms of concurrent validity, there was reasonable agreement between the two IPAQ forms. The pooled coefficients for comparisons between the short and long form were 0.67 (CI: 0.64–0.70).

The criterion validity of the IPAQ data against accelerometers (CSA model 7164) was assessed on total reported physical activity for both the long and short forms. There was fair to moderate agreement between the two measures, with pooled coefficients of 0.33 (95% CI 0.26–0.39) for the long forms against the accelerometers and 0.30 (CI: 0.23–0.36) for the short forms and accelerometers[227]. The 12-country evaluation of the short and long IPAQ forms demonstrated that both outcome measures were reliable and valid instruments to use for prevalence data and population surveillance purposes[227 228]. Even though participants from South Africa participated in the 12-country evaluation of the short and long forms of IPAQ, the IPAQ is not available in South African languages, other than English. The IPAQ was selected for this study and translated into Afrikaans and isiXhosa as described later in this chapter.

3.2.1.3 Contextual factors

Assessing self-efficacy – Self-efficacy for managing chronic disease 6-item scale (PROM)

The assessment of self-efficacy of osteoarthritis and associated chronic diseases of lifestyle will be discussed next. A few self-efficacy scales have been developed based on the evaluations of Chronic disease Self-Management Courses conducted by Stanford University[231]. During the course evaluation, participants indicated that the perception of one's personal ability to affect the consequences of disease was lacking in the courses. Therefore, self-efficacy scales were developed as a measuring tool of perceived self-efficacy[231].

The Self-efficacy for Managing Chronic Disease 6-item Scale (SE-6) was developed by the Stanford Patient Education Research Centre[232]. The SE-6 scale was developed to test the efficacy of chronic disease education Programmes and is found to be less burdensome for participants to complete than the Arthritis self-efficacy scale[231]. This scale consists of six items that are common across many chronic diseases. The items are related to fatigue, physical discomfort or pain, emotional distress, symptom control, physical function and communicating with physicians. This questionnaire instructs participants to rate their confidence levels in doing activities on a scale from 0 to 10, with 0 being "not confident at all" and 10 being "totally confident". The total score is the mean of the six items with higher scores indicating higher self-efficacy[154]. The SE-6 has excellent internal consistency reliability (Cronbach alpha of 0.91)[154].

Furthermore, validation of a translated isiXhosa version has been done in South Africa[44]. Convergent validity was explored between the SE-6 Xhosa with the EQ-5D-3L VAS with a significant positive correlation between the SE-6-Xhosa scores and the EQ-5D-3L VAS (r_s = 0.32; $p < 0.05$). The tool had acceptable internal consistency (Cronbach alpha 0.74), and moderate test-retest reliability (Pearson's r = 0.68; n = 29; $p < 0.05$)[44]. This tool has also been translated into Afrikaans and appears to be a suitable tool to use in a South African context[153] [151]. Therefore, the SE-6 was selected as an appropriate tool for this study.

3.2.2 Conclusion regarding selection of instruments

Standardised outcome measures that are valid and reliable were needed to screen for OA and CDL, monitor the presence of and change in functional limitations, pain, health-related quality of life (HRQoL), physical activity levels, BMI and levels of self-efficacy. The outcome measures described here are all valid and reliable instruments. However, some outcome measures lacked cross-cultural adaptation and translation into local languages for people living in South Africa. The selected outcome measures were the EQ-5D-3L (health-related quality of life), WHODAS 2 (disability), BPI (pain) and SE-6 (Self Efficacy Scale) – all of which are available in both Afrikaans and isiXhosa languages. The COPCORD (prevalence of joint pain) and the IPAQ (levels of physical activity) were also selected, however, this required translation and validation for use in Afrikaans and isiXhosa. To inform the translation and validation of these instruments, a theoretical framework for translation will be discussed in detail in the following section.

3.3 Theoretical framework of translation strategies

3.3.1 Introduction

The selection and validation of appropriate outcome measures is an essential prerequisite for successful quantitative research. Standardised instruments are more commonly selected and used for research as they provide comparable results from other international and national studies and give the confidence that they accurately measure what they are supposed to measure[233]. However, a valid and reliable instrument in one country and context does not necessarily indicate that it would be valid in another country, culture or context[234 235]. Thus, researchers should be encouraged to translate instruments to use in different contexts and cultures. However, it is not acceptable to just translate an instrument in a different language and context to obtain linguistic equivalence[234] as the translated instrument will probably not be appropriate to answer questions that are not relevant to the population's context and culture. Therefore, it is important to ensure that a translated instrument is valid, reliable and adapted to the research context and culture of the population to be investigated[235]

Cross-cultural adaptation of an instrument is a process whereby an instrument is culturally adapted and translated for use in a different cultural context, language and time[234 236 235 237 238].

3.3.1.1 Theories of cross-cultural adaptation

To fully understand the importance of developing cross-cultural instruments, some theories underpinning cross cultural adaptation should be highlighted. There are two common theories relating to cross-cultural research. According to Herdman (1998)[234], the absolutist theory supposes that concepts and constructs do not change in different cultures or contexts. It is acceptable for translated instruments to be linguistically equivalent, assuming that a translated instrument conveys the same message that the original instrument conveys, for use in a different culture and context. Even though this approach to translation of instruments seems to be easier and more cost effective for researchers, it only considers linguistic equivalence in translation and ignores the cultural component thus undermining the cultural validity and accuracy of results from different cultures.

The second theory refers to the universalist approach which is different to the latter as it considers concepts that are universal across cultures. Thus, translated instruments should reflect the impact that a culture has on a language by keeping the cultural aspects of the original instrument in the translated instrument.

By doing this, the translated instrument facilitates a cross-cultural understanding of the topic at hand. This approach seems to be more difficult to employ in research as the development and translation of the instrument should be informed by cultural norms, values, and information of the different contexts. Thus a model of equivalence is useful for cross-cultural adaptation and translation of instruments[234].

3.3.1.2 Cultural equivalence for translating and adapting instruments

In cross-cultural research, the translation of instruments is usually not adequate to obtain cultural equivalence as the instrument does not capture the perceptions of the culture of interest[239]. Therefore, it is pertinent to obtain cultural equivalence in a translated instrument to use in research. To understand the cross-cultural adaptation process better, descriptions of types of equivalence are highlighted below.

According to Herdman (1998)[234], a model of equivalence linked to the universalist approach was developed to describe the cross-cultural adaptation and translation of health-related quality of life (HRQoL) instruments. This model has six types of equivalence namely: conceptual, item, semantic, operational, measurement and functional equivalence. Brief descriptions of the types of equivalence according to Herdman (1998) are described in Box 3 below.

Box 3: Description of types of equivalence

- **Item equivalence** is related to the validity and relevance of items when measuring a specific domain, as domains may differ across cultures. An instrument will have item equivalence when items evaluate similar parameters on the underlying characteristic being assessed, and when items are relevant and acceptable in both cultures.
- **Conceptual equivalence** of an instrument is when a domain measures the same concept found in the target culture and in other cultures as well. For the translated instrument to have conceptual equivalence, a relationship with the underlying concept in both the target culture and other cultures should exist.
- **Semantic equivalence** is about the transfer of meaning of words across languages and in achieving the same effect on participants in different languages. The level of the language used in the target culture should always be considered as the direct translation of some words may not be understood by people from a different culture due to the level of language of the original instrument.
- **Operational equivalence** is the use of the original version of the instrument's design, format, instructions about questions, mode of administration and methods of measurement in the translated version. Operational equivalence can be attained when the above-mentioned elements do not affect the results of the study. However, some measurement methods (Likert scales, VAS, yes/ no questions) might not always be appropriate for some cultures, the feasibility and relevance of different methods should be assessed. Time or recall of events (questions about the past week or past seven days) is another component to consider as some cultures do not have similar concepts of time.
- **Measurement equivalence** is the extent to which the psychometric properties (reliability, responsiveness, construct validity) of the translated versions are the same as the original version of the instrument. For measurement equivalence to be achieved, the translated versions should have acceptable levels of reliability, validity and responsiveness as the original instrument.
- **Functional equivalence** is when an instrument does what it is supposed to do in several cultures. To achieve functional equivalence, it is important to highlight how the underlying characteristic of the instrument is being defined in the target culture, how well the instrument reflects the underlying characteristic and how the results obtained from the instrument are compared across cultures. This type of equivalence highlights that all types of equivalence discussed previously are important to achieve cross-culturally equivalent instruments.

Herdman (1998)[234] formulated a model of equivalence to ensure cross-cultural adaptation and translation from a universalist perspective based on the assumption that what is important about the concept of HRQoL may be different across cultures and that these differences in cultures should be explored during the adaptation and translation process of instruments.

A model of six types of equivalence (conceptual, item, semantic, operational, measurement and functional equivalence) was developed for the adaptation of HRQoL instruments and provides an adequate framework for attaining cultural equivalence in translated instruments. Even though this study did not translate any HRQoL instruments, the model of equivalence linked to the universalist approach was adopted as an appropriate model to use for translating the COPCORD (prevalence of joint pain) and the IPAQ (levels of physical activity) instruments within the ICF framework. The reason for using this model is so that the COPCORD and IPAQ questionnaires may be translated into instruments that would reflect how South African culture, specifically in Cape Town, impacts on a language by keeping the cultural aspects of the original instrument in the translated instrument.

3.3.2 Process of translation

Different approaches or methods to translating instruments for cross-cultural research have been described, with the back-translation method the most highly recommended[240 241]. However, this approach can be expensive and time consuming[242 243]. Therefore, it is recommended to use multiple translation techniques in cross-cultural research[241].

Cross-cultural translation may require a few translators who are fluent in both the target language and the source (English) version of the instrument. The process should start with *forward translation* of each word (highlighting conceptual and contextual equivalence of terms) of the source (English) version of the instrument into the target language by one translator. Thereafter, a *panel of bilingual local experts* should review the completed target-language version and address any discrepancies relating to the translation. The reviewed draft translated version is then *back translated* into English with an emphasis on conceptual and cultural equivalence by a separate translator who had not been exposed to the translated or original versions of the instrument. Should any discrepancies arise through this translation, *the panel of experts* will need to review and address such issues and repeat the review process until a satisfactory version is produced. Pre-testing of the translated version of the instrument would need to be conducted on a sample of the target-culture population followed by *cognitive debriefing* of all participants to reflect on the meaning of words. After these steps have been completed, modifications to the translated version of the instrument are done by a *panel of experts* to produce a final version of the translated instrument[244 245 243 241 240].

The methodology used in the translation process of the COPCORD and the IPAQ instruments will be discussed later in the chapter following the next section that will highlight the adaptation and validation process for the COPCORD questionnaire.

3.4 Adaptation and content validity of COPCORD

3.4.1 Introduction

Content validity is an important process as it involves the evaluation of individual items of a questionnaire by experts[246]. The content experts should provide their opinion about whether the items or questions are appropriate and clear to understand. A quantitative method is most used for this process whereby an instruction document is forwarded to the experts via email or mail. The experts are able to complete the evaluation and return the completed evaluation within an allocated time frame[246].

The aim was to adapt and validate the Community Oriented Programme for Control of Rheumatic Diseases (COPCORD) for use in South African populations before translating the questionnaire into Afrikaans and isiXhosa.

The specific objectives were:

- To culturally adapt the COPCORD questionnaire and establish content validity through a panel of experts before translating it into the two languages.
- To identify and address the issues highlighted by the panel of experts to ensure that the questions in the COPCORD questionnaire are important, easy to understand and acceptable.

3.4.2 Methods

A panel of experts in academic positions (one from USA, two from South Africa) were recruited from Northeastern University in Boston, USA and the University of Cape Town and approached to review and validate the adapted COPCORD questionnaire. These experts were selected based on their expertise in research, and knowledge in global health, specifically related to musculoskeletal conditions and chronic diseases of lifestyle. Demographic information about the experts is presented in Table 3.

Expert 1 (MH) was a Mellon Research Scholar at UCT at the time of the validation of the COPCORD and worked at the Department of Health and Rehabilitation Sciences at UCT to assist academic staff in research development through a mentorship Programme. Expert 1 was a Fulbright Scholar in education with a speciality in global public health and developing research on benefits of exercise in childhood and adult obesity, and exercise in chronic diseases with an emphasis on HIV/AIDS.

Expert 2 (JJ) was an NRF rated scientist and was the co-ordinator of the postgraduate degree by dissertation Programme at the Division of Physiotherapy at UCT. She serves as a member of the Functioning and Disability Group of the WHO Family of International Classifications Network and the EuroQol Foundation and is an expert in Research Methodology and Biostatistics. Expert 2 has a special interest in research in global health, specifically relating to health-related quality of life and the use of the International Classification of Functioning in different contexts and health conditions.

Expert 3 (RP) was an expert clinician, educator and researcher in pain and musculoskeletal physiotherapy with a special interest in chronic pain in people living with HIV/AIDS and in other musculoskeletal conditions. As a clinician, her expertise includes working with patients in various settings (rheumatology, musculoskeletal, orthopaedic and sports) in different countries (SA, USA and UK). Expert 3 was currently serving as the Vice-President of the national chapter of the International Association for the Study of Pain, was the founding member of the health education non-profit organisation - Train Pain Academy and was the Chair of the National Physiotherapy Educators Forum of the South African Society of Physiotherapy.

Table 3: Demographic information of the panel of experts for validation of COPCORD

Expert	**Profession**	**University**	**Country**
Expert 1 (MH)	Emeritus professor in Physiotherapy	Northeastern University in Boston	USA
Expert 2 (JJ)	Professor in Physiotherapy	University of Cape Town	South Africa
Expert 3 (RP)	Associate Professor in Physiotherapy	University of Cape Town	South Africa

All the experts reviewed the adapted COPCORD individually and provided comments for the PI to consider for amendments. The additional questions, responses, comments by experts and proposed changes for COPCORD phase 1 questionnaire are displayed in Appendix F-1. The following questions, responses and comments by experts and changes were made to the COPCORD phase II questionnaire in Appendix F-2.

3.4.3 Results

The experts validated all the additional questions of the COPCORD and provided comments either to change the question or the responses to the question. Two (JJ and RP) of the three experts provided similar comments on some of the items and these comments were taken into consideration for amendment. To have reached consensus, at least two of the three experts had to agree of the item.

For COPCORD phase I, most of the comments were related to changing some questions with categorical responses to open-ended questions to obtain more accurate responses from potential participants. These changes were made specifically to the following items:

- Number of children
- Highest level of education
- Smoking
- Drinking alcohol

Comments were made to expand the description on the responses, specifically about the type of chronic diseases, to the following question:

- ***"Have you changed work due to any illness/ injury? If yes, why?"***

Comments were made to change the responses of three questions to categorical responses. The items were:

- Pension or other grants
- Time of diagnosis of chronic conditions
- Follow an exercise Programme

Other comments were related to combining two questions into one question and to change a question to include a specific time. The following questions were changed:

- ***"Did you use medication for these chronic diseases in the last 3 months and what medication did you use?" were combined into one question***
- ***"Do you use the prescribed medication?" was changed to "In the last two weeks, did you take your medicine every day as instructed by the clinic sister?***

A few comments were made for the COPCORD phase II. Comments were made to combine two questions related to treatment for pain.

- ***"Have you received any type of treatment, other than medication, for pain and If yes, please specify the type of treatment that you received at the day hospital?" was combined into one question***

The other comment was to add "how long did you have relief of pain" and to change it to an open-ended question.

- ***"Did the above treatment reduce your joint pain or stiffness?***

The last comment was about the treatment that worked the best for pain and stiffness and it was recommended to change the question to "what treatment gave you longer relief of pain and stiffness - tick all that apply?"

3.4.4 Conclusions

The adapted COPCORD (phase I and II) was validated by a panel of experts through critically reviewing the additional questions to see whether it was important, clear, and acceptable to use for screening of musculoskeletal conditions and chronic diseases of lifestyle for the epidemiological study in women attending primary health care facilities in Cape Town. There was a total of 13 comments made to the additional questions and responses that needed careful consideration and amendment. All the comments were accepted for amendment. Thus, content validation was achieved through this process of validating the adapted COPCORD questionnaire by research experts in musculoskeletal and chronic diseases familiar with the context and culture.

The content validated version of the COPCORD questionnaire was translated into isiXhosa and Afrikaans to obtain cross cultural adaptation of the instrument. The next section will provide a description of the translation process, the results of the pre-testing and cognitive debriefing of the translated questionnaires.

3.5 Translation and cognitive debriefing of the COPCORD and IPAQ questionnaires

3.5.1 Introduction

To ensure thorough cross-cultural translation of the COPCORD and IPAQ questionnaires into Afrikaans and isiXhosa languages, it was decided to use the translation process by Sartorius (1994)[244]. Multiple translation techniques including forward-translation, back-translation, review by panel of local experts, pre-testing of translated instruments with patients followed by review by panel of local experts were used to translate the two instruments.

3.5.2 Methods

The translation process described earlier in section 3.3.2 was used to translate the adapted COPCORD and IPAQ questionnaires. Two separate translation teams were recruited to assist with the translation process of both questionnaires into isiXhosa and Afrikaans. A discussion with both the translation teams took place to ensure that the translated questionnaires were culturally sensitive to local communities of low socioeconomic status and low levels of education. The translated questionnaires should contain the same format and layout of questions in the original questionnaires. The translators started the translation process with forward translation of the English questionnaires into isiXhosa or Afrikaans. Secondly, the panel of experts reviewed the translated versions and provided feedback. Thirdly, the translated versions were back translated into English by a different translator and the panel of experts repeated the review process until the translated version was completed. Field-testing of the translated versions was done, followed by cognitive debriefing and modifications to produce the final versions[244] (Figure 5).

For the translation of the COPCORD and IPAQ questionnaires into isiXhosa, the Stellenbosch University language centre was approached, and the Head of the isiXhosa division of the language centre was recruited as the editor in chief to manage the translation process. The editor in chief was briefed about the translations of the two questionnaires and recruited four translators, who were fluent in isiXhosa and English, to assist with the process.

Two translators (A+B) were involved in the forward translation of both the COPCORD and IPAQ questionnaires. Translator A was female, 35 years old with a M.A. in languages and was employed as an isiXhosa freelance translator at the Department of Health.

Translator B was female, 35 years old, had a B.A. in languages and was an isiXhosa language teacher at the Kayamandi High School in Stellenbosch. Two translators (C+D) were involved in the back translation of the questionnaires.

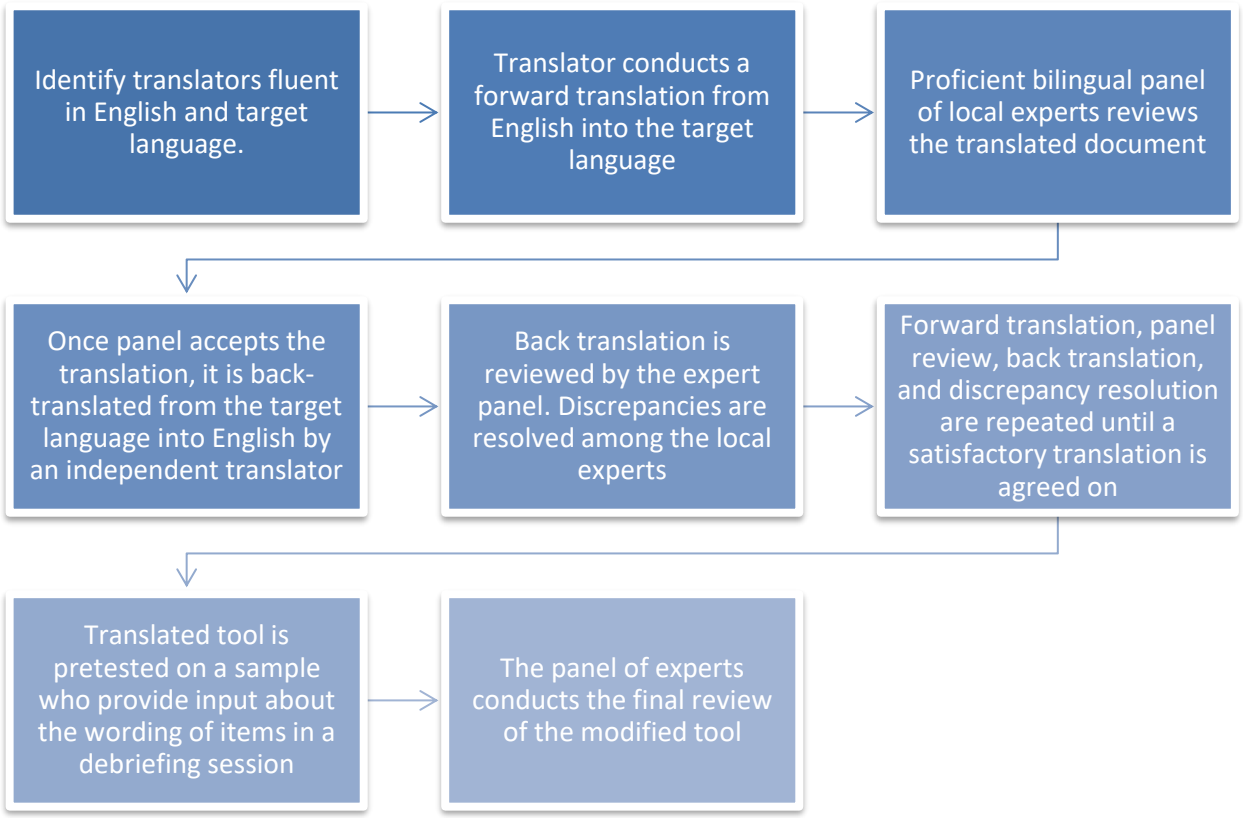


Figure 5: Translation method of instruments

Translator C was a male of 27 years of age, had an MPhil. in Languages and was an isiXhosa freelance translator at Stellenbosch University. Translator D was a female of 40 years of age, had M.A. in Languages and was an isiXhosa lecturer at Stellenbosch University.

The Department of Afrikaans and Dutch at Stellenbosch University in Cape Town was approached to assist with the translation of the adapted COPCORD and IPAQ questionnaires into Afrikaans. A lecturer in translation and Afrikaans linguistics was recruited as the editor in chief to manage the translation process. Thereafter, four translators, who were fluent in Afrikaans and English, were recruited to assist with the translation of questionnaires into Afrikaans. Translator E was female, 58 years old and was an accredited member of the South African Translator's Institute. She was a freelance translator and therefore experienced in translation of documents.

Translator F was female, 54 years old with B.Sc. and BA (Honours) degrees and works as a freelance translator. Both translators (E and F) were involved in the forward translations of the COPCORD and IPAQ questionnaires. Translator G was female, 64 years old and had a PhD in Education management. She was employed at Chartered Secretaries Southern Africa at the time of the translations. Translator H was female, 62 years old and had a BA HED and a Diploma in Methodology of Translation and Editing. She worked as a freelance language practitioner. Both translators (G and H) were recruited to assist with the back translations of the COPCORD and IPAQ questionnaires.

3.5.2.1 Forward translations of questionnaires of COPCORD and IPAQ into isiXhosa and Afrikaans

Translators A and B, and E and F were provided with the English versions of the COPCORD and IPAQ questionnaires and were briefed about the need for cross-cultural translations of both questionnaires into isiXhosa and Afrikaans, respectively. The translators independently reviewed and translated both questionnaires into isiXhosa and Afrikaans. Once the translations of the questionnaires were completed, a consensus meeting was held between the two translators and the editor in chief to discuss any issues with questions and translated items to consolidate the final forward translated versions of the two questionnaires into isiXhosa and Afrikaans.

The forward translated questionnaires (isiXhosa and Afrikaans) were submitted to the principal investigator (PI) for review and comments. Any comments made were addressed by the panel of translators to produce a synthesised forward version of the questionnaires.

3.5.2.2 Backward translations of questionnaires of COPCORD and IPAQ from isiXhosa into English

The final isiXhosa and Afrikaans version of the COPCORD and IPAQ questionnaires were submitted to Translators C and D, and G and H for review and back translation into English. The translators had not seen or worked on the source English version of the instruments before and translated both questionnaires into English independently. Once the translations were completed, the translators had a consensus meeting with the editor in chief for a final review of the back translated version of the questionnaires. The panel of translators discussed each question to ensure cultural equivalence and discussed unclear translated questions and responses.

The final back translated questionnaires (isiXhosa and Afrikaans) were submitted to the PI for review and feedback.

Any comments made by the PI were forwarded to the panel of translators and were addressed to consolidate the translated versions of the questionnaires. The panel of translators reviewed and discussed the comments and produced the final translated questionnaires for pre-testing and cognitive debriefing (Figure 6). Each phase of the translation process for both questionnaires, including the comments by the translators, were recorded, and filed. All the translated versions (forward and back) of the two questionnaires were filed.

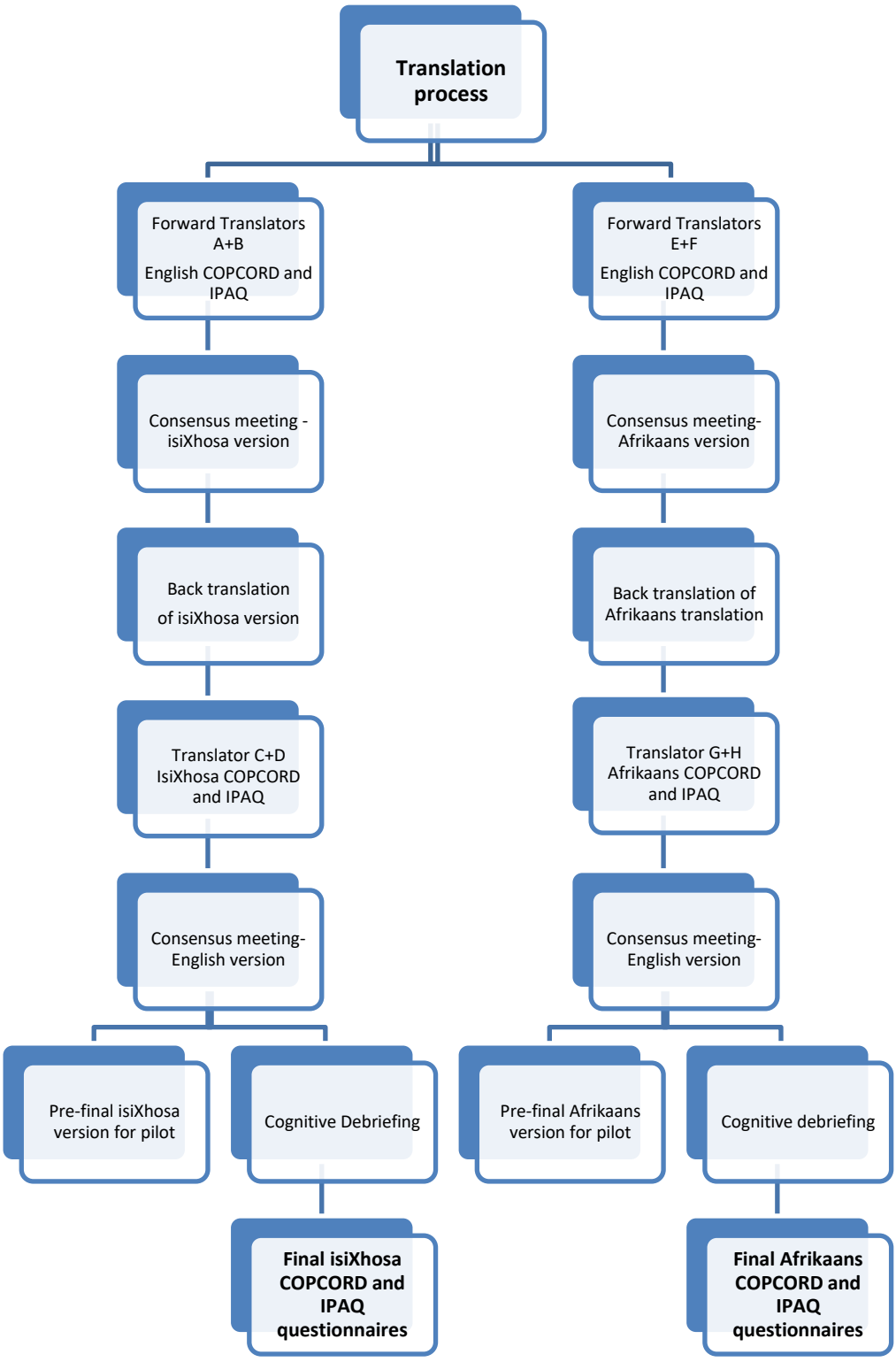


Figure 6: Translation process of COPCORD and IPAQ questionnaires

3.5.2.3 Piloting and cognitive debriefing of isiXhosa and Afrikaans versions of the COPCORD and IPAQ questionnaires

Ethical approval was obtained from the University of Cape Town, Faculty of Health Sciences Research Ethics Committee (HREC Ref 100/2014) (Appendix A-3). The pre-final isiXhosa and Afrikaans versions of the COPCORD and IPAQ questionnaires were piloted in two different samples, a sample of isiXhosa speaking and Afrikaans speaking people from each of the local communities. The questionnaires were administered by trained research assistants (final year physiotherapy students) whose first language was isiXhosa or Afrikaans.

A group of five participants reviewed and completed the isiXhosa versions of the COPCORD and IPAQ questionnaires and a group of four participants completed the Afrikaans versions of the COPCORD and IPAQ questionnaires. On completion of the questionnaires, the participants were asked to provide responses to the following questions: *(1) do you understand the questions and are the response options consistent?, (2) would you reword it in another way?, (3) if you want to reword the question, state how?, (4) what does this question mean to you or can you rephrase this in your own words? A*ll the comments were written down by the research assistants. At the end of the pilot testing, the comments made by the participants were forwarded to the PI and thereafter to the isiXhosa and Afrikaans editors in chief to finalise the translated versions of the COPCORD and IPAQ questionnaires.

3.5.3 Results

3.5.3.1 Report on the translation of the isiXhosa versions of COPCORD and IPAQ

A. COPCORD-Xhosa

The forward translated COPCORD questionnaire into isiXhosa could not be reviewed by the PI as she is not literate in isiXhosa. There were some problems identified with the direct translation of words, sentence structuring and composition when the back translated English version of the COPCORD-Xhosa questionnaire was reviewed. A few words were highlighted and discussed with the panel of translators which were amended. The specific issues relating to the back translated English version of COPCORD-Xhosa and comments provided by the PI that were considered by the panel of translators for amendment, are highlighted in Table 4.

Since the COPCORD was primarily used as a screening tool for OA, and no specific construct was being measured, direct translation from isiXhosa into English was somewhat challenging for the translators and the correct meaning of words was of greatest importance. This ensured semantic equivalence of the translated questionnaire. The panel of translators discussed the highlighted words and agreed to make the recommended changes to ensure agreement with the meaning of the word. Thereafter, amendments were made and the pre-final isiXhosa version of the COPCORD questionnaire was synthesised.

Table 4: Consensus meeting about the back translation of the COPCORD questionnaire

Source English version	Back translated version by panel	Comments by PI
Muscusloskeletal Conditions and Chronic diseases Questionnaire	Questionnaire of Conditions and Chronic Pains of Muscles	The meaning is incorrect, should rather include chronic joint pain and other chronic diseases of lifestyle
This questionnaire is about chronic joint pain, obesity, hypertension, and diabetes mellitus type II.	This questionnaire is about chronic pains of joints, extreme body weight, high blood pressure and type II of diabetes mellitus.	Consider revising… questionnaire is about chronic joint pain, obesity, high blood pressure and sugar disease (diabetes mellitus).
This questionnaire is completely anonymous. The data will be used to develop a health promotion Programme.	This questionnaire will not state your name. The data will be used to develop a procedure to promote health.	First sentence is okay. Please change "procedure" to Programme.
Do you have a diagnosed musculoskeletal problem in the joints or spine?	Were you treated for your problem of muscles in your joints or spine?	Please change...Do you have problems with your joints or muscles in your spine or body?
If yes, do you attend the rehabilitation/ exercise classes at physiotherapy?	If it is yes, are you attending the class of rehabilitation / exercise for physiotherapy?	Change to… are you attending exercise and treatment classes at physiotherapy?
Do you suffer from chronic diseases of lifestyle?	Do you perhaps have chronic illnesses of lifestyle for the manner of living?	Change to… Do you have other chronic medical illnesses?
Do you attend the chronic care club at the day hospital?	Do you go to clubs that care for chronic illnesses at day hospital?	Change to… Do you attend chronic care clubs for chronic illnesses at a day hospital?
None	Nothing else	Change to none
Cold/ flu	coldness/ flu	Change to cold or flu
acute musculoskeletal injuries (muscle pain, sprain)	accidental injury of pains for joints (pains of muscles, strains	Change to accidental injuries to muscles and joints of the body
intellectual/ cognitive impairments	intellectual/ cognitive injuries	Change to intellectual/ problems with learning
Fractures	Cracks	Change to broken bones
DEMOGRAPHIC INFORMATION	DETAILS OF POPULATION AND DIFFERENT GROUPS	Change to demographic information
Housewife	Wife that stays at home looking after the children. Teacher	Remove teacher

Source English version	Back translated version by panel	Comments by PI
Desk job	Desk work Working at a shop or business	Change “desk work” to… working at a desk/computer at a company
Moderate	In-between	Change to moderate
Musculoskeletal condition (stiff joints/ spine)	conditions of muscles (stiff joints/ spine)	Change to chronic joint pain (body/ spine)
Never used alcohol	Never used alcohol Am using alcohol currently	First one is okay. Remove am using alcohol currently and change to I am drinking alcohol now
□ High blood (Hypertension) □ Obesity (overweight)	□ High blood (Hypertension) □ Sugar (Diabetes Mellitus Type II) □ extreme body weight (overweight) □ Cholesterol (hyperlipidaemia)	All options are okay but change extreme body weight to obesity
Obesity	extreme body weight	Change to obesity
Did you use medication for these chronic diseases in the last 3 months?	Did you use medicine at these chronic illnesses in the past 3 months?	Change to…did you use medicine for these chronic illnesses in the past 3 months?
Some tablets make me feel sick, drowsy or sleepy	Other pills make me sick, sleepy or sleepy	Change to other pills make me tired, sick and sleepy
Nature of traumatic injury	Status of traumatic accident	Change status to kind
□ Fracture □ Sprain □ Paralysis □ Other	□ Fracture □ Sprain □ Shrinking □ Other	Change shrinking to disabled
Result of traumatic injury	Reasons for traumatic accident	Change reasons to what is the effect of traumatic accident
Has your doctor/ nurse ever told you to follow an exercise Programme?	Did your doctor/ nurse ever told you that you to follow the Programme of exercising the body?	Change to Did your doctor/ nurse ever told you to follow an exercise Programme?
If yes, have you followed an exercise Programme yet?	If it is yes, follow the Programme of exercising the body yet?	Change to…if yes, did you follow an exercise Programme yet?

Source English version	Back translated version by panel	Comments by PI
During the last 3 months have you experienced pain, aching, swelling, stiffness (tightness) in or around your joints or back which is not related to an injury / accident?	During the last past 3 months did you experience any pain, aches, swelling, joint stiffness or at the back related to injury / accident?	Change to During the last past 3 months did you experience any pain, aches, swelling, joint stiffness in the body or back which is not related to an injury/accident
During the last 7 days have you experienced pain, aching, swelling, stiffness (tightness) in or around your joints or back which is not related to an injury / accident?	During the last past 7 days did you experience any pain, aches, swelling, joint stiffness or at the back not related to injury / accident?	Change to During the last past 7 days did you experience any pain, aches, swelling, joint stiffness in the body or back which is not related to an injury/accident
The following questions ask about your joint or muscle pain, stiffness / tightness or swelling around your joints, or less movement in any joints	The following questions are about your joints or joint pains, stiffness or swelling in areas of your joints, or less movement in any joints	Change to The following questions are about your joint pain or muscle pain, stiffness/ tightness or swelling around your joints or less movement in any joints.
Please indicate on the figure below, with a √ all the sites where you have experienced pain in the last 3 months and with a X all the sites where you have experienced swelling.	Please show the picture below, with all the places where you experienced pains in the past 3 months and with an X show all the places where you experienced swelling.	Change to…please indicate √ on the picture below where you experienced pain in the past 3 months and with an X all the places where you experienced swelling.
Please indicate on the figure below, with a ✓ all the sites where you have experienced pain in the last 7 days and with a X all the sites where you have experienced swelling.	Please show picture below, with √ all the places where you experienced pains in the past 7 days and with X show all places where you experienced swellings.	Change to…please indicate on the √ on the picture below where you experienced pain in the past 7 days with an X all the places where you experienced swelling.
□ Less than 7 days ago, □ 3 months to 1 year ago	□ Less than past 7 days □ in the past 3 months □ in the past 3 months to 1 year ago □ More than past 1 year	Change less than past 7 days to less than 7 days ago change in the past 3 months to 3 months to 1 year ago
When is the pain most intense?	When is the intense pain?	Change to… when is the pain most intense/worse
Have you been diagnosed with arthritis or other joint diseases like rheumatism?	Have you been diagnosed with bones aching (arthritis) or other illnesses of joints like rheumatism (i-rheumatism)?	Please remove bones aching and keep arthritis
Have you been taking any medication for joint or back pain, not related to an injury, in the last 3 months?	Did you drink medicine for joint pains or spine, not related to injury, in the past 3 months?	Change to Did you drink medicine for joint pain or back pain, not related to injury, in the past 3 months?

Source English version	Back translated version by panel	Comments by PI
□ Exercise □ Massage □ Herbal/ natural □ Acupuncture □ electrotherapy machines □ Joint mobilizations □ Strapping/ bracing □ Other	□ Exercise □ Studies □ Massage □ Herbal/ natural □ Acupuncture □ electrotherapy machines □ Joint mobilizations □ Strapping/ bracing □ Other	Please remove studies

B. IPAQ-Xhosa

The pre-final back translated English version of the IPAQ-Xhosa was submitted to the PI for further comments. During the review of the back translation, there were some problems with the direct translation of isiXhosa words and phrases into English.

The problematic phrases were discussed with the panel of translators and it was agreed to change these phrases to the recommended changes to ensure semantic equivalence of words as the panel of translators felt that direct translation was the main problem due to the use of incorrect language and selection of words.

There were some contextual issues with some words as it was not appropriate for the culture of the target population and could possibly cause some confusion to the question. The back translated questions and comments by PI for amendments are shown in Table 5.

Table 5: Consensus meeting about the back translation of the IPAQ

Source questionnaire	Back translated version	Comments by PI
We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives	We are interested in finding the hands-on activities done by people as part of the everyday life routine.	Change all to: We are interested in finding the kinds of physical movements done by people as part of the everyday life routine.
Please answer each question even if you do not consider yourself to be an active person.	Please answer each question even if you do not consider yourself as someone who works.	Please answer each question even if you do not regard yourself to be an active person
Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.	Please think about other activities you do at work, as part of house and yard work, to get from place to place, and in the time you enjoy yourself, exercise, and sport.	Please think about everyday activities you do at work, as part of house and garden work, to get from one place to another place, and in the free time for hobbies.
Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal.	Strong physical activities refer to effortless difficult hands-on activities and makes you breath difficult than the usual.	Vigorous physical activities refer to the activities that are difficult without effort to do and make you breathe much harder than usual.
Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.	Activities inside refer to works that takes effort inside the body and makes you breathe better than the usual.	Moderate activities refer to activities that are less difficult to do and make you breathe a little harder than usual.
Skip to part 2: transportation	Jump Section 2: Transportation	Skip Part 2: Transportation
The next questions are about all the physical activity you did in the last 7 days as part of your paid or unpaid work.	The following questions are about all the hands-on activities that you did in the previous 7 days just like your work that pays or does not pay	The following questions are about all the physical activities that you did in the past 7 days as part of your paying or unpaid work.
Skip to question 4	Jump to question 4	Skip to question 4

Source questionnaire	Back translated version	Comments by PI
During the last 7 days, on how many days did you do moderate physical activities like carrying light loads as part of your work?	For a period of the previous 7 days, how many days do you do these hands-on activities by lifting heavy things, digging, heavy construction, or climbing upstairs as part of your work?	During the past 7 days, how many days did you do moderate physical activities include carrying lighter objects
Skip to question 6	Jump to question 6	Skip to question 6
During the last 7 days, on how many days did you walk for at least 10 minutes at a time as part of your work?	During the previous 7 days, how many days did you walk for 10 minutes as part of your work?	During the past 7 days, how many days did you walk at least for 10 minutes as part of your work?
Please do not count any walking you did to travel to or from work.	Please do not count any walking you did going or coming from work	Please do not count any walking you did while travelling to and from work.
Skip to PART 2: TRANSPORTATION	Jump to question 2: TRANSPORTATION	Skip to question 2: TRANSPORTATION
These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on	This question is about how you went from the one place to the other, including going to a place like work, shops, movies, and so on.	These questions are about travel from the one place to another, including going to places like work, shops, movies, and so on.
During the last 7 days, on how many days did you travel in a motor vehicle like a train, bus, car, or tram?	During previous 7 days, how many days did you go by car, train, bus, car or tram?	During past 7 days, how many days did you travel by train, bus, car or taxi?
No traveling in a motor vehicle	Not going by motor vehicle	No travelling by a vehicle

Source questionnaire	Back translated version	Comments by PI
How much time did you usually spend on one of those days traveling in a train, bus, car, tram, or other kind of motor vehicle?	How much time do you normally spend during any of those days by going with train, bus, tram, or any other motor vehicle?	How much time do you normally spend on one of those days travelling in a train, bus, car, taxi or any other vehicle?
Now think only about the bicycling and walking you might have done to travel to and from work, to do errands, or to go from place to place.	Now think only of going by bicycle and by foot that you might have done going and coming from work, to do what you were sent to do, or to go from the one place to the other.	Now think only of riding a bicycle and walking that you might have done going and coming from work, to do your errands, or going from one place to another.
During the last 7 days, on how many days did you bicycle for at least 10 minutes at a time to go from place to place?	During the previous 7 days, how many days you used the bicycle for 10 minutes to go from the one place to the other?	During the past 7 days, how many days did you ride a bicycle at least for 10 minutes to go from one place to another?
During the last 7 days, on how many days did you walk for at least 10 minutes at a time to go from place to place?	During the previous 7 days, how many days did you walk by foot for 10 minutes coming from the one place going to the other?	During the past 7 days, how many days did you walk at least for 10 minutes while coming from the one place going to another?
How much time did you usually spend on one of those days walking from place to place?	How much time do you normally spend during one of these days going by foot going from one place to the other?	How much time do you normally spend on one of those days walking from one place to another?
Think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, chopping wood, shoveling snow, or digging in the garden or yard?	Think also about the physical works only you did in 10 minutes. During the previous 7 days, how many days you did physical activities like lifting heavy things, chopping wood, shovelling snow, or digging in the garden	Think about those physical activities you did for 10 minutes a time. During the past 7 days, how many days did you do vigorous physical activities like lifting heavy things, chopping wood, shovelling, or digging in the garden or in the yard?

Source questionnaire	Back translated version	Comments by PI
This section is about all the physical activities that you did in the last 7 days solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.	This part is about other hands on activities you did in the previous 7 days in your home only in recreation, sports and hands on activities or leisure time. Please do not include any other activities you already included.	This part is about all the physical activities you did in the past 7 days for hobbies, sport, exercise or holiday. Please do not include any activities you have already mentioned.
Think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do vigorous physical activities like aerobics, running, fast bicycling, or fast swimming in your leisure time?	Think about those hands-on activities only you did for about 10 minutes. During the previous 7 days, how many days you did hands on activities of aerobics, to run, use the bicycle, or swim very fast during your leisure time?	Think about those physical activities only you did for about 10 minutes a time. During the past 7 days, how many days did you do vigorous physical activities aerobics, running, using the fast bicycle, or swimming very fast during your free time?
Again, think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do moderate physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis in your leisure time?	Also, think about those hands-on activities only you did for about 10 minutes. During previous 7 days, how many days you did moderate hands on activities like riding a bicycle very fast, swimming, also tennis of two people during you leisure time?	Again, think about those physical activities only you did for about 10 minutes a time. During the past 7 days, how many days did you do moderate physical activities like riding a bicycle at a normal speed, swimming at a normal speed and play double tennis in your free time?

Source questionnaire	Back translated version	Comments by PI
The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.	Final questions about the time you spent sitting down while at work, at home, while doing educational work or during your leisure time. This includes time spent sitting down on a desk, visiting a friend, studying or in community or lying on your back watching tv. Do not include any other time sitting down in a motor vehicle you already mentioned.	Final questions about the time you spent sitting down while at work, at home, while doing educational work or during your free time. This includes the time spent sitting in front of a desk, visiting friends, reading or sitting or lying down to watch TV.. Do not include any other time sitting down in a motor vehicle you already mentioned.
During the last 7 days, how much time did you usually spend sitting on a weekday?	During the previous 7 days, how much time do you normally sit down a day per week?	During the past 7 days, how much time do you normally spend sitting down during the week?
During the last 7 days, how much time did you usually spend sitting on a weekend day?	During the previous 7 days, how much time do you spend sitting down a day per week end?	During the past 7 days, how much time do you normally spend sitting down during the weekend?

3.5.3.2 Report on Translation of Afrikaans versions of COPCORD and IPAQ

A. **Afrikaans COPCORD**

The pre-final back translated Afrikaans version was submitted to the PI for further comments. There were fewer discrepancies found between the translated items compared to the isiXhosa translated version. The discrepancies were related to the selection of words and not the meaning of words or direct translation of the words. Table 6 highlights the back translated questions and recommendations made by the PI for amendments. All recommendations were discussed by the panel and agreed upon in synthesizing the pre-final Afrikaans COPCORD for pre-testing and cognitive debriefing.

Table 6: Consensus meeting about the back translation of the Afrikaans COPCORD

Source questionnaire	Back translation	Comments from PI
If yes, do you attend the rehabilitation/ exercise classes at physiotherapy?	Q2 b. If yes, do you attend the rehabilitation/exercise classes at a physiotherapy unit?	If yes, do you…. at physiotherapy (remove unit)
Do you suffer from chronic diseases of lifestyle?	Q3 a. Do you suffer from any of the chronic diseases that are listed in Question 3b?	Rephrase to do you suffer from chronic diseases of lifestyle? Because they might have a CDL that is not listed but that can be marked off in the "other" box
Some tablets make me feel sick, drowsy or sleepy	Some pills make me feel sick, drowsy or sleepy.	I think you can include moeg/ tired in the questionnaire
Agriculture / Field	farm/outdoors	Keep veld in the questionnaire
Deformity	Maimed or disabled	I think that the participant will get confused with both questions asking about disability. Delete this response
Education	Guidance	Is guidance referring to advice or health education because I would like to include health education?
Education	Guidance	If you changed this in previous question, please do the same here.

B. Afrikaans IPAQ

The PI found a few discrepancies with some of the translated items and questions in the IPAQ. The main problem was the incorrect direct translation of questions from Afrikaans into English in the back-translation version. Recommendations for amendments were made and submitted for further discussion to the panel of translators. One phrase: "sweeping leaves" was deemed inappropriate as it was not relevant to a South African context and was not an example of vigorous physical activities, therefore it was recommended to change it to "shoveling" as the latter proves to be a more difficult physical activity than sweeping leaves and relevant to context. All the recommendations for amendments are found in Table 7. The recommendations were agreed upon and accepted by the panel of translators and the pre-final Afrikaans IPAQ was produced for pre-testing and cognitive debriefing.

Table 7: Consensus meeting about the back translated Afrikaans IPAQ

Source questionnaire	Back translation	Comments from PI
The questions will ask you about the time you spent being physically active in the last 7 days	The questions that you must answer try to determine how long you were active over the past 7 days.	Change to: The questions that you must answer will determine how long you were physically active in the past 7 days
Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.	Moderate physical activities that require an average physical effort and make you breathe slightly more heavily than usual.	Moderate physical activities are activities that require moderate physical effort and make you breathe slightly more heavily than usual
These are asked in Part 3.	These activities are dealt with in Part 3	These activities are discussed in part 3
Think about only those physical activities that you did for at least 10 minutes at a time.	Think only about the activities that continued for more than 10 minutes at a time.	Please change this question as you included more than 10 minutes instead of at least 10 minutes
During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, chopping wood, shoveling snow, or digging in the garden or yard?	During the past 7 days, on how many days did you do strenuous physical activities, like picking up heavy objects, chopping wood, sweeping leaves, or digging in the garden or in the yard?	Should rather change sweeping to shovelling, because sweeping is not a vigorous activity
During the last 7 days, on how many days did you do moderate physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis in your time.	During the past 7 days, on how many days did you do moderate physical activities in your free time e.g. restful cycling, restful swimming or playing doubles tennis?	Change question to During the past 7 days, on how many days did you do moderate physical activities in your free time e.g. cycling, swimming or playing double tennis at a regular speed
Do not include any time spent sitting in a motor vehicle that you have already told me about	It does not include any time that you sat in a vehicle (as already mentioned).	Do not include any time that you sat in a vehicle that you have already told me about

3.5.3.3 Results from field-testing and cognitive debriefing of the translated isiXhosa and Afrikaans questionnaires

Two different samples of participants were approached to complete the two translated questionnaires. A group of five participants[1] (males, n=3 and females, n=2) with a mean age of 26.2 years (Table 8) reviewed and completed both the isiXhosa COPCORD and IPAQ questionnaires within an average time of 24.8 minutes. In addition, a second group of four participants (male, n=1 and females, n=3) with a mean age of 44.2 years completed the Afrikaans versions of the COPCORD and IPAQ questionnaires within an average time of 23.3 minutes. The questionnaires were administered by final year physiotherapy students (n=4) who were fluent in isiXhosa and Afrikaans. The questionnaires were self-administered and the students were available for any questions relating to the questionnaires. All the comments that were made by the participants were forwarded to the PI and editor in chief to address.

Table 8: Demographics of respondents of the field-testing of the isiXhosa and Afrikaans COPCORD and IPAQ questionnaires

Questionnaire	Age (years)	Gender	Profession	Time (minutes) to complete questionnaires
isiXhosa COPCORD and IPAQ	P1: 36	Female	Caterer	25
	P2: 21	Male	Student	30
	P3: 35	Female	Catering company manager	29
	P4: 19	Male	Student	19
	P5: 20	Male	Student	21
Mean Age (years)	26.2			
Mean time (minutes)				24.8
Afrikaans COPCORD and IPAQ	P1: 19	Female	Housewife	No time
	P2: 49	Female	HR Manager	20
	P3: 54	Male	Retired teacher	30
	P4: 55	Female	Primary school teacher	20
Mean Age (years)	44.2			
Mean time (minutes)				23.3

[1] Participants are abbreviated as P1-P5 in the table

Feedback from isiXhosa speaking respondents after the pilot testing of questionnaires

A. Translated isiXhosa COPCORD questionnaire:

There were two major concerns highlighted by all the participants (N=5). The following questions were highlighted by the participants with recommendations for the editor in chief to consider. The first question below was not clearly understood by all five participants as there were English words mixed in with the isiXhosa words which made the question confusing and incomprehensible.

"Ukuba nguewe, did you follow an exercise Programme yetingaba sele uyilandele inkqubo yokuziqeqesha umzimba?"

The second question below had a similar problem to the first question as it was unclear to the participants. All five participants reported difficulty in understanding the question as there were English words in the isiXhosa sentence.

"Did you drink medicine for joint pain or back painIngaba ubusela amayeza ukwenzela ingqaqambo yamalungu okanye ingqaqambo yomqolo, angabhekiselelanga kumonzakalo, kwiinyanga ezi-3 ezidlulileyo?"

Both concerns were highlighted to the editor in chief and after reviewing the participants' feedback, he reported that an error occurred during the track changes of the translated version, whereby some English words were erroneously included in the isiXhosa version which caused the confusion. There were no problems with the translation of the questions. Subsequently, the editor in chief removed the English words, added the correct isiXhosa words to the two questions and synthesised the final isiXhosa COPCORD questionnaire.

First question changed to: ***"Ukuba nguewe, ingaba sele uyilandele inkqubo yokuziqeqesha umzimba"***. The Second question changed to***: "Ingaba ubusela amayeza ukwenzela ingqaqambo yamalungu okanye ingqaqambo yomqolo, angabhekiselelanga kumonzakalo, kwiinyanga ezi-3 ezidlulileyo?"***

B. Translated isiXhosa IPAQ questionnaire:

The questionnaire had very few problems with the pilot testing. There were some phrases in two questions that the participants had some difficulty with. The isiXhosa word "candela" found in the opening line in the instructions, underneath part 1: the job-related physical activity section of the IPAQ, was incorrect. The participants suggested changing it to "candelo". This feedback was given to the editor in chief to review and amend. He reported that it was a typographical error and amended it to "icandelo".

The second word "nephakathi" found in the third question underneath part 3: housework, house maintenance, and caring for family was highlighted as being incorrect by the participants. The editor in chief reviewed the word and realized that it was a typographical error as it should refer to "moderate" and changed it to "ephakathi" in the questionnaire.

The third isiXhosa word that was difficult to understand was "ezemithambo" found in the instructions, underneath part 4: recreation, sport, and leisure-time physical activity of the questionnaire. The editor in chief reviewed the word and reported that it refers to "physical training" which is an old term used in isiXhosa in higher grades and that there is no other isiXhosa word to replace it. No changes were made to the word. All the amendments were made to produce the final isiXhosa IPAQ questionnaire.

Feedback from Afrikaans speaking respondents after the pilot testing of questionnaires

A. Translated Afrikaans COPCORD questionnaire:

There were no comments made by the participants about the COPCORD questionnaire. All the participants felt that the questions were easy to read and to understand and that no questions needed to be rephrased or changed.

B. Translated Afrikaans IPAQ questionnaire:

The IPAQ questionnaire required some changes. Some words and phrases in questions were highlighted by participants to be reviewed and amended. The following phrases were highlighted by the participants with recommendations for the editor in chief to consider:

"matige fisieke aktiwiteite is aktiwiteite wat matige fisieke inspanning eis en jou effens swaarder as gewoonlik laat asemhaal" and recommended to change to "minder". The feedback was submitted to the editor in chief, and she agreed to change the word to "minder".

"Gedurende die afgelope 7 dae, op hoeveel dae het jy strawwe fisieke aktiwiteite gedoen, soos die optel van swaar voorwerpe, graafwerk, swaar bouwerk of trappe klim as deel van jou werk?"

The respondents recommended that it should be change to: *"Op hoeveel dae het jy strawwe fisieke aktiwiteite gedoen as deel van jou werk, soos die optel van swaar voorwerpe, graafwerk, swaar bouwerk of trappe klim, gedurende die afgelope sewe dae?"* The editor in chief accepted the recommendation and changed the question.

"Gedurende die afgelope 7 dae, op hoeveel dae het jy matige fisieke aktiwiteite soos die dra van ligte voorwerpe as deel van jou werk gedoen?" and recommended to change to: *"Op hoeveel dae het jy matige fisieke aktiwiteite soos die dra van ligte voorwerpe as deel van jou werk gedoen, gedurende die afgelope sewe dae?"* The recommendation was accepted and was changed accordingly.

"Gedurende die afgelope 7 dae, op hoeveel dae het jy vir ten minste 10-minute op 'n slag as deel van jou werk geloop? It was recommended to change to: *"Op hoeveel dae het jy vir ten minste 10-minute op 'n slag as deel van jou werk geloop, gedurende die afgelope sewe dae?* This was accepted and changed.

"Gedurende die afgelope 7 dae, op hoeveel dae het jy vir ten minste 10-minute op 'n slag fietsgery om van plek tot plek te kom?" and was recommended to change to: *"Op hoeveel dae het jy ten minste 10-minute op 'n slag fiets gery om van plek tot plek te kom, gedurende die afgelope 7 dae?".* This recommendation was accepted and changed.

"Gedurende die afgelope 7 dae, op hoeveel dae in jou vrye tyd het jy strawwe fisieke aktiwiteite soos oefen, draf, vinnige fietsry of vinnige swem gedoen?" and was recommended to change to:
"Op hoeveel dae in jou vrye tyd het jy strawwe fisieke aktiwiteite soos oefen, draf, vinnige fiets gery of vinnige swem gedoen, gedurende die afgelope 7 dae?". This recommendation was accepted and changed.

"Gedurende die afgelope 7 dae, op hoeveel dae in jou vrye tyd het jy matige fisieke aktiwiteite gedoen, bv. in 'n rustige pas fietsgery, geswem of dubbelspel tennis gespeel?" was recommended to change to: *"Op hoeveel dae in jou vrye tyd het jy matige fisieke aktiwiteite gedoen, bv. In 'n rustige pas fiets gery, geswem of dubbelspel tennis gespeel, gedurende die afgelope 7 dae?"* and was accepted and changed.

“Gedurende die afgelope 7 dae, vir hoe lank het jy gewoonlik op ’n weeksdag gesit?” change to: *“Vir hoe lank het jy gewoonlik op 'n weeksdag gesit, gedurende die afegelope 7 dae?”* and was accepted and changed.

“Gedurende die afgelope 7 dae, vir hoe lank het jy gewoonlik op ’n Saterdag of Sondag (naweekdae) gesit?” should be changed to*: “Vir hoe lank het jy gewoonlik op 'n Saterdag of Sondag (naweekdae) gesit, gedurende die afgelope 7 dae?”* and it was accepted and changed.

The following questions were recommended to be combined into one question:

“Vir hoe lank het jy gewoonlik op daardie dae in jou vrye tyd geloop?” and “Dink slegs aan die fisieke aktiwiteite wat jy vir ten minste 10-minute op ’n slag gedoen het”. The editor in chief did not agree with this recommendation and no changes were made.

“Vir hoe ’n lang tyd het jy gewoonlik op daardie dae in jou vrye tyd strawwe fisieke aktiwiteite gedoen?” and “Dink weereens slegs aan die aktiwiteite wat jy vir ten minste 10-minute op ’n slag gedoen het”. This recommendation was not accepted and no changes were made.

All the necessary changes were made to synthesise the final COPCORD and IPAQ translated questionnaires to be used for data collection in the upcoming studies (Appendix D-8, D-9).

3.5.4 Discussion

This section of the chapter discussed the translation process of the COPCORD and the IPAQ questionnaires into isiXhosa and Afrikaans. The translation method used the forward-translation, back-translation process to ensure cross-cultural translation of the two questionnaires. During the translation process, some issues were highlighted and addressed by a panel of translators to ensure that cultural equivalence was attained. It was necessary to establish semantic and linguistic, operational and functional equivalence in the two translated questionnaires. Therefore, the primary aim of the synthesised translated questionnaires (COPCORD and IPAQ) was to convey the same intended message as the source questionnaires to people speaking both isiXhosa and Afrikaans languages.

3.5.4.1 Semantic and linguistic equivalence

Translated COPCORD questionnaire

It was noted that both the isiXhosa and Afrikaans COPCORD questionnaires had a few minor errors with the selection of words which was highlighted in the back-translation process. Equivalence was ensured by the panel of translators who had reviewed, discussed, and amended the problematic words. During the cognitive debriefing sessions, both the isiXhosa and Afrikaans COPCORD questionnaires were well understood and accepted by all the respondents, as no comments or recommendations were made to any questions.

Translated IPAQ questionnaires

There were some problems with the direct translation of questions for both the isiXhosa and Afrikaans IPAQ questionnaires. The use of incorrect language and selection of words were highlighted and addressed by the panel of translators. Cognitive debriefing raised few errors from the respondents as the two problems highlighted with the isiXhosa version were due to typographical errors. Therefore, the isiXhosa IPAQ questionnaire was well understood and accepted for use.

The Afrikaans IPAQ questionnaire had a few problems with the direct translation of terms and phrases. It was apparent that the translators did not fully comprehend the meaning of some questions related to vigorous activity. These errors were discussed by the panel of translators and amendments were made accordingly. During the cognitive debriefing session, the participants reported problems with the direct translation of nine questions.

All these problems were highly relevant, and changes were necessary. The translated questions were reviewed and amended to improve the comprehension of questions and equivalence of the instrument for future studies.

Operational equivalence

In the beginning of the translation process, all translators were informed about the purpose of the translation of the COPCORD and IPAQ questionnaires. Those involved with the forward translation process, were given the English source questionnaires, and were told to use the same design, format, and instructions of the source questionnaires for the translated versions. During the translation, nothing was added to or deleted from the translated versions. Thus, the translated isiXhosa and Afrikaans COPCORD and IPAQ questionnaires attained operational equivalence as they had the same structure and format; and produced accurate and equivalent results during the cognitive debriefing sessions as the source questionnaires.

Functional equivalence

During the cognitive debriefing sessions of both translated versions of the COPCORD and IPAQ questionnaires, various questions were asked to the respondents to review and complete. It was important to establish the participants' comprehension of the questionnaires as an indication of functional equivalence of the translated instruments. For both questionnaires, all participants provided constructive feedback about some unclear questions and recommendations for possible changes. The recommendations suggested by the respondents were appropriate and valuable to consider and were accepted for amendment. By implementing this evaluation process, the translated questionnaires reflected that the underlying characteristics of the instruments were well defined in the target (Xhosa and Afrikaans) cultures and the results can be compared across cultures.

3.5.5 Conclusion

3.5.5.1 Strengths and limitations of the translation process

The translation of the both the COPCORD and IPAQ followed a rigorous process. The fact that language experts were recruited from an accredited well-recognized tertiary institution, contributed to the assurance that the translated questionnaires were of good quality and precision. Another strength was that all the translators involved in the process were qualified Xhosa or Afrikaans language educators or lecturers.

A limitation was that the back translators had some challenges in selecting appropriate words and complex phrases or sentences for both the isiXhosa and Afrikaans COPCORD and IPAQ questionnaires. These words and phrases did not have the same meaning as those in the source questionnaires and thus needed to be reviewed and amended. The translators involved in the isiXhosa and Afrikaans IPAQ questionnaire were faced with difficulty in understanding a few complex words such as “vigorous and moderate physical activities” and provided inappropriate words and phrases which needed to be amended. This could be due to the lack of vocabulary in isiXhosa and Afrikaans for the source words. Despite the few limitations highlighted, the main researcher (PI) had the assurance that the translated versions of the COPCORD and IPAQ questionnaires had attained cultural equivalence and can be used in cross-cultural research.

The following section will discuss the feasibility and validation of the translated instruments.

3.6 Validation and feasibility of translated instruments

3.6.1 Introduction

Scientific evidence is dependent on appropriate and adequate measurements as weak measurements ultimately produce weak results which in turn compromise follow-up research and clinical activities [247]. Therefore, all practitioners and researchers in health care should have a good understanding about the concepts of validity and reliability in psychometric assessments [248].

Validity is an indication of how sound, good, or strong your research is and applies to the design and methods of the research. Validity is a description of whether you can trust the results of an outcome measure or a test that was used for its intended purpose. Furthermore, it is the degree to which the results scores reflect the intended underlying construct and refers to the interpretation of results rather than the instrument being used [248]. Validity is further divided into types of validity, and the descriptions of the types of validity according to Fitzner (2007, p.776)[249], are described in Box 4.

Reliability refers to the degree to which an outcome measure produces the same score during different assessments when the construct being assessed remains unchanged[250]. In other words, it is the consistency of scores from one assessment to another[251]. Reliability can be assessed through different types of reliability namely: test-retest, internal consistency, interterm consistency, inter-rater and intra-rater reliability[249]. Definitions of the key types of reliability according to Fitzner (2007, p.776)[249], are found in Box 5 below. Reliability is not the same as validity, it is necessary to obtain but it is not sufficient to determine validity[252].

Box 4: Descriptions of types of validity

- **Face validity**: A subjective judgment of whether the tool or question is a good measure or not. Does it measure what it is intended to measure?
- **Content validity**: An exhaustive review by an expert panel to decide whether the types of questions (items) adequately cover the behaviour that you are interested in measuring.
- **Criterion validity**: How well your measurement agrees with other approaches for measuring the same behaviour and predicts an outcome?
- **Construct validity**: The amount of agreement between a theoretical concept and a specific measuring device or procedure. Example: When you implement a healthy eating Programme, is the label an accurate one and is what you were measuring what you had in mind? If the Programme actually targets both exercise and healthy eating, then the validity relating to the label healthy eating Programme would be in question.
- **Convergent validity** (a subcategory of construct validity): Checks to see if different measures of the same thing are highly correlated.
- **Concurrent validity**: Do other tools give similar results? If a new test measures satisfaction with diabetes education and gives similar results as another tool that was validated in past, the new measurement has concurrent validity.
- **External validity**: The degree to which the results can be generalized to other settings or groups.
- **Internal validity**: Did the thing you are interested in actually cause the change or outcome?

In clinical research, it is often difficult to do multiple measurements of the same outcome in an individual, thus it is important to investigate the evidence relating to the reliability of scores before using the instrument in practice. If the instruments used in research do not produce reliable scores, the interpretation of the scores will not be valid either[248].

Box 5: Descriptions of types of reliability

- **Test-retest:** The ability of an outcome measure to replicate or reproduce the same scores over time
- **Internal consistency reliability**: The consistency of scores across multiple items within an outcome measure
- **Inter-rater reliability**: It is the degree of agreement between different interviewers (raters) to be able to achieve the same results
- **Interterm consistency**: It is the consistency of scores across multiple written or verbal responses in an outcome measure of an outcome measure
- **Intra-rater reliability:** It is the degree of agreement between the scores of repeated administrations of a test by a single interviewer (rater)

3.6.2 Aim and objectives

Following the translation of the COPCORD and the IPAQ questionnaires, the translated version of the two questionnaires were validated in a feasibility study using the same methodology and procedures of the main epidemiological study (Phase I) at the Woodstock Community Health Centre (CHC) in Cape Town.

The aim of this sub-study was to determine the validation and feasibility of the English, Afrikaans, and isiXhosa versions of the COPCORD and IPAQ questionnaires within a context like that of the main epidemiological study.

The specific objectives were:

- To establish the criterion validity of the translated COPCORD questionnaire by examining agreement with previously validated Brief Pain Inventory (BPI) questionnaire.
- To establish group validity of the translated IPAQ questionnaire by comparison of physical activity levels, BMI, and the chronic pain question in the COPCORD questionnaire, should the COPCORD pain question prove to be valid.
- To determine the feasibility of using these translated instruments, in terms of mode of administration, response rate, completion rate and time to complete all outcomes, in participants attending the Woodstock community health centre (CHC).

The main epidemiological study would be feasible if the following success criteria were achieved in this feasibility study:

- If 100% (N=45) or at least 95.5% (n=43) of participants could be recruited to participate in this study in one week *(power calculations for the epidemiological study indicated the need to recruit 43 to 45 participants per week to recruit a minimum of 512 participants over a period of 12 weeks – see Chapter 4).*
- If at least 90% of participants (n=40) could complete all outcome measures and clinical tests.
- If participants could complete all outcome measures and clinical tests within 45 minutes *(main study requires an average of 45 minutes for each participant to collect data from at least 8 participants per day to obtain the required sample of 512 participants over a 12-week period).*

The outcome of the feasibility study could be one of the following:

1. Stop - main study not feasible (if all criteria were not achieved)
2. Continue, but modify protocol - feasible with modifications (if two criteria were achieved)
3. Continue without modifications - feasible (if all criteria were achieved)

3.6.3 Methods

A descriptive, cross-sectional, and correlational research design was used.

3.6.4 Sample

A sample of convenience was used for this study. Participants older than 18, were recruited from the Woodstock CHC. Individuals were approached while waiting in queues for medical or rehabilitation care at various sections of the CHC. The following inclusion and exclusion criteria were used to select appropriate participants.

The inclusion criteria included the following:

- Women and men older than 18 years attending the Woodstock CHC for treatment of non-traumatic MSD and CDL for more than three months
- Participants who were able to read, speak and understand English, Afrikaans or isiXhosa
- Participants who were willing to provide informed consent to participate in the study

People were excluded if they:

- Had previously been diagnosed with severe intellectual impairments
- Had acute traumatic musculoskeletal disorders, such as fractures, requiring medical attention
- Were unable to read and answer in English, Afrikaans or isiXhosa

3.6.5 Outcome measures

The two translated questionnaires (COPCORD and the IPAQ), and the translated versions of the Brief pain inventory (BPI) were administered to eligible participants and measurements such as height, weight, waist, and hip circumference was taken to determine the Body mass index (BMI) and Waist-to-hip ratio (WHR).

- **COPCORD**

The COPCORD questionnaire was used to collect data relating to demographic information, presence of chronic and acute musculoskeletal pain, presence of chronic diseases of lifestyle, previous medical history and current treatment[167].

- **BPI**

The Brief Pain Inventory was administered to determine the Pain Severity Score (PSS) and the Pain Interference Score (PIS)[183].

- **IPAQ**

The International Physical Activity Questionnaire (IPAQ) was used to collect date about the level of physical activity in individuals[227].

- **BMI**

Body weight was measured on the calibrated digital Adam Health and Fitness scale (MDW 250L weight and height scale)[253]. The height of each participant was recorded to the nearest 0.1 cm using a measuring tape that was placed securely against a flat wall at a right angle to the wall and the measurement was taken without shoes[254]. The BMI was calculated as described previously[193].

- **Waist to hip ratio**

The waist and hip circumference of each participant was measured to determine the waist to hip ratio. The participant stood erect with arms at the side and feet close together. All measurements were taken over the undergarments to get as close as possible to the skin for accuracy.

For waist circumference, a measuring tape was used to measure the smallest portion of the waist around the midpoint between the superior tip of the iliac crest and the last palpable rib. The measurements were taken at the end of expiration. For the hip circumference, the tape measure was positioned around the widest part of the buttocks. The waist-hip ratio was calculated by dividing the waist circumference by the hip circumference measurements[255].

3.6.6 Procedure

Ethical approval for the feasibility study was obtained from both the University of Cape Town Faculty of Health Sciences Huma Research Ethics Committee (HREC: 100/2014) and the Western Cape Department of Health (RP 030/2014). Permission was obtained from the facility manager and the head physiotherapist of Woodstock CHC.

Four final year physiotherapy students acting as research assistants approached people waiting in queues at the Woodstock CHC from 9:00am-2:00pm for five days for one week in May 2014. Background information and procedures related to the study were explained to each potential participant by the researchers. Individuals, who were eligible and who were interested in participating in the study, could ask any relevant questions related to the study and thereafter signed the informed consent form. Three questionnaires (COPCORD, IPAQ, BPI), according to the preferred home language (English, Afrikaans, or isiXhosa) were administered to each participant in the waiting areas of the CHC.

Following this, participants were escorted to the physiotherapy gym to complete clinical tests while a different student sat in the participant's seat to retain the participant's place in the queue. The physical tests included weight, height, waist, and hip measurements. Once the participant had completed all the tests, they were escorted back to their seat in the waiting room.

3.6.7 Data management and statistical analysis

Data were analysed using descriptive and inferential statistics. Data were summarised as mean, standard deviations (SD) and frequencies. In the case of missing responses, it was decided *a priori* that a total of 12% (11 or more cases out of 92 responses) indicated that there was a problem with that item of the COPCORD or the IPAQ. This *a priori* decision was based on the impact of large missing data (Range: 10%-20%) on statistical analyses and accuracy of results[256]. Criterion validity of the COPCORD was tested using the previously validated BPI as the "gold standard" measure.

It was assumed that the Pain Severity and Pain Interference scores would be significantly higher in those who reported chronic pain.

According to the scoring protocol for the IPAQ long form, continuous and categorical scores were analysed. To ensure that the results were accurate and comparable to other studies, rigorous data cleaning was done. All cases, in which the total minutes of combination of walking, moderate and vigorous time variables were more than 960, were excluded from the analysis as unreasonably high values are regarded as inaccurate and deemed as outliers. If data were missing for time or days, the case was removed from analysis[230]. The Metabolic Equivalent of Tasks (METs) scores from the IPAQ were calculated to determine whether participants had low, moderate, or high physical activity levels. Relationships between health conditions and risk factors (physical activity levels and obesity) were determined by chi-square test, t-test, or Mann Whitney u test at the p value <0.05, depending on the normality of data.

3.6.8 Results

3.6.8.1 Description of sample

A. Responses to COPCORD

A total of 120 individuals were approached during the data collection period. The recruitment process of participants is outlined in Figure **7**.

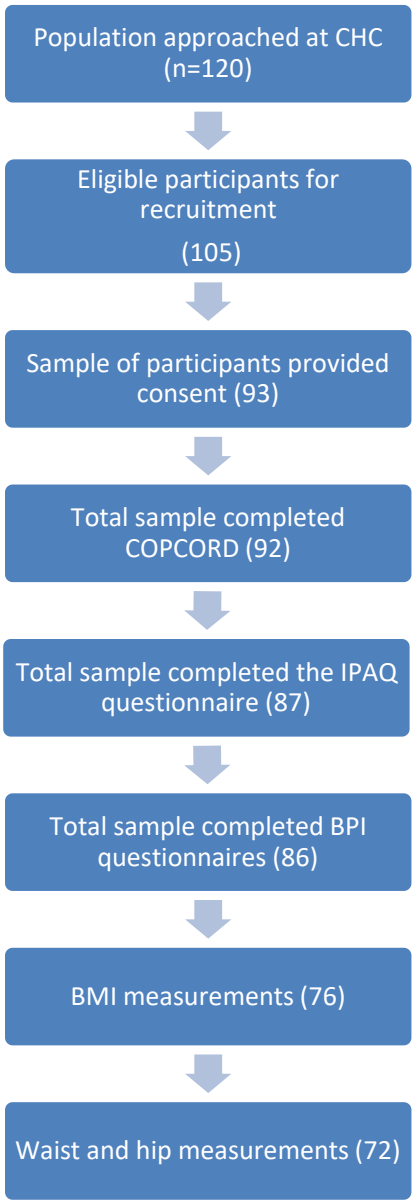


Figure 7: Flow chart of recruitment of participants

Most participants (63%, n=58) spoke English, isiXhosa (18.4%, n=17) and Afrikaans (16%, n=15). Of the 92 subjects, 73 (79%) were female and 17 (18%) were male.

The participant's mean age was 54.8 years (SD=13.8, Range: 18-87). There were no significant differences between the ages of the English, Afrikaans and isiXhosa speaking groups ($F_{2, 85}$=1.026, p=0.362). The socio-demographic information relating to marital status, children, employment, and educational level is highlighted in Table 9 below.

Table 9: Socio-demographic information of sample of participants (n=92)

Variable	Category	Frequency (%)	Mean ± SD	Median (Range)
Age	Age (years)		54.8 ± 13.8	54 (18 – 87)
Gender	Female	73 (79)		
	Male	17 (18.4)		
	Missing	2 (2)		
Languages	English	58 (63)		
	isiXhosa	17 (18.4)		
	Afrikaans	15 (16)		
	Missing	2 (2)		
Employment Status	Retired	27 (29)		
	Unemployed	23 (25)		
	Housewife	14 (15)		
	Other	11 (12)		
	Administrative	6 (7)		
	Domestic worker	4 (4)		
	Factory worker	3 (3)		
	Shop assistant	2 (2)		
	Missing	2 (2)		
Educational Level	No formal schooling	3 (3)		
	Grade R to 3	5 (5)		
	Grade 4 to 6	9 (10)		
	Grade7 to 9	26 (28)		
	Grade 10 to 12	33 (36)		

Variable	Category	Frequency (%)	Mean ± SD	Median (Range)
	Diploma or equivalent	11 (12)		
	Missing	1 (1)		
Marital Status	Single	17 (18)		
	Partner	4 (4)		
	Married	40 (43)		
	Divorced	15 (16)		
	Widowed	14 (15)		
	Missing	2 (2)		
Number of children	None	10 (11)		
	1 child	9 (10)		
	2 children	24 (26)		
	3 children	24 (26)		
	>3 children	22 (24)		
	Missing	3 (3)		

The responses to the adapted COPCORD related to musculoskeletal disorders (MSD) are relevant to highlight as this outcome measure will be used later in the two main studies to describe the prevalent MSDs. In this study, 89.4% of participants (76 of 85) reported chronic joint pain (pain in the joints during the last three months), of which 83% were reported by females (n=63) and 17% by males. Further analysis showed that chronic joint pain was not associated with language group (Chi-sq=1.387, p=0.239). Nearly half of the sample (42%) reported chronic joint pain in the lumbar spine, 33% in the cervical spine, 25% and 20% in unilateral knee and hip regions, respectively. Of those with chronic joint pain and who received rehabilitation (25 of 76), 68% (n=17), reported that exercise and a combination of strapping, acupuncture and education was the most effective treatment. Lastly, a high proportion of participants (77.3%, 65 of 84) reported acute musculoskeletal pain (pain in the last seven days). This acute pain could have been related to a previous joint problem but unfortunately the questionnaire did not have follow-up questions to determine whether this was the case.

Most of the participants (74%, n=68) also reported having a chronic disease of lifestyle (CDL) which was not associated with any language group (Chi-sq=0.004, p=0.948). Hypertension (HPT) (59%, n=55) and

diabetes mellitus type 2 (DM2) (26%, n=24) were the two most common CDL reported by the participants (n=7 missing). With regards to medication for CDL, 56% (n=52) of the participants with HPT and 25% (n=23) with DM2 reported using prescription medication for the past three months.

B. Responses to IPAQ

Only 87 participants completed the IPAQ questionnaire (n=5 missing). According to the scoring protocol, unreasonably high data (more than 960 minutes or 16 hours) are considered outliers and should therefore be excluded from the data set[230]. For this reason, 10 additional participants were removed from the analysis as they reported more than 960 minutes for the total time for activities (walking, moderate and vigorous) and analyses were done on 77 participants. The possible reason for the missing responses could be due to participants leaving during the data collection period as it was their turn to see the doctor, pharmacist, or other health professional. The mean MET min/week values[2] for walking, moderate-intensity and vigorous-intensity activities as per the scoring protocol[230] are illustrated in Table 10. Furthermore, the total physical activity MET min/week was one of the criteria used to determine the categorical levels of physical activity. More than half (57%, n=44) of the participants fell into the high physical activity category, 34% (n=26) in the moderate physical activity level and 9% (n=7) in the low physical activity level.

Table 10: The mean MET min/week for physical activities (IPAQ) (n=77)

Physical activity in MET min/week	Mean	Standard Deviation	Range (min-max)
Walking (MET min/week)	2430.8	2968.1	0-11088
Moderate activity (MET min/week)	2556.7	4480.1	0-23520
Vigorous activity (MET min/week)	582.8	3141.9	0-26880
Total physical activity (MET min/week)	5751.1	6361.2	0-28800

[2] MET min/week = Metabolic equivalent task in minutes for a week. MET-minute represent the amount of energy expended during physical activities. MET-minute scores are calculated by multiplying the MET score of an activity by the minutes performed. A MET is a multiple of the resting metabolic rate.

C. Responses to BPI

The participants' reported their pain severity and interference with activities according to the BPI questionnaire. There were a few missing responses (n=6) to part of the questions related to pain severity and pain interference highlighted in the data analysis. The possible reason for these missing responses could be that the participants had to leave the interview as it was their turn to see the doctor, pharmacist, or other health professional. The responses of those who completed the BPI were used to calculate the total scores, see Table 11. There were no significant differences in PSS and PIS between respondents who had different home languages.

Table 11: Participants' responses to the BPI (n=86)

Brief Pain inventory	**Mean ± SD**	**Median (Range)**	**Comparison between languages**
Pain Severity Score	**5.25 ± 1.88**	**5 (1 – 9)**	$F_{2, 82}$=1.232, p=0.296
Worst pain	7.81 ± 2.18	8 (2 – 10)	
Least pain	3.79 ± 2.40	4 (0 – 10)	
Average pain	5.66 ± 2.27	5 (0 – 10)	
Current pain	3.91 ± 3.37	5 (0 – 10)	
Pain Interference Score	**4.58 ± 2.62**	**4.7 (0 – 9.5)**	$F_{2, 82}$=1.553, p=0.217
Interference with activity	5.32 ± 3.30	5 (0 – 10)	
Interference with mood	5.11 ± 5.33	5 (0 – 10)	
Interference with ability to walk	5.09 ± 3.57	5 (0 – 10)	
Interference with ability to do normal work	4.81 ± 3.30	5 (0 – 10)	
Interference with relations with other people	3.03 ± 3.45	1 (0 – 10)	
Interference with sleep	5.14 ± 3.43	6 (0 – 10)	
Interference with enjoyment of life	3.95 ± 3.60	4 (0 – 10)	

D. BMI and Waist to Hip ratio

For the clinical measures, 76 participants had their BMI[3] calculated (n=16 missing) and classified according to WHO (2016)[192] and 72 participants had their waist to hip ratio (WHR)[4] calculated (n=20 missing)[255], refer to

Table **12**. A possible reason for the high number of missing responses for both BMI and WHR measurements could be due to the tests being done in a different venue, which caused the participants to leave their seat in the queue. Even though their place in the queue was retained, some participants expressed that they did not want to leave their place as they did not want to lose their appointments with the doctor or health professional. Another reason was that some participants had completed the questionnaires but were called for their appointments before they could do the BMI and WHR measurements. Therefore, the analyses were done for BMI on 76 participants and for WHR on 72 participants. There were no significant differences found in mean BMI scores between groups with and without chronic joint pain (t=0.11, p=0.905); and groups with and without acute pain (t=0.725, p=0.470).

Table 12: BMI and Waist-hip ratio scores for participants (n=76)

Variable	Groups	Mean± SD	Range (min-max)	Statistical analysis
BMI (kg/m^2)	Total sample (n=76)	30.5 ± 6.78	15.2 - 48	
BMI (kg/m^2)	Chronic pain (n=66)	30.1 ± 6.56		t=0.11, p=0.905
	No chronic pain (n=7)	29.8 ± 6.81		
BMI (kg/m^2)	Acute pain (n=59)	30.2 ± 6.48		t=0.725, p=0.470
	No acute pain (n=13)	28.8 ± 6.45		
Waist-hip ratio (WHR)	Total sample (n=72)	0.84 ± 0.1	0.45 - 1.36	

[3] BMI is used to classify overweight and obesity in adults. WHO (2016)[192]. WHO. Obesity and overweight fact sheet 2016 [Available from: http://www.who.int/mediacentre/factsheets/fs311/en/. defines overweight as a BMI greater than or equal to 25; and obesity as a BMI greater than or equal to 30.

[4] WHR is used as a measurement of obesity. WHO (2011)[255]. WHO. Waist circumference and waist-hip ratio: Report of a WHO expert consultation, Geneva, 8-11 December 2008. 2011. states that abdominal obesity is defined as a waist-hip ratio above 0.90 for males and above 0.85 for females, or a body mass index (BMI) above 30.

3.6.8.2 Validation of COPCORD

A. Missing responses for COPCORD

Demographic information was completed by most of the participants; with less than five missing responses to questions relating to socio-demographic variables. Missing responses to questions related to chronic diseases of lifestyle (CDL), past injuries and pain are also highlighted in Table 13.

Table 13: Missing responses to questions in the COPCORD

Variables	**Questions related to variables**	**Missing responses**
Demographics	Gender	<5 missing
	Language	
	Children	
	Level of education	
	Current job	
Work	Stopping work due to illness	20 to 26 missing
	Type of illness	
	Change work due to illness	
	Reasons for changing work	
Income	Receiving a pension or grant	10 missing
	Specifying amounts of income	52 missing
Lifestyle	Breadwinner	2 to 10 missing
	Smoking	
	Alcohol	
CDL	Presence of chronic diseases	
	Time of diagnosis	
	Use of chronic diseases medication	
	Reasons for not using medication	
Past injuries	Past traumatic injuries	
	Results of injuries	
	Following an exercise Programme	
Pain	Chronic pain (more than 3 months)	7 missing
	Pain for last 7 days	8 missing
	Onset of pain	5 to 6 missing

Variables	Questions related to variables	Missing responses
	Duration of pain	
	Intensity of pain	
	Joint stiffness	
	Whether movement reduces stiffness	17 missing
	What rehabilitation treatment was most effective	15 missing
	Arthritis	5 to 11 missing
	Medication for arthritis	
	Other treatment for joint pain	

B. Criterion validity of the COPCORD pain questions

The BPI-Xhosa, which has been previously validated in amaXhosa women with HIV/AIDS in South Africa[189], was used to test criterion validity by comparing the BPI PSS and PIS between those with chronic joint pain or acute MSD (seven-day pain) using the adapted COPCORD questionnaire. We theorised that those with acute MSD on the COPCORD would have more severe or higher PSS on the BPI than those with chronic joint pain. According to the adapted COPCORD, chronic joint pain (pain during last 3 months) was reported by 89.4% (76 of 85) and acute MSD (seven-day pain) by 77.3% (65 of 84) of participants. The number of participants having both acute and chronic pain is summarized in Table 14.

Table 14: Number of participants reporting acute MSD and chronic joint pain (n=83)

Chronic Joint Pain	Acute MSD Yes	Acute MSD No	Row Totals
Yes	62 (95%)	14 (78%)	76
No	3 (5%)	4 (22%)	7
Column Total	65	18	83

Approximately 9 missing one or other response, % refers to column percentage.

In terms of criterion validity, there was a significant difference in the BPI-Pain Severity Score (PSS) between those who had acute MSD and those who did not (p=0.004). There was a significant difference in BPI-Pain Interference Score (PIS) between participants with chronic joint pain and those without (p=0.050) (Table 15).

Table 15: Comparison between Acute MSD and Chronic joint pain and BPI scores (n=82)

Variable	BPI	N (Yes)	Mean (Yes)	SD (Yes)	N (No)	Mean (No)	SD (No)	t-value	P-value
Chronic joint Pain	Pain severity score	74	5.30	1.80	8	4.93	2.76	0.52	0.607
	Pain interference score	74	4.78	2.61	8	2.85	2.36	1.99	**0.050**
Acute MSD	Pain severity score	63	5.61	2.09	18	4.16	1.72	2.986	**0.004**
	Pain interference score	63	4.71	3.31	18	4.44	2.38	0.386	0.701

Approximately 10 missing responses to one or other of the questions

3.6.8.3 Validation of IPAQ

A. Missing responses to IPAQ

Participants reported on their daily physical activities using the IPAQ long questionnaire. There were 15 participants who either did not answer the IPAQ questions (n=5 missing) or reported more than 960 minutes for total walking, moderate and vigorous time variables (n=10), as defined by the IPAQ scoring protocol[230], and were excluded from the final analysis. One-way ANOVA indicated that the mean total physical activity MET min/week scores were not significantly different between the language groups ($F_{2, 73}$=1.870, p=0.161).

B. Criterion and construct Validity of IPAQ

There is no recognised "gold standard" of measurement for physical activity[257]. To test the construct validity of the IPAQ questionnaire, in the absence of a gold standard, known-groups validity was examined[258]. Based on the prior analysis, the COPCORD question was assumed to be validated and thus could be used to define known groups. Known group validity, a form of construct validity, of the IPAQ was tested by comparing activity levels between those who had chronic joint pain and those who did not, theorising that those with pain would be less active.

Chi-square tests were initially done to determine if there were any associations between physical activity categorical levels, acute MSD, and chronic joint pain. However, this analysis could not continue as there were less than five respondents in a cell. Thus, a Fisher exact test, specifically a 2x3 table, was necessary.

The Fisher exact test indicated no association between physical activity level, in terms of categories, and the presence/absence of chronic joint pain (p=0.351). Furthermore, there was no association found between physical activity categories and acute MSD (p=0.838)[5].

Further analysis was done to determine if there were any differences between physical activity MET min/week and those with acute MSD and chronic joint pain and those without pain. T-tests were done and indicated no significant difference between PA MET min/week and chronic joint pain (t value=1.243, p=0.217). There was no significant difference found between PA MET min/week and acute MSD as well (p=0.603) (Table 16).

Table 16: Comparison between seven day and three-month pain and Physical activity (n=74)

IPAQ	Variable	N (Yes)	Mean (Yes)	SD (Yes)	N (No)	Mean (No)	SD (No)	t-value	P-value
Total physical activity MET min/ Week	Chronic joint pain	65	5535.8	6151.1	9	8376.1	8270.5	1.243	0.217
	Acute MSD	55	5777.0	6377.7	16	4894.7	4100.6	0.521	0.603

It was assumed that a relationship existed between physical activity and BMI, whereby people with normal BMI will have higher physical activity MET min/week and those with high BMI will have lower physical activity MET min/week values indicating a negative correlation on a scatterplot. A scatterplot was done to confirm such a relationship and there was no correlation between total physical activity MET min/week and BMI (r=-0.0148, p=0.906) found.

In addition, One-way ANOVA indicated that the mean BMI scores were not different between the physical activity categories ($F_{2, 63}$=1.270, p=0.287) as people with higher BMI scores fell into the moderate and high physical activity categories and those with lower scores (mean=26.6 kg/m^2) had low physical activity levels. Therefore, no relationship between physical activity and BMI was found in this sample.

[5] Fisher exact probability test for 2x3 table was calculated with VassarStats http://vassarstats.net/fisher2x3.html

3.6.8.4 Feasibility of translated outcomes

As mentioned previously in this chapter in section 3.6.2, the following criteria were needed to be achieved to determine the feasibility of the translated outcomes:

- If 100% (N=45) or at least 95.5% (n=43) of participants could be recruited to participate in this study in one week *(power calculations for the epidemiological study indicated the need to recruit 43 to 45 participants per week to be able to recruit a minimum of 512 participants in a period of 12 weeks – see Chapter 4).*
- If at least 90% of participants (n=40) could complete all outcome measures and clinical tests.
- If participants could complete all outcome measures and clinical tests within 45 minutes *(main study requires an average of 45 minutes for each participant in order to collect data from at least 8 participants per day to obtain the required sample of 512 participants over a 12-week period).*

A. Response rate of participants

Four final year physiotherapy students approached individuals waiting in the queue, recruiting 5-10 individuals each per day. A total of 120 individuals were approached during the one week of data collection. However, only 105 eligible individuals were recruited, of which 93 (88.5%) gave informed consent to participate in the study. A total of 92 individuals participated in the study and thus a response rate of 87.6% (92 out of 105) was obtained, thereby meeting the first criterion.

B. Completion rate of all outcomes

A total number of 86 participants (93.4%, 6 missing) completed all three questionnaires. However, a total of 72 participants (78%, 20 missing) completed all the questionnaires and the BMI and WHR measurements. Therefore, the second criterion was achieved as there were more than 40 participants that completed all outcomes measures.

C. Time to complete questionnaires

The mean time to administer the COPCORD was 11.67 minutes (SD=3.64, Range: 5-21.18 minutes). The mean time for the BPI was 4.15 minutes (SD=1.67, Range: 1.05-9.21) and for the IPAQ was 7.83 minutes (SD=4.28, Range: 2.20-20.22). Measurements were recorded for height, weight, hip, and waist circumference three times taking a mean time of 1.73 minutes (SD=1.03, Range: 1-5). Therefore, an average of 25.38 minutes was needed to complete all three questionnaires and the clinical measures[6].

[6] Note that not all the questionnaires that were included in the main epidemiological study were included here as the aim of this section was to validate the amended and translated questionnaires only.

Even though there was a high number of missing responses for recording the time of the outcomes (the above mean time was calculated from a range of 32 to 66 responses), the third criterion was achieved. According to the results, all three criteria were successfully achieved.

3.6.9 Discussion

The aim of the feasibility study was to establish validation and determine the feasibility of the translated versions of the COPCORD and IPAQ questionnaires in a sample of participants attending the Woodstock CHC, in Cape Town.

3.6.9.1 Overview of sample of study

This sample was representative of the anticipated epidemiological and intervention studies described later in the thesis (in chapter 4 and 6). There were no differences found in the characteristics of the three language groups (English, isiXhosa, and Afrikaans) in terms of age, gender, presence of pain or CDL. Since there were no differences noted between the three language group responses, this could suggest that the language versions of the measurement instruments were equivalent and that the responses to the different outcome measures should be the same.

3.6.9.2 Validation of translated COPCORD questionnaires- isiXhosa and Afrikaans

A high number of missing responses were evident for some questions in the COPCORD. The question about receiving a pension or grant had less than 10 missing responses, however, 54% (n=50) of missing responses were found for the follow-up question specifying the *amount of income received*. Many factors could have influenced the high number of missing responses. Possible reasons could be that some participants did not want to admit and report their monthly income, or perhaps some women did not feel the need to disclose their income compared to men[259]. Other factors could be age, race or being disabled[260]. Unfortunately, it remains unclear why so many participants avoided answering this question.

Specific questions related to *stopping work due to illness; the type of illness that was the reason for stopping work, change work due to illness and reasons for changing work* had a range from 22 to 27 missing responses. This high missing response rate (24% to 29%) was rather confusing as these participants responded to previous questions about their current employment and nature of work.

These follow-up questions were intended to find out whether people who were unemployed or retired had to stop or leave their work due to having chronic joint pain or CDL. Even though some people (10%) indicated that chronic joint pain and CDL were the reasons for stopping work, the remaining participants responded not applicable (N/A) to this question as they did not stop work due to any illnesses and could have been retired or lost their jobs. This is understandable in a society like South Africa as the unemployment rate is considerably high[261].

The pain-related questions in the COPCORD (pain for more than three months and pain for the last seven days) had seven and eight missing responses, respectively. During the assessment of the responses to these questions, four participants stopped completing the questionnaire after the questions related to past medical history and injuries. These questions preceded the pain-related questions in the COPCORD. Therefore, one could assume that these participants were either disinterested in completing the rest of the questionnaire as it was too long or perhaps, they discontinued as they were next in line to see the doctor at the clinic. Another reason could be related to the self-report mode of administration of the COPCORD questionnaire. It is recommended that future studies of this type would need to ensure collection of data by interview administration.

The discriminative ability of the two COPCORD pain-related questions was demonstrated by the comparison of BPI scores. The BPI has been used in different cross-cultural studies and validated in several South African languages[262]. The significant difference in the mean PSS, with higher scores found in the group with acute MSD (seven-day pain), and the significant difference in the mean PIS in those with chronic joint pain indicate acceptable agreement between the instruments. Therefore, the agreement between the COPCORD pain questions and the BPI indicate acceptable criterion validity of the isiXhosa and Afrikaans versions of the COPCORD.

3.6.9.3 Validation of translated IPAQ questionnaires - isiXhosa and Afrikaans

There were 15 participants (cases) who did not answer the IPAQ questions (n=5) or who gave unreasonably high values and inappropriate responses (n=10) that were excluded from the analysis. The high missing response rate could imply that these participants had a challenge with the comprehension of some questions and that the questionnaire was too long. In addition, perhaps the self-report mode of administration of the IPAQ long form contributed to the high missing response rate. Similar problems were encountered in Nigeria with the self-report administration of the IPAQ-long form[263]. It is therefore recommended to do interview administration of the IPAQ long form in future studies as this method was the preferred method to use in developing countries and in Africa[227 263].

Further analysis indicated that there were no significant differences between the mean total physical activity MET min/week scores and the three language groups ($F_{2, 73}$=1.870, p=0.161). In other words, all the participants were able to understand the questions from the IPAQ, irrespective of their preferred home language. This could possibly infer that the translated isiXhosa and Afrikaans versions of the IPAQ were valid in this sample as the IPAQ scores were similar across languages.

Since there was no "gold standard" of measurement for physical activity available[257], construct validity of the IPAQ questionnaire was established through known-groups validity[258]. Known-groups validity is established when a test or questionnaire can discriminate between two groups that are known to possibly differ on the variable of interest[258]. Therefore, the previously validated COPCORD pain questions were used to define known groups and were compared to the categorical physical activity levels in the IPAQ.

There was no association between physical activity level categories and the presence or absence of chronic joint pain (three-month pain) (p=0.351). There was no association found between physical activity categories and acute MSD (seven-day pain) (p=0.838). Further analysis was done and no significant difference between physical activity MET min/week and chronic joint pain was found. In addition, there was no significant difference between physical activity MET min/week and acute MSD. The results of this study are inconsistent to other international and local studies. People with chronic joint pain, chronic low back and neck pain had lower intensity of everyday physical activity, compared to healthy people[264 265]. A more recent local study found similar results as participants with chronic pain had reduced levels of physical activity reported on the IPAQ[266]. Unfortunately, this was not the case in this study and known group validity, using the COPCORD pain questions, could not be established for the IPAQ questionnaire.

In addition to analysing the pain questions, the results showed no correlation between total physical activity MET min/week and BMI (r=-0.0148, p=0.906). There were also no differences found in the mean BMI scores and the physical activity categories ($F_{2, 63}$=1.270, p=0.287). These results are unexpected and inconsistent with the literature as one would assume that people with high BMI would have lower physical activity levels [267].

A local study by Parker et al., (2017)[266] found similar results to the latter study, with a higher mean BMI (29.36 kg/m^2) in the chronic pain group with low physical activity levels in all groups.

This finding could infer that people with chronic pain with higher BMI could have low physical activity levels, as was assumed for the sample of this study but was not the case. Therefore, the validity of the IPAQ in comparison to BMI is questionable in this sample. The possible reasons for the inconsistent results found in the IPAQ could be due to the lack of power estimations to detect a meaningful relationship between physical activity and chronic joint pain and BMI, even though a relatively large sample was used.

Another reason could be that physical activity was measured with the self-report IPAQ which could have led to reporting bias or misinterpretation of questions[268]. Unfortunately, there were no comparisons between self-reported physical activity levels and an objective physical activity outcome measure, which could have further supported the accuracy and validity of the responses to the physical activity items on the IPAQ. Finally, the results could be due to the poor comprehension of the physical activity items in the translated IPAQ long form. These findings highlight that even though the IPAQ long and short forms have been previously validated in both urban and rural areas in South Africa[227], known group validity of the IPAQ long form could not be established in this sample of participants.

3.6.9.4 Feasibility of using the translated outcome measures in research

To achieve the feasibility objective, the response rate, completion rate and time to complete all the outcome measures were assessed in the participants attending the Woodstock community health centre (CHC). This study had a response rate of 87.6% with a total of 92 individuals with most participants being female (79%). This high response rate (79%) of females is similar to the results of a local study by Parker & Jelsma (2010)[27]. These findings suggest that females are more likely to attend primary health care clinics for medical care than males. This finding is supported by international literature as females utilise health services more frequently than males[269 270].

A high number of participants completed all three questionnaires (92%); however, only 78% of participants completed both the questionnaires and the clinical tests. A relatively high proportion of people completed the questionnaires and left their place in the waiting area willingly to have their weight, height, waist, and hip measures taken by the researcher. This could imply that people considered research about their health conditions to be important, while knowing that their place in the waiting area might be affected.

The reported mean time to administer all three questionnaires (COPCORD, IPAQ and BPI) and the clinical tests was 25 minutes with the longest time spent on the administration of the COPCORD questionnaire (Mean time=11.67 minutes, SD=3.64) and the IPAQ long form (Mean time=7.83 minutes, SD=4.28). Unfortunately, no comparison data on the mean time of administering the COPCORD questionnaire was available from other studies as they did not report the mean time of the administration of these questionnaires. However, the mean time for administering the COPCORD and the IPAQ during the cognitive debriefing of the translated versions of the questionnaires (as documented in Chapter 3) was recorded and used for comparison. The recorded mean time of 24 minutes for the administration of the COPCORD and the IPAQ together in that translation study was longer than the mean time (19.5 minutes) reported in this feasibility sub-study. The longer time recorded could have been due to the participants requiring more time as they needed to read each question and answer the related cognitive debriefing questions ("do you understand the question, would you reword it in another way, are the response options consistent, can you rephrase this in your own words?"). Another reason could be due to some errors in the isiXhosa version which were amended after the cognitive debriefing. Therefore, the amended translated COPCORD and IPAQ questionnaires used in the feasibility sub-study were better and quicker to complete. Therefore, it seems possible to complete both the COPCORD and IPAQ questionnaires in any of the three languages in less than 20 minutes.

The results showed that this sub-study complied with the feasibility criteria set in section 3.6.2. Therefore, it is possible to assume that this sub-study was feasible and that all the outcome measures could be used for the main epidemiological study with minor recommendations to administer the questionnaires via interview mode. The implication of using interview methods is that it can be more time consuming than questionnaires as the researcher will engage in face-to-face interviews with participants; it is more expensive as the researcher needs to be drive to the research venues daily to gather data; participants might be unwilling to express their thoughts and feelings freely if being recorded; and may create opportunities for bias responses as the researcher may influence the interview with their perceptions and expectations [271].

3.6.10 Conclusion

Even though a high missing response rate was evident for some questions of the COPCORD, the results of the validation of the pain-related questions of the COPCORD with the PSS and PIS of the BPI showed acceptable agreement thus indicating acceptable criterion validity. Furthermore, the missing responses could possibly indicate that some questions of the COPCORD were too personal to answer, were too difficult to understand and the overall length of the questionnaire was a problem for some participants. It is therefore, recommended to change the self-report mode of administration of the COPCORD to interview mode to reduce the high missing response rate in future studies.

The validity of the IPAQ, the pain-related questions of the COPCORD and BMI showed inconsistent results compared to other local and international studies. There were no significant differences between people with acute or chronic pain, and no relationship between obesity and physical activity levels. Thus, known group validity could not be established with the translated IPAQ. Therefore, the validity of the use of the IPAQ long form is questionable in determining certain aspects of physical activity in people attending a local primary health care clinic in Cape Town. The high missing response rate of the IPAQ could imply that these participants had a challenge with the comprehension of some questions and that the questionnaire was too long. It is therefore recommended that the interview mode of administration of the IPAQ and possibly the IPAQ short form should be considered for use in future studies.

In terms of feasibility outcomes, the results showed that the outcome measures used in this study had successfully achieved the feasibility criteria as the response rate, completion time and time for administration of outcomes were within the parameters set. Therefore, it is possible to assume that this study would be feasible, and all the outcome measures could be used in the epidemiological study with the recommendation of collecting data using these outcome measures through interview mode.

4 CHAPTER 4: THE PREVALENCE, CHARACTERISTICS AND FUNCTIONAL IMPACT OF CHRONIC MUSCULOSKELETAL DISEASE AND COMORBIDITIES IN WOMEN ATTENDING A COMMUNITY HEALTH CENTRE IN CAPE TOWN

4.1 Introduction

In Chapter 2, osteoarthritis (OA) was identified as a major health problem affecting millions of elderly people across the world. The literature reviewed highlighted that OA is considered a chronic degenerative joint disease[66] and is reported mostly by older women[52, 63, 272]. However, some studies report that people in their early 40's have been diagnosed with OA and are suffering from this chronic disabling joint disease[23, 273]. The early onset of OA has a greater potential to affect the person's ability to function in the home and community. Therefore, it may be reasonable to assume that middle-aged people living with osteoarthritis are more likely to have reduced activity and functional limitations as they become older[23]. Multiple factors may contribute to this reduced activity and functional limitation.

The literature reviewed highlighted that middle-aged women with OA reported having more chronic diseases of lifestyle (CDL) such as hypertension (HPT) and diabetes mellitus type 2 (DM2) than men[22 272 36]. These findings suggest that a potential relationship between OA and CDL may exist[22] and that such a relationship might have an impact on functional activities at work and home, physical activity levels and health-related quality of life. As discussed in Chapter 1, patients with OA in Cape Town are often managed by physiotherapists and are recruited into group classes or clubs, while patients with CDL are managed by nurses using health promotion strategies at chronic care clubs in Community Health Centres (CHCs). Unfortunately, there appears to be no cross-over management for patients with OA and associated CDL in South Africa as they are being managed separately in primary health care clinics.

Modifiable factors, such as obesity and lack of physical activity, are associated with OA[21 110]. These modifiable risk factors are common for CDL (HPT and DM2) and for OA in women[3, 104, 113]. Since these chronic diseases share the same modifiable risk factors, it is reasonable to assume that a relationship could exist between OA and CDL. Should such a relationship exist, appropriate and contextually relevant management strategies addressing the risk factors and the conditions need to be developed. To develop and implement such an intervention strategy, a description of the population and an understanding of the interrelationships between OA and CDL are needed.

4.2 Aim and objectives

This study aimed to inform the development of a contextually relevant intervention for disadvantaged women affected with both OA and CDL, by establishing the profile of women attending a CHC to understand the burden of chronic disease and the interrelationship between OA and CDL in this population. This phase of research aimed to establish the prevalence of OA and CDL, and describe the characteristics, physical activity levels, and health-related quality of life of women with both OA and CDL attending a Community Health Centre (CHC). Since some patients would be attending the CHC for a consultation for the first time and might not have been previously diagnosed with OA, the term "chronic joint pain", based on the COPCORD, was used. This term was operationally defined as "self-reported pain, aching, swelling, stiffness in or around the joints or back which was not related to an injury or accident during the last three months".

The specific objectives were:

- To ascertain the prevalence, characteristics and functional impact of chronic joint pain and common chronic diseases of lifestyle in women older than 18 years attending a CHC using an adapted version of the COPCORD and the WHODAS questionnaires.
- To identify what clusters of chronic diseases of lifestyle (e.g. hypertension, diabetes, cardiovascular conditions etc.) and chronic joint pain occur in women attending the health centre.
- To explore possible associations between women with chronic joint pain and common chronic diseases of lifestyle with other factors (age, obesity, lack of physical activity) by measuring body mass index (BMI), physical activity (PA) and health-related quality of life (HRQOL) in these participants using clinical measurements, the International Physical Activity Questionnaire (IPAQ) and EQ-5D-3L, respectively.

4.3 Methodology

A cross-sectional, descriptive, analytical design was used for this phase of the study. Purposive sampling was used to identify a CHC in which both the cross-sectional and the intervention studies could be conducted. Criteria for the selection of the CHC included:

- Servicing an under-resourced and disadvantaged area in Cape Town
- Of sufficient size to generate an adequate sample for this study, a minimum of 2500 patient visits per week
- Clinical management is willing to participate and make resources available.
- Offer both chronic care clubs for those with CDL and education or exercise groups for those with chronic joint pain or OA

There are 35 Community Health Centres (CHCs) in the Cape Metropole Region in Cape Town [274], of which eight met the above criteria. Of these eight, only three (Mitchells Plain, Elsies River and Retreat CHC) were willing to participate. Finally, the Mitchells Plain CHC was chosen for the study as the other two CHCs did not have adequate space to conduct both phases of this study.

Mitchells Plain CHC is one of the largest CHCs in the Cape Metropole region serving approximately 1.2 million people, who are disadvantaged by the lack of basic services, low levels of education, unemployment, and inadequate housing. The majority of the population (80.5%, n=966 000) are dependent on public health care services as they do not have medical aid[275]. Furthermore, while there are nine health care facilities in Mitchells Plain, the Mitchells Plain CHC is the only health care facility that offers comprehensive primary health care (PHC) services to approximately 46 000 patients per month. This CHC has a staff complement of 170 people and provides the following care services [275]:

- 24-hour trauma unit
- Outpatient department
- Mental health services
- Paediatric services (< 5 years old)
- Maternity obstetric unit (MOU)
- Reproductive health
- Pharmacy and dispensary
- Chronic Diseases of Lifestyle (CDL) clinic and CDL clubs
- Antiretroviral (ARV) clinic

- Allied health professional services (physiotherapy, dietician, occupational therapy, social worker, dentists, optometry etc.)

4.3.1 Sample

The population considered for the recruitment of eligible participants for this study was all people residing in Mitchells Plain and the sampling frame was all people attending the Mitchells Plain CHC for medical treatment.

4.3.1.1 Participants

The following inclusion criteria were used to select eligible participants:

- All women older than 18 years attending the CHC for any medical reason
- All women who were willing to participate in the study

The decision to restrict recruitment to women was based on the following:

- a higher prevalence of chronic joint pain is found in women compared to men[16 27 276];
- the prevalence of isolated chronic diseases of lifestyle (CDL) is higher in women[3];
- multimorbidity (two or more diseases) is more prevalent in women than in men[276];
- the majority of those who attend CHCs are women[27]

In addition, middle-aged to older women living in South Africa are often "lone mothers" who are responsible to provide for unemployed or sick adult children, grandchildren whose parents have died due to illness; and their own children due to absent fathers[277 119]. Therefore, these women living in Mitchells Plain are dependent on public health care services for treatment for chronic diseases.

Participants were excluded due to the following criteria:

- Too ill to participate (cold/flu, diarrhoea, gastroenteritis, acute traumatic MSD injuries, fever, infection) upon questioning on days of data collection, the patient was excluded as the patient may have been disoriented and unable to answer questions appropriately
- Presenting with neurological conditions (such as stroke), recent trauma, or previously diagnosed severe intellectual impairments as these patients may not be able to comprehend the questions in the questionnaires

4.3.1.2 Sample size calculation

The sample size was calculated based on the recommendation by Formann (1984) (as quoted by Dolnicar, 2002)[278] that the minimal sample size should include no less than 2^k cases (k = number of variables). The variables that were included in the analysis were: age, presence of diabetes, high blood pressure, cardiovascular disease, MSD, obesity, level of physical activity, health-related quality of life, and disability (nine variables). Therefore, the minimal sample size needed was 512 women (2^9).

4.3.2 Instrumentation

The data were collected using the following outcome measures, as previously discussed in detail in Chapter 3 (Appendix D):

- COPCORD
- Brief Pain Inventory (BPI)
- WHODAS 2 12-item
- EQ-5D-3L
- IPAQ
- BMI

4.3.3 Procedure

Ethical approval was obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Cape Town (HREC Ref: 093/2014) (Appendix A-1) and permission obtained from the Western Cape Department of Health (RP 030/2014) (Appendix A-2). Permission for access to the CHC was negotiated and obtained from the facility managers and heads of physiotherapy departments (Appendix C). The facility manager, the physiotherapist in charge and all the nurses and doctors working at the CHC were informed of the purpose and procedure of the study. A calendar of dates for data collection and an information sheet describing the study was given to the facility manager to inform the staff.

Female research assistants were recruited from the post-graduate students of the UCT Division of Physiotherapy. Final (4^{th}) year undergraduate physiotherapy students from UCT were recruited as research assistants and were trained on the aims and objectives of the study, research methods, outcome measures and procedures using the research protocol as a training document.

During the data collection phase, the study co-ordinator was available daily with the research team to ensure that the data collection procedures were conducted according to the protocol. The PI met with the study co-ordinator weekly to discuss any challenges regarding recruitment of participants or data collection procedures. These discussions were useful to ensure that the planned research activities and procedures stipulated in the protocol were carried out accordingly. Fortunately, there were no deviations from the research protocol as the data collection phase ran smoothly.

On the days of data collection (Monday to Friday), a research assistant approached all women waiting in queues to be seen by other health professionals and explained the purpose of the research study. Patients who were interested in participating were provided with informed consent forms outlining study procedures and granting access to their medical records (Appendix B). On completion of the consent forms, the participants were escorted to a separate room to complete the questionnaires. The research assistant administered the self-reported questionnaires (adapted COPCORD questionnaire, BPI, EQ-5D-3L, WHODAS 2, IPAQ) (Appendix D) to the participant and confirmed information relating to chronic diseases from the participant's medical folder. Thereafter, participants were sent to a different research assistant, trained in taking clinical measurements, to measure weight and height.

During the data collection of each participant, another research assistant held the participant's place in the queue. After all questionnaires and tests were completed, the participants were informed about the second phase of the study (intervention study) and those who were interested in participating, provided their contact details to the research assistant for future correspondence.

4.3.4 Data management and Statistical Analysis.

The free Magpi mobile data application[279] was used to develop electronic versions of the questionnaires and 3G enabled Android tablets were used by the research assistants to gather, record and send data to a central online database. The data were downloaded, cleaned, and organised for analysis. The data files were protected with a password and it was stored on a server that was backed up by an external hard drive. Both the server and the external hard drive was firewall protected.

Missing data, from participants that did not complete all the instruments, were managed according to the scoring protocols of each instrument. For the IPAQ, if data were missing for the time or days variable, that case was removed from the analysis. If the total minutes of combination of walking, moderate and vigorous time variables were more than 960, that case was removed from the analysis[230].

The missing data for the other instruments were included in the analysis and for some outcomes, additional analyses through Chi-square tests were done to test for possible relationships with missing responses.

Descriptive statistics were used to describe the prevalence, characteristics, functional impact, physical activity levels, health-related quality of life and management of chronic joint pain and CDL. As the sample size was greater than 30, the "central limit theorem" was applied and in most cases, parametric statistics were used for numerical data.

The central limit theorem states that if a sample size is large enough (>30), the means of the sample would be closer to the mean of the population and would approach a normal distribution of the mean regardless of the distribution of the population and normality of the data[280]. However, histograms were scrutinized to ensure that the data were not grossly abnormally distributed. In cases, where gross abnormality was identified, non-parametric statistics were employed.

The prevalence of chronic joint pain and common CDL was calculated as a percentage with 95% confidence intervals. Comparisons and relationships were analysed between those with chronic joint pain and CDL and those without disease with other variables of interest (age, obesity, physical activity, health-related quality of life and functional limitations). Differences were examined between the participants' with and without chronic diseases using t-tests for parametric data, chi-squared tests for nominal data, Mann-Whitney U test for ordinal data and Spearman correlations for numerical data. All data were presented as the mean ± standard deviation. Statistical significance was accepted as $p< 0.05$.

Decision tree analysis (CHAID) was used to establish if there were relationships between chronic joint pain, CDL, and risk factors such as age, BMI and physical activity levels using a tree image to visualize possible pathways[281]. Chi-squared IBM SPSS Automatic Interaction Detector (CHAID) is a statistical, multi-way tree algorithm that explores data quickly and efficiently, and builds segments and profiles concerning the desired outcome[282]. The CHAID algorithm builds non-binary trees (trees where more than two branches can attach to a single root or node), based on a relatively simple algorithm that is particularly well-suited for the analysis of larger datasets[283].

4.3.5 Ethical considerations

As mentioned in the Procedure, ethical approval, and permission to access the facilities were obtained from all relevant authorities. The study conformed to the principles of the Declaration of Helsinki (Brazil, 2013)[284].

4.3.5.1 Autonomy

Participants were informed that participation in the study was voluntary and that it would not affect their scheduled appointments at the Community Health Centre. Participants were informed that they could withdraw from the study at any stage without being penalised in any way. An information sheet was provided to the participant in their preferred language (English, Afrikaans, or isiXhosa) and informed consent forms were administered to the participants and signed before completing the questionnaires. Demographic and personal information of all participants was kept confidential and were used for the research study only. All hard copies of data related to participants were filed and stored in a secured and locked cabinet. Participants were informed that the results of the study might be published in a medical/health care journal or newspaper to create an awareness of the profile of women with chronic joint pain and comorbidities at the CHC.

4.3.5.2 Beneficence, Non-maleficence, and Risks

This study used a cross-sectional design and due to the nature of the design, participants were interviewed once and did not receive any remuneration for participation. However, the participants were informed that they would contribute to society by providing information about their health profile and whether they had chronic joint pain or not to determine the burden of disease and need for interventions in women attending the CHC. In addition, the participants were informed that they might have the opportunity of participating in the intervention (Phase 2) study.

The cross-sectional study was an observational study which posed no or minimal risk of injury or harm. The University of Cape Town provided a no-fault insurance for all participants. Participants had the right to claim compensation for an injury in the event of negligence by the researchers.

4.3.5.3 Justice

The participants were recruited from a population that has been previously marginalized within the South African context: women and those of Black or mixed (Coloured) descent, living in a resource constrained setting such as Mitchells Plain. These groups of women were unlikely to have access to private medical care and are dependent on the public health care system for health services. In terms of distributive justice, this was deemed an appropriate target population.

4.4 Results

Data were collected from 1 June 2014 to 30 September 2014 at Mitchells Plain CHC in Cape Town. A total sample of 803 participants was included in the study (Figure 8).

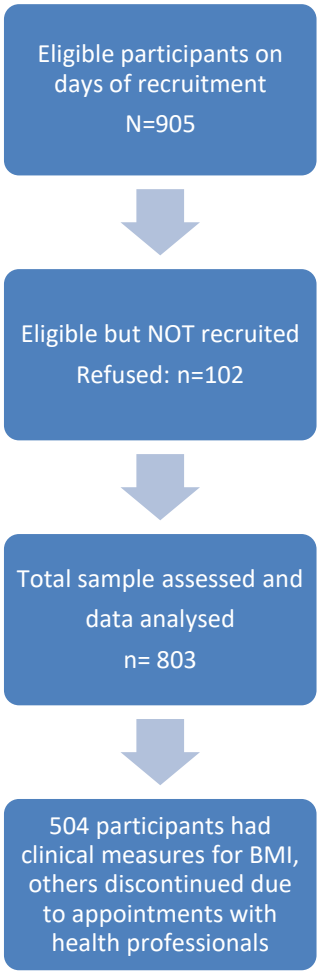


Figure 8: Recruitment process

4.4.1 Demographic and socio-economic profile of sample

There were 803 women recruited with a mean age of 48.4 years (Standard deviation (SD) =16.6; Range: 18-89), see Figure 9.

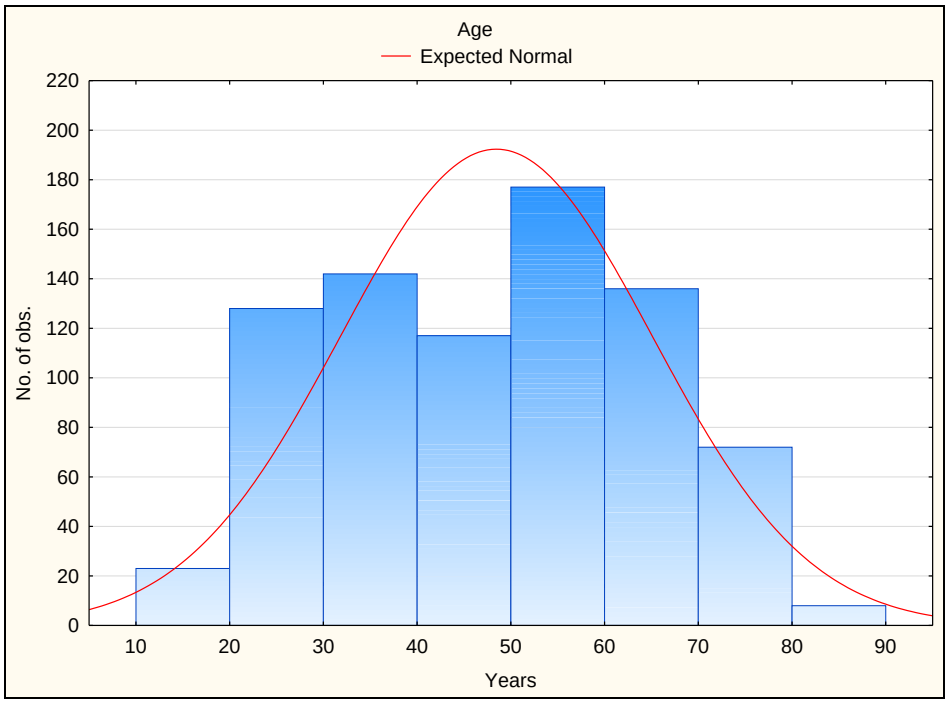


Figure 9: Histogram of the ages of participants

There were 36% of the participants who spoke isiXhosa, 35% who spoke Afrikaans and 27% were English speaking. Most participants were married (42.5%), approximately one third were single and 10% had no children. Nearly a third of the participants had completed Grade 7 (primary school) or less, whereas more than half had attended high school (55.7%) (Table 17).

Unemployment was reported by 43.7% of the women, whereas about 30% were in paid employment. Furthermore, 35% of the women reported that they do not receive a social services grant, whereas 30% received a pension and 78% earned a monthly income of less than R2000. A high proportion (44.2%) of participants reported that they were the breadwinner (head of the household) of their families (Table 18).

Table 17: Demographic information of sample (n=803)

Variable	Category	Frequency	Percent
Home Language	IsiXhosa	292	36.2
	Afrikaans	285	35.4
	English	218	27
	Other	8	0.9
	Total	**803**	100
Marital status	Married	342	42.5
	Single	291	36.1
	Widowed	114	14.1
	Separated/divorced	56	6.9
	Total	**803**	100
Number of Children*	0	76	9.5
	1	138	17.2
	2	178	22.1
	3	175	21.8
	4	110	13.7
	5	69	8.6
	6 or more	57	7
	Missing	1	0.1
	Total	**803**	100
Level of education (grade)	0	8	0.9
	1	6	0.7
	2	3	0.3
	3	18	2.2
	4	11	1.3
	5	18	2.2
	6	74	9.2
	7	49	6.1
	8	73	9.0
	9	82	10.2
	10	85	10.5
	11	76	9.4
	12	131	16.3
	13**	25	3.1
	Missing	144	17.9
	Total	**803**	100

**Not specified if living or dead, ** Tertiary education*

Table 18: Socio-economic status of participants (n=803)

Variable	Category	Frequency	Percent
Current employment	Unemployed	352	43.7
	Housewife	200	24.8
	Administration	66	8.2
	Retired	57	7
	Manual	49	6
	Professional	17	2.1
	Security	12	1.4
	Other	46	5.7
	Missing	4	0.6
	Total	**803**	**100**
Social grants*	Pension	184	22.9
	Temporary DG	67	8.3
	Permanent DG	111	13.8
	Childcare grant	174	21.7
	Foster care grant	2	0.2
	Other grant	5	0.6
	No grant	285	35.4
	Total	**828**	**103**
Income (Rand per month)	0-1000	249	31
	1001-2000	376	46.8
	2001-3000	77	9.6
	3001-5000	40	5
	5001-7000	16	2
	>7000	11	1.4
	Missing	34	4.4
	Total	**803**	**100**

** Several respondents received multiple grants.*

The participants were asked about smoking and use of alcohol. Most of the participants reported that they never smoked cigarettes (66%) and never consumed alcohol (74%). A smaller proportion (12%) of participants reported that they had stopped drinking alcohol and 13% were still consuming alcohol. Of those who indicated that they smoked cigarettes, 12% reported that they stopped smoking and 22% were currently smoking.

4.4.2 Chronic joint pain and other chronic diseases

To establish the burden of chronic joint pain in this sample, the following question was asked from the COPCORD: "*During the last 3 months have you experienced pain, aching, swelling, stiffness (tightness) in or around your joints or back which is not related to an injury/accident?".* A chronic joint pain (referred to as MSD in figures and tables) prevalence of 45.3% (95% Confidence Intervals [CI] =41.9-48.8%) was found with 43.4% (158 of 364) of those having been medically diagnosed with OA previously (Table 19). Hypertension (HPT) was the most diagnosed chronic disease (52.6%) followed by other CDL (30.2%) and diabetes mellitus type 2 (DM2) (23%). The "other CDL" could refer to HIV/AIDS as the CHC provides two separate clinics for chronic diseases, one for treatment of CDL and the other for HIV/AIDS. However, the researchers did not ask the women to disclose information about other chronic diseases of lifestyle (Table 19).

In addition, almost one third (31%) of the participants reported that they had attended the CHC on the day of data collection to visit the medical practitioner for an initial assessment of CDL (10.3%) and for other health problems (21%). Only a small proportion of women (4.6%, n=37) attended the CHC and waited in the queue for physiotherapy for assessment and treatment of osteoarthritis or other health conditions.

Table 19: Prevalence of Medical conditions reported by sample (n=803)

Medical condition	**Frequency**	**Percent**	**95% CI**
Hypertension	422	52.6	49.1-55.0
Chronic joint pain (MSD)	364	45.3	41.9-48.8
*Diagnosed with OA (included in Joint pain above)**	*158*	*43.4*	*38.4-48.5*
Other CDL	243	30.2	27.2-33.5
Diabetes Mellitus Type II	186	23.1	20.4-26.2
Hypercholesterolemia	179	22.3	19.6-25.3
Respiratory disease	97	12.1	10.0-14.5
Cardiovascular diseases	55	6.8	5.3-8.8
Mental illness	18	2.2	1.4-3.5

*Note that participants could report more than one condition. *Of those reporting joint pain, only 158 had been given a diagnosis of OA (43.4% of those with joint pain). Confidence Interval of a Proportion was calculated using Vassarstats, http://vassarstats.net/prop1.html*

Figure 10 illustrates that 13% of the women (n=104) reported having chronic joint pain (MSD) with no comorbidity, whereas 20% (n=161) had MSD plus hypertension and 2% had MSD plus DM2 (n=14). Eleven percent of women (n=85) had all three chronic conditions.

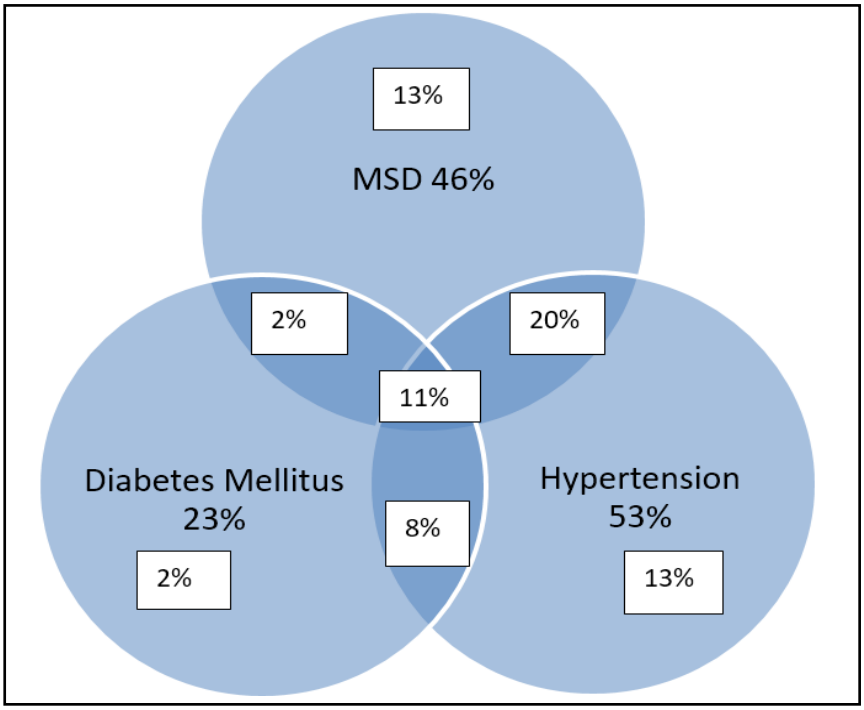


Figure 10: Proportion of participants with multiple chronic diseases

Note that percentage refers to total number of participants who were interviewed (n=803, missing=9 responses for chronic joint pain) and not those who had health problems.

As the prevalence of HPT was so high and many participants reported comorbidity with MSD, the impact of HPT on HRQoL and functioning was examined further. There was a significant difference in age between those that had hypertension (HPT), diabetes mellitus type II (DM2), cardiovascular disease (CVD), hypercholesterolemia (HCL) and chronic MSD compared to those who did not report these chronic diseases, with an older age in those with the chronic diseases (Table 20).

Table 20: Comparison of ages of those with and without MSD and chronic diseases

Condition	Mean ± SD of Age (with the disease)	Mean ± SD of Age (without disease)	Statistic
HPT	58.4 ± 12.1	37.4 ± 13.7	t=22.8; p<.001
DM2	59.1 ± 12.0	45.2 ± 16.5	t=12.5; p<.001
CVD	60.7 ± 11.1	47.5 ± 16.6	t=8.1; p<.001
HCL	58.4 ± 11.1	45.6 ± 16.8	t=11.9; p<.001
Chronic joint pain (MSD)	53.0 ± 13.4	44.5 ± 17.9	t=7.6; p<.001

All conditions were tested with separate variances as the F value was significant

There was a large rise in the prevalence of all conditions from the 40-49 age category to the 50-59 age category. From this point, the patterns of prevalence diverged with HPT and DM2 continuing to rise with increasing age. MSD dropped from a peak prevalence of 76% at 50-59 to 57% at 60 years and 39% at 70. HCL decreased after 60-69 years. Cardiovascular disease remained constant after 50 years (Figure 11).

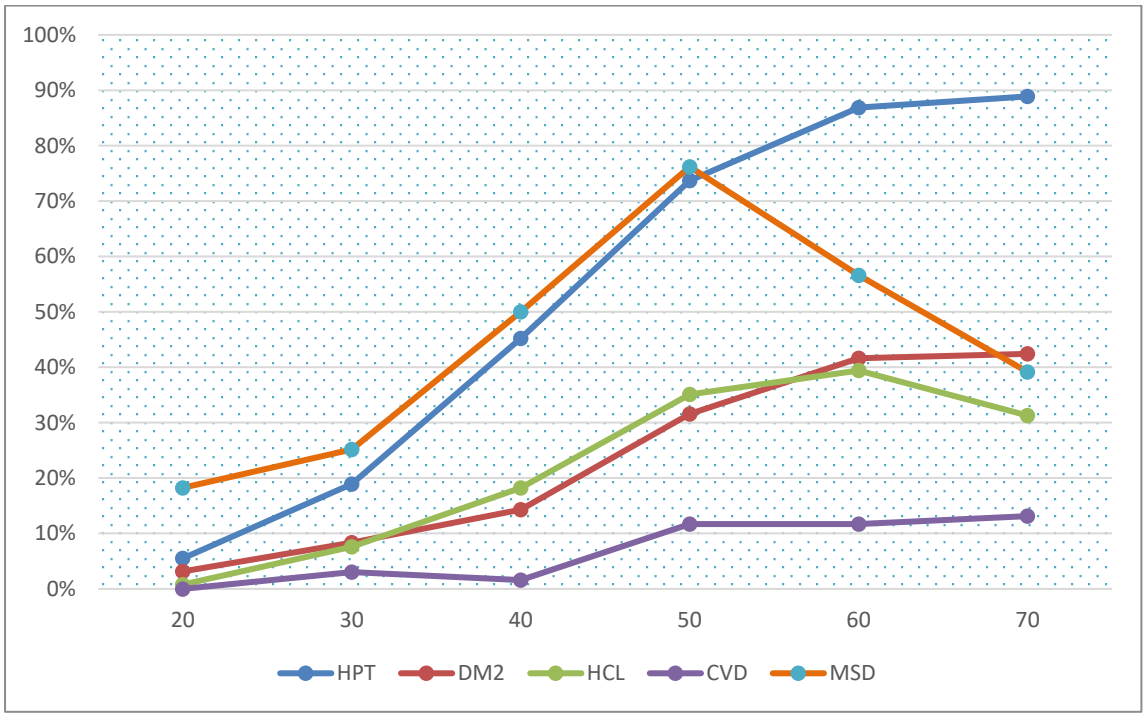


Figure 11: Percentage of women with each medical condition per age category

The participants' reported on the medication they used for their chronic diseases. Glucophage/Metformin used for Diabetes mellitus type II was the medication most reported (30%), followed by Enalapril/Pharmapress and Aspirin (26.4%) that is used for Hypertension. A quarter of the sample used Ridaq/Hydrochlorothiazide (HCT) for Hypertension and other CDL medication (26%) respectively (Table 21).

Table 21: Medication for chronic diseases (n=803)

Condition	Medication	Frequency	Percent
Hypertension (HPT)	Pharmapress/Enalapril	212	26.4
	Ternomin/Atenolol	73	9
	Ecotrin/Aspirin	212	26.4
	Ridaq/ HCT	207	25.7
Diabetes mellitus type II (DM2)	Glucophage/Metformin	241	30
	Insulin	119	14.8
Hypercholesterolemia (HCL)	Zocor/Simvastatin	62	7.7
Cardiovascular disease (CVD)	Lasix/Furosemide	13	1.6
	Thiazide	5	0.6
	Lotensin/Benazepril	9	1.1
Other medical problems	Panado/Paracetamol	77	9.5
	Brufen/Ibuprofen	44	5.4
	Ultram/Tramadol	84	10.4
	Elavil/Amitriptyline	16	1.9
	Stilpane/Paracetamol+Codeine	13	1.6
	Voltaren/Diclofenac Sodium	18	2.2
Other CDL	CDL meds	205	25.5

Some respondents used more than one medication for CDL

4.4.2.1 Characteristics of pain, pain severity and pain interference

The most common sites of chronic joint pain were the knee (62%) and shoulder (43%) (Table 22). More than half of those with pain (57.7%, n=210), reported that the pain started more than a year ago. Pain lasting for a few hours was reported by 51.4% (n=187) and is most intense at night by 39.3% (n=143). Morning joint stiffness was reported by 73% (265 of 364) (95% CI: 0.68-0.77) of those with MSD, particularly in the knee (49%), lower back (41%) and shoulder (32%).

Table 22: Anatomical sites of pain (n=364)

Sites of pain	Frequency	Percent of those with MSD
Knee	226	62
Shoulder	156	42.8
Lower back	150	41.2
Hand/Fingers	130	35.7
Hip	88	24
Foot/Toes	85	23.3
Ankle	83	22.8
Elbow	76	20.8
Wrist	73	20
Neck	58	15.9
Mid back	41	11.2
Missing	49	13.4

Note that participants could report more than one site of pain

Questions related to the medical treatment received for chronic joint pain (MSD) at the CHC were asked to all participants. Unfortunately, these questions did not ask the specific types of analgesia or NSAIDs but only asked whether the participants had received analgesia, NSAIDs, injection and other medication. Of the 364 participants with MSD, only 14% reported receiving no medication. The majority (70.4%) were using prescribed oral analgesia and/or prescribed oral non-steroidal anti-inflammatory drugs (NSAIDs). Relief of symptoms by medication was reported by 64% (Table 23).

Of those with MSD, 37 participants (10%) reported visiting the physiotherapy department at the CHC on the day of the interview. The participants' who had physiotherapy reported that the top three non-pharmacological interventions for chronic joint pain were exercise (20%), massage (7%) and education about the condition (6.6%). Of those with MSD, 14.8% and 14.6% reported that exercise and medication respectively were the best interventions that reduced their symptoms (Table 23).

Table 23: Medical and non-pharmacological treatment for MSD pain (n=364)

MSD Treatment	Frequency	Percentage of those with MSD
Medication		
OTC analgesia	85	23.4
OTC NSAIDs	11	3.0
Prescribed oral analgesia	190	52.2
Prescribed oral NSAIDs	66	18.1
Injection	10	2.7
Other medication	9	2.5
Natural remedies	19	5.2
Effect of Medication		
Relieved symptoms	234	64.3
Did not relieve symptoms	39	10.7
Missing	40	10.9
Did not receive medication	51	14.0
Non-pharmacological Treatment		
Education	24	6.6
Electrotherapy	9	2.5
Exercise	70	19.2
Joint mobilisation	17	4.7
Massage	25	6.9
Strapping /Bracing	1	0.3
Dry needling	7	1.9
Other treatment	8	2.2
Natural	8	2.2
Best treatment modality		
Medication	53	14.6
Exercise	54	14.8
Education	14	3.8
Massage	13	3.6
Joint mobilizations	7	1.9
Acupuncture	3	0.8
Electrotherapy	4	1.1
Injection	3	0.8

OTC- Over the counter, Note- participants could receive more than one intervention

The pain severity and pain interference scales of the BPI were completed by 229 and 227 participants respectively who reported pain in the previous week. The mean pain severity score (PSS) was 5.3 (SD= 1.45) and the mean pain interference score (PIS) was 4.9 (SD= 2.26) for 227 participants. The mean worst pain severity was 8 (SD=1.69) and current pain severity was 4.4 (SD=3.15). Pain interfered mostly with general activity (mean: 5.86, SD=2.83), normal work (mean: 5.76, SD=3.09) and sleep (mean: 5.74, SD=3.46) (Table 24).

Table 24: Mean (SD) scores for pain severity and pain interference in women (n=229)

Brief Pain Inventory	**Mean ± SD**
Pain Severity Score	***5.34 ± 1.45***
Worst pain	8.06 ± 1.69
Least pain	3.35 ± 2.02
Average pain	5.53 ± 1.94
Pain now	4.44 ± 3.15
Pain Interference Score	***4.88 ± 2.26***
Pain interference with general activity	5.86 ± 2.83
Pain interference with mood	5.32 ± 3.38
Pain interference with ability to walk	5.44 ± 3.25
Pain interference with ability to do normal work	5.76 ± 3.09
Pain interference with relations with other people	2.59 ± 3.10
Pain interference with sleep	5.74 ± 3.46
Pain interference with enjoyment of life	3.74 ± 3.28

Further details regarding the normality of the Pain severity data and the histograms of the Pain interference-physical functioning and the psychological domains are reported in Appendix F.

4.4.3 Modifiable risk factors for MSD and CDL

4.4.3.1 Body mass index (BMI) (n=504)

The mean BMI of the participants was 30.8 (SD=7.54, range 17.2-59.3). As there were many missing responses (n=299) due to time pressure in the clinics when data collection took place, the Chi-Square test was used to test if the presence of diagnostic categories was related to having missing responses. The missing responses were not related to the presence or absence of HPT (Chi Sq=0.506, p=0.477), DM2 (Chi Sq=0.225, p=0.635), HCL (Chi Sq=2.144, p=0.143), CVD (Ch Sq=0.019, p=0.890) or MSD (Chi Sq=3.005, p=0.083). It was unlikely that the missing responses would bias the findings.

Of the 504, 22.3% had a normal BMI, 26% were overweight and the remaining 51% were obese. As there were such a high number of obese participants (n=259), the BMI categories were collapsed into Other (underweight, normal, and overweight) and Obese categories. There was a significant association between BMI and MSD (Chi Sq=5.24, p=.022) with 48% of obese participants reporting MSD compared to 38% of participants in the Other BMI category. Participants with cardiovascular diseases (CVD) and MSD had significantly greater BMI (Table 25).

Table 25: Comparison of the mean BMI of females with chronic diseases

Condition	Mean ± SD in those with the condition	N with condition	Mean ± SD in those without the condition	N without condition	Statistic
HPT	31.0 ± 7.7	260	30.6 ± 7.2	244	t=0.5; p=0.61
DM2	31.2 ± 7.5	114	30.7 ± 7.5	390	t=0.5; p=0.55
CVD	34.9 ± 10.8	35	30.5 ± 7.1	469	***t=2.3; p=0.02***
HCL*	31.7 ± 8.4	104	30.6 ± 7.2	400	t=1.2; p=0.23
MSD*	31.8 ± 7.8	217	30.0 ± 7.1	282	***t=2.6; p<0.01***

* *Tested with separate variances*

4.4.3.2 Physical activity levels (PA) (n=803)

Physical activity information was obtained from 803 participants and was presented as Total Physical activity Metabolic Equivalents of Task (MET) minutes per week (MET min/week). The scores were grossly abnormally distributed and non-parametric statistics were used. The median value of Total Physical activity MET-min/week (PA MET) was 2499 (IQR: 3363, Range: 13.2-18774). The median value for MET-min/week for vigorous activities was 0 (IQR: 240, Range: 0-13440), for moderate activities was 480 (IQR=1680, Range: 0-8400) and for walking was 693 (IQR: 1716, Range: 0-14454).

The Mann Whitney U test was used to determine differences between levels of PA MET by chronic diseases in the sample. The sum of ranks for PA MET was significantly lower in women with each of the chronic diseases (Table 26).

Table 26: Comparison of Total PA MET-min/week in women with chronic diseases

Condition	PA MET Rank sum in those with the condition	N with condition	PA MET Rank sum in those without the condition	N without condition	Statistic
HPT	130190.5	384	138087.5	348	***Z=3.69; p<0.001***
DM2	57501.50	170	210776.5	562	***Z=1.98; p=0.04***
CVD	16252.50	51	252025.5	681	Z=1.67; p=0.09
HCL	55216.50	164	213061.5	568	***Z=2.04; p=0.04***
MSD	112909.5	330	148816.5	393	***Z=2.34; p<0.001***

Tested with Mann-Whitney U test; PA MET = Total Physical activity MET-min/week

More than one third (38%) of participants reported High PA levels within a period of 7 days. The number of participants that reported Low and Medium PA levels were approximately equal (Table 27).

Table 27: Physical activity categories for participants (n=803)

PA category	Frequency	Percent
Low PA levels	251	31.2
Medium PA levels	236	29.3
High PA levels	304	37.8
Missing	12	1.61
Total	803	100

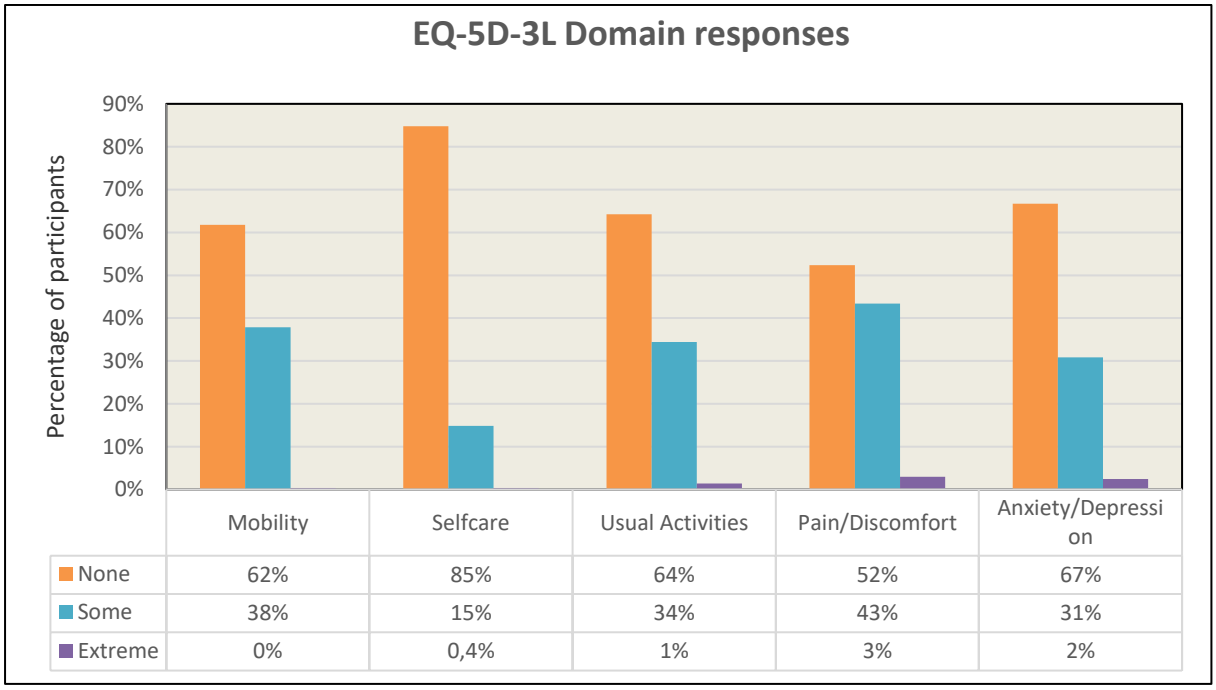
There was an association between MSD and PA level (Chi Sq=18.5, p<0.001) with a higher proportion of women with MSD reporting Low PA levels compared to those without MSD. Hypertension and PA levels were also associated (Chi Sq =17.96, p<0.001), with more women with hypertension reporting Low PA levels compared to those without hypertension (Table 28).

Table 28: Relationship between categories of physical activity levels and MSD and HPT (n=803)

Condition	PA Low	PA Moderate	PA High	Statistics
MSD				Chi Sq=18.5 p<0.001
Yes	126 **(34.6%)**	112 (30.7%)	123 (33.7%)	
No	123 (28.6%)	118 (27.4%)	180 (41.8%)	
HPT				Chi Sq=17.96 p<0.001
Yes	160 **(38.1%)**	120 (28.5%)	140 (33.3%)	
No	91 (24.5%)	116 (31.2%)	164 (44.2%)	

4.4.4 Health-related quality of life (n=779)

Approximately 40% of the women had some problems in the domains of Mobility, Usual activities and Anxiety/Depression, about 50% had some problems with Pain/Discomfort. Less than 15% had some problems with Self-care (Figure 12).



	Mobility	Selfcare	Usual Activities	Pain/Discomfort	Anxiety/Depression
None	62%	85%	64%	52%	67%
Some	38%	15%	34%	43%	31%
Extreme	0%	0,4%	1%	3%	2%

Figure 12: Responses of participants to domains of EQ-5D-3L
N=779, 24 Missing responses not included

Comparisons between women with MSD and those without were done across the domains. Higher proportions of women with MSD reported having some problems in all five domains compared to women without MSD.

Significant associations were found between having MSD and all five domains namely: EQ-5D-3L mobility (Chi-Sq=106.5; p<0.001), EQ-5D-3L self-care (Chi-Sq=63.9; p<0.001), EQ-5D-3L usual activities (Chi-Sq=86.6; p<0.001), EQ-5D-3L pain and discomfort (Chi-Sq=148.2; p<0.001) and EQ-5D-3L anxiety/depression (Chi-Sq=37.5; p<0.001) (Figure 13).

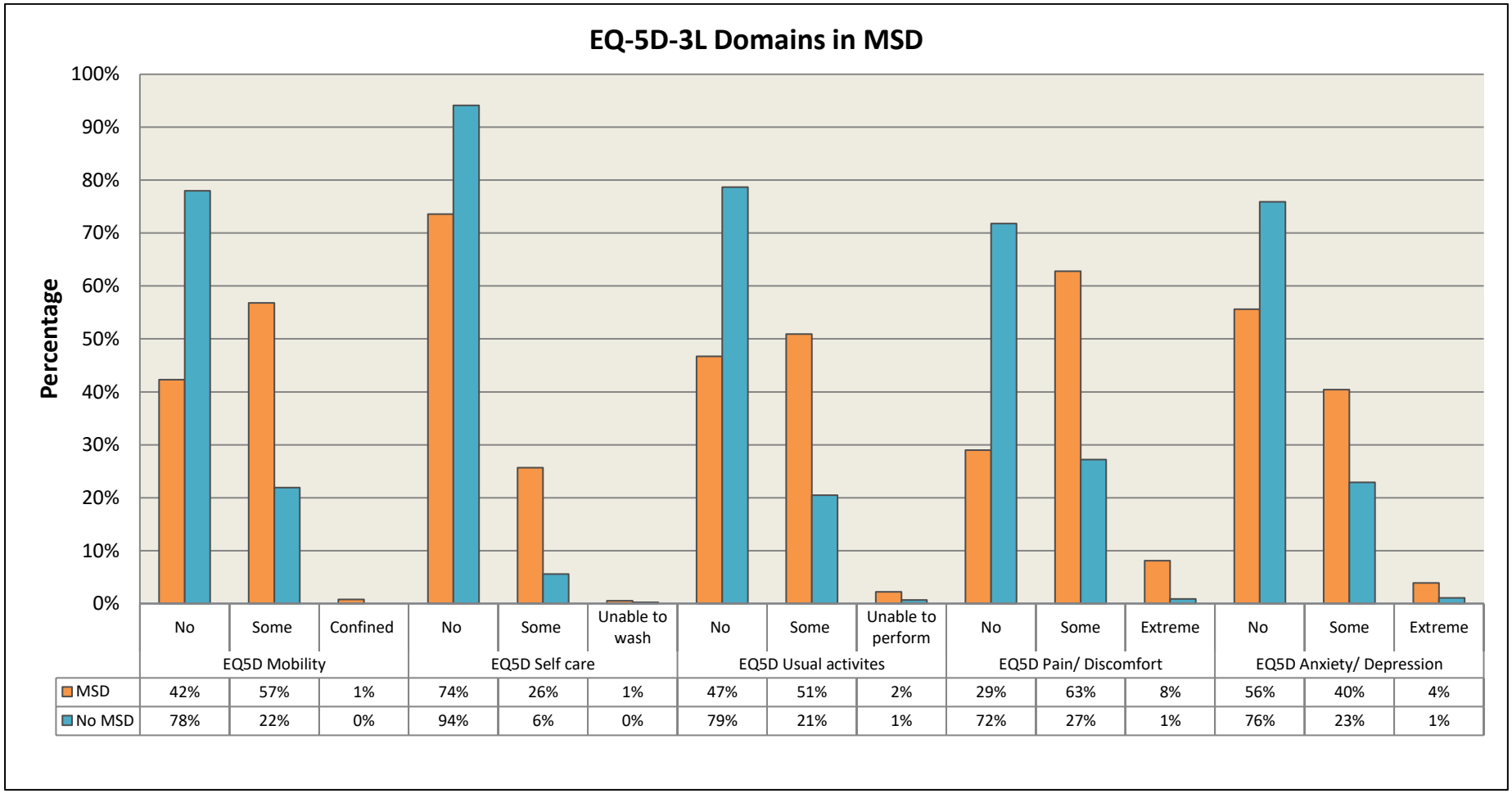
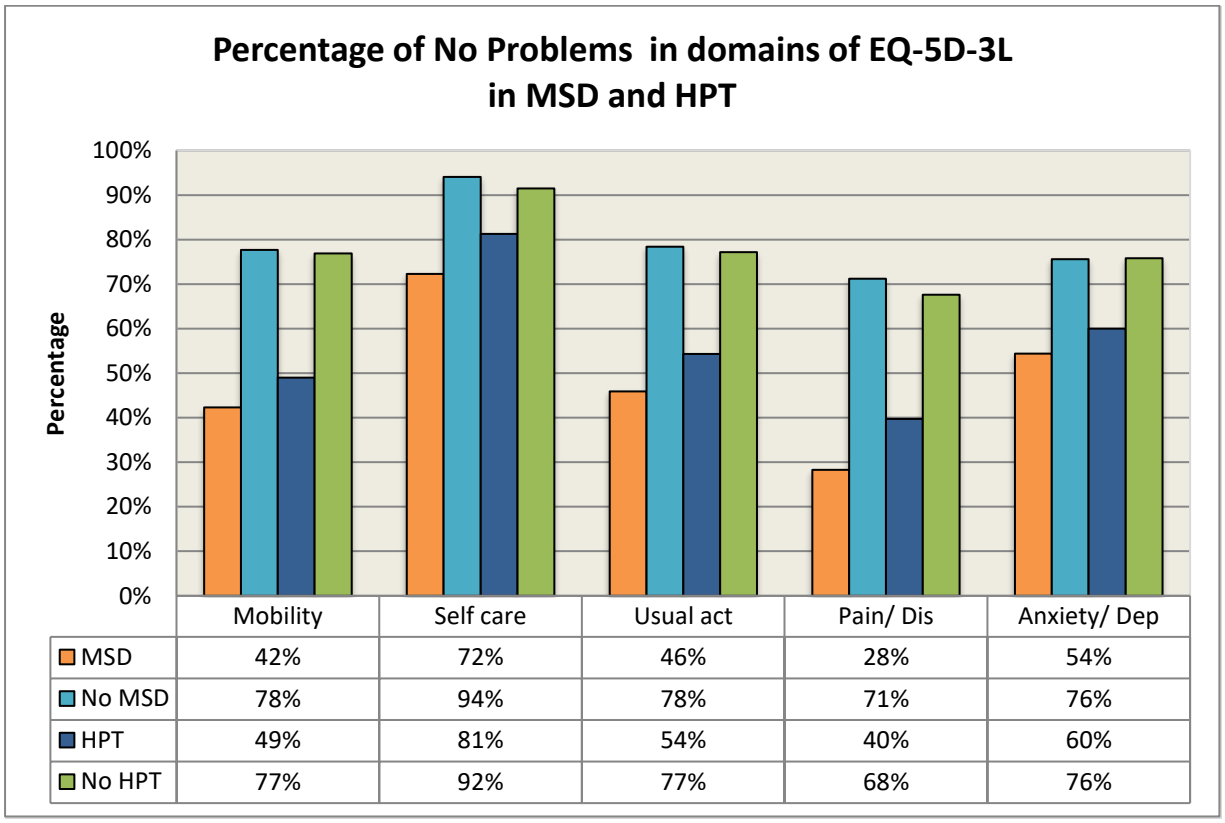


Figure 13: EQ-5D-3L domain responses of women with and without MSD (n=785)

Higher proportions of women with MSD and/or HPT (note several women were presenting with both conditions) reported having some problems in all five domains compared to women without MSD and/or HPT. This was substantiated by the significant associations found between MSD and HPT in all five domains (Chi Square statistic was significant at the $p<0.001$ level) (Figure 14).



	Mobility	Self care	Usual act	Pain/ Dis	Anxiety/ Dep
MSD	42%	72%	46%	28%	54%
No MSD	78%	94%	78%	71%	76%
HPT	49%	81%	54%	40%	60%
No HPT	77%	92%	77%	68%	76%

Figure 14: Percentage of women with and without MSD and/or HPT reporting no problems on the EQ-5D-3L domains.

N=364 with MSD, 430 without MSD; 420 with HPT and 371 without HPT.

The mean value for the EQ-5D-3L VAS scale was 69.4 (SD=22.5, n=785). Most women (71%) rated their health status on the VAS scale more than 50%, with the highest proportions (17%) falling between 41-50 and 91-100% respectively, which implied best state of health (Figure 15).

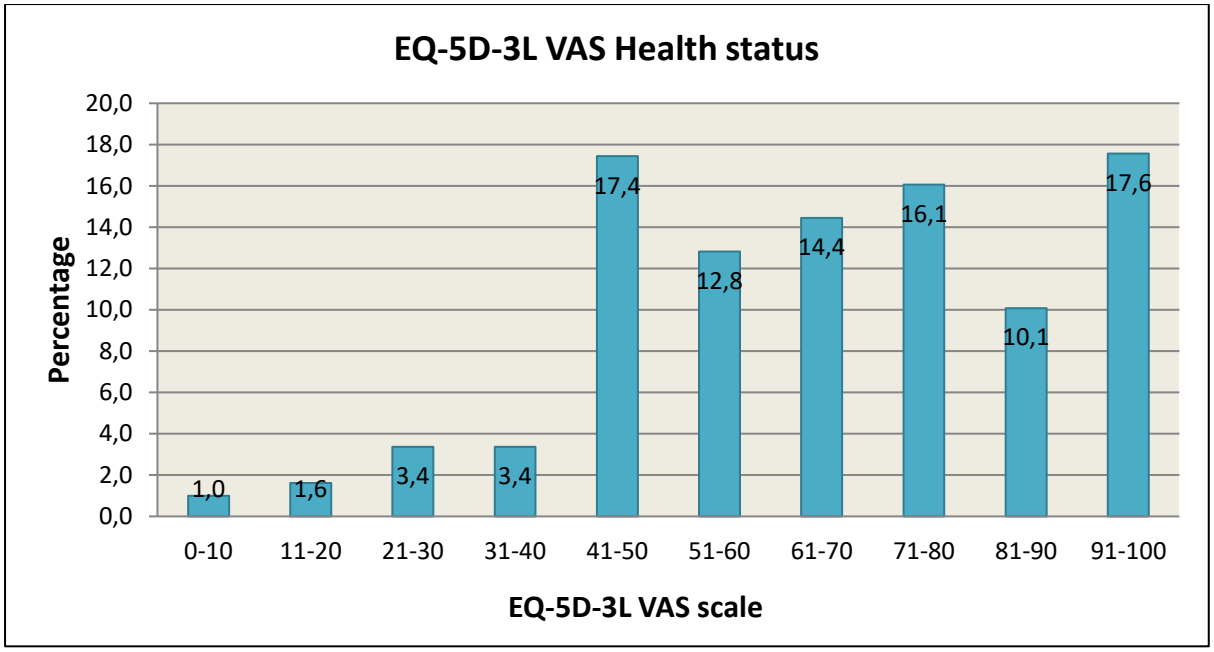


Figure 15: Responses of participants to the EQ-5D-3L VAS scale (n=785)

The mean EQ-5D-3L health utility (HU) score was 0.76 (SD=0.17, n=779). There were significant differences in the mean EQ-5D-3L health utility (HU) scores detected across all chronic diseases, including MSD (Table 29).

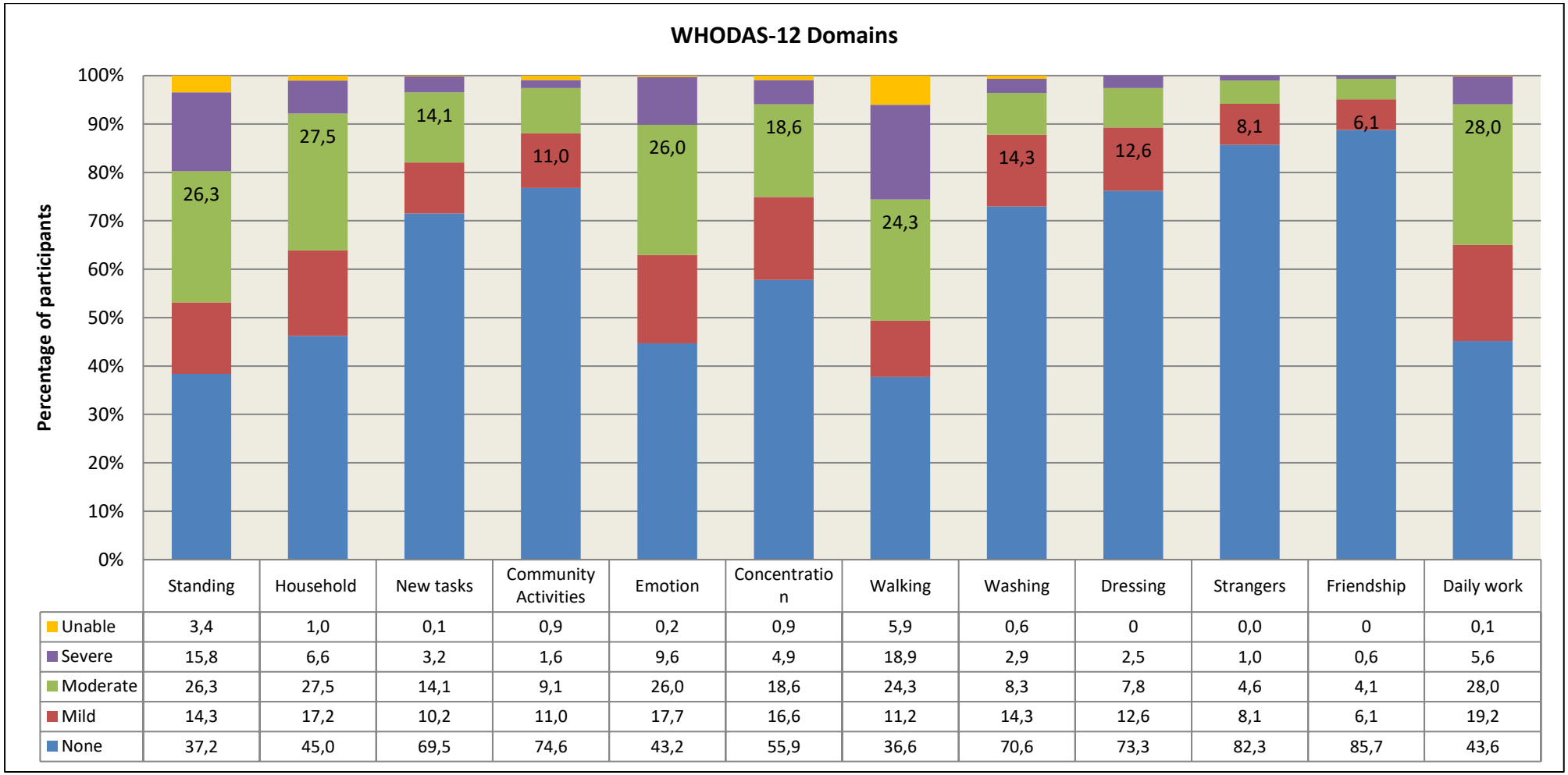
Table 29: Comparison of EQ-5D-3L Health Utility scores and VAS between women with and without chronic diseases

Condition	Outcome	Mean ± SD in those with condition	N with condition	Mean ± SD in those without condition	N without condition	Statistic
HPT	HU Score	0.72 ± 0.17	412	0.81 ± 0.61	367	***t=7.16; p<0.001***
	VAS	68.3 ± 22.2	412	70.6 ± 22.8	373	t=1.41; p=0.15
DM2	HU Score	0.72 ± 0.18	180	0.77 ± 0.17	599	***t=3.91; p<0.001***
	VAS	69.0 ± 22.3	181	69.5 ± 22.6	604	t=0.30; p=0.76
CVD	HU Score	0.70 ± 0.19	54	0.76 ± 0.17	725	***t=2.83; p<0.001***
	VAS	63.8 ± 24.0	53	69.8 ± 22.3	732	t=1.86; p=0.06
HCL	HU Score	0.69 ± 0.17	173	0.78 ± 0.16	606	***t=6.51; p<0.001***
	VAS	67.0 ± 22.0	174	70.1 ± 22.6	611	t=1.56; p=0.11
MSD*	HU Score	0.68 ± 0.17	355	0.83 ± 0.13	424	***t=13.3; p<0.001***
	VAS	69.3 ± 22.5	350	69.4 ± 22.5	426	t=0.07; p=0.93

* *Tested with separate variances*

4.4.5 Functional limitations and Disability (n=781)

Functional limitations and disability were measured using the WHODAS 2. The median WHODAS 2 value was 7 (IQR: 12, range 0-37) out of a maximum of 48 (higher scores indicate higher disability or loss of function). Responses in the 12 domains of the WHODAS 2 indicated that approximately one quarter of the women had moderate difficulty with functional activities such as daily work (28%, n=225), household responsibilities (27.5%, n=221), standing (26.3%, n=211) and walking (24.3%, n=195), and 26% (n=209) reported that they were moderately affected emotionally by their health problems (Figure 16). Areas in which over 70% reported no problems included Learning new tasks, Taking part in Community Activities, Washing, Dressing, and interacting with Strangers and Friends.



	Standing	Household	New tasks	Community Activities	Emotion	Concentration	Walking	Washing	Dressing	Strangers	Friendship	Daily work
Unable	3,4	1,0	0,1	0,9	0,2	0,9	5,9	0,6	0	0,0	0	0,1
Severe	15,8	6,6	3,2	1,6	9,6	4,9	18,9	2,9	2,5	1,0	0,6	5,6
Moderate	26,3	27,5	14,1	9,1	26,0	18,6	24,3	8,3	7,8	4,6	4,1	28,0
Mild	14,3	17,2	10,2	11,0	17,7	16,6	11,2	14,3	12,6	8,1	6,1	19,2
None	37,2	45,0	69,5	74,6	43,2	55,9	36,6	70,6	73,3	82,3	85,7	43,6

Figure 16: Participant responses to the WHODAS 2

N=781, Missing n=22

Chi Square tests indicated that there were significant differences in all the domains between those with and without MSD, apart from the domains of engaging in Community Activities and Dealing with Strangers.

The percentage of women with MSD reporting no problems with Walking was 26%, 30% had no problems with Standing, 38% had no problems with daily work while a higher proportion of women (70% and 81%) had no problems for items related to Social Interaction (Figure 17).

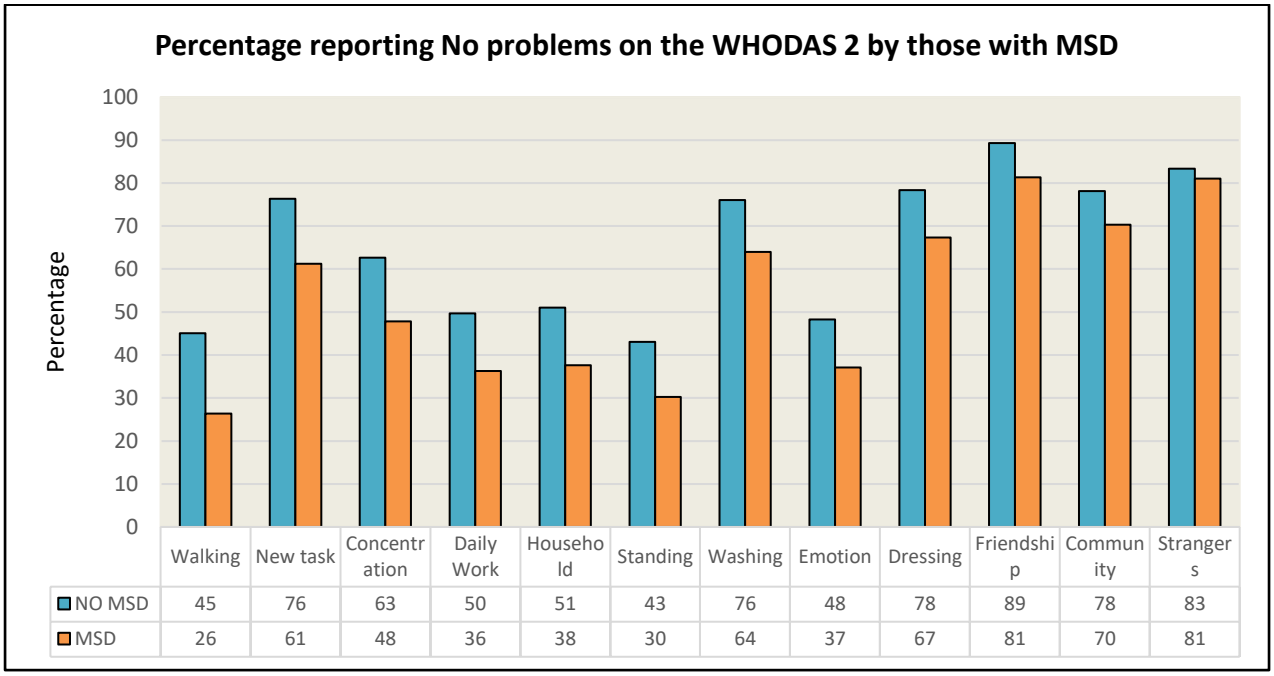


Figure 17: Comparison of the percentage of women with (n=364) and without MSD (n=439) reporting no problems on the WHODAS 2.
With MSD n=364, Without MSD n=439

The percentage of women with HPT reporting no problems in any domain were 3% and 10%, apart from Community Activities (Figure 18).

The mean number of days over the past 30 days on which participants experienced difficulties were 11 (SD=10.3). The number of days that they could not perform usual activities were 5 (SD=7.6) and number of days for reducing usual activities were 8 (SD=9.3).

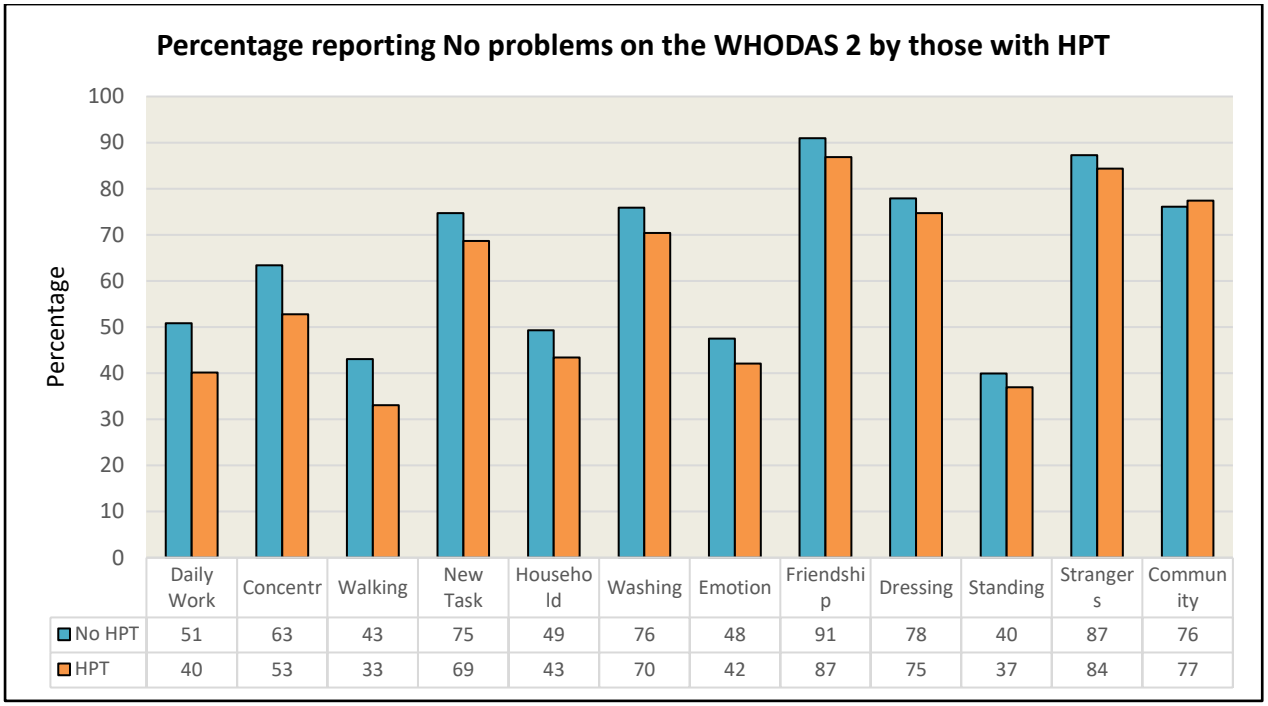


Figure 18: Comparison of the percentage of women with (n=411) and without HPT (n=364) reporting no problems on the WHODAS 2.

With HPT N=411, Without HPT N=364.

The median score on the WHODAS 2 of women with MSD (n=350) was 9 (IQR: 13) versus 5 (IQR: 11) in those without MSD (n=422) (

Figure 19). The mean ranking of the WHODAS 2 score was significantly higher in women with MSD (z=5.38, p<0.001), indicating a poorer level of functioning and disability compared to those without MSD. This was also the case for the women with HPT whose mean ranking of the WHODAS 2 score was significantly higher than in those without HPT (Table 30).

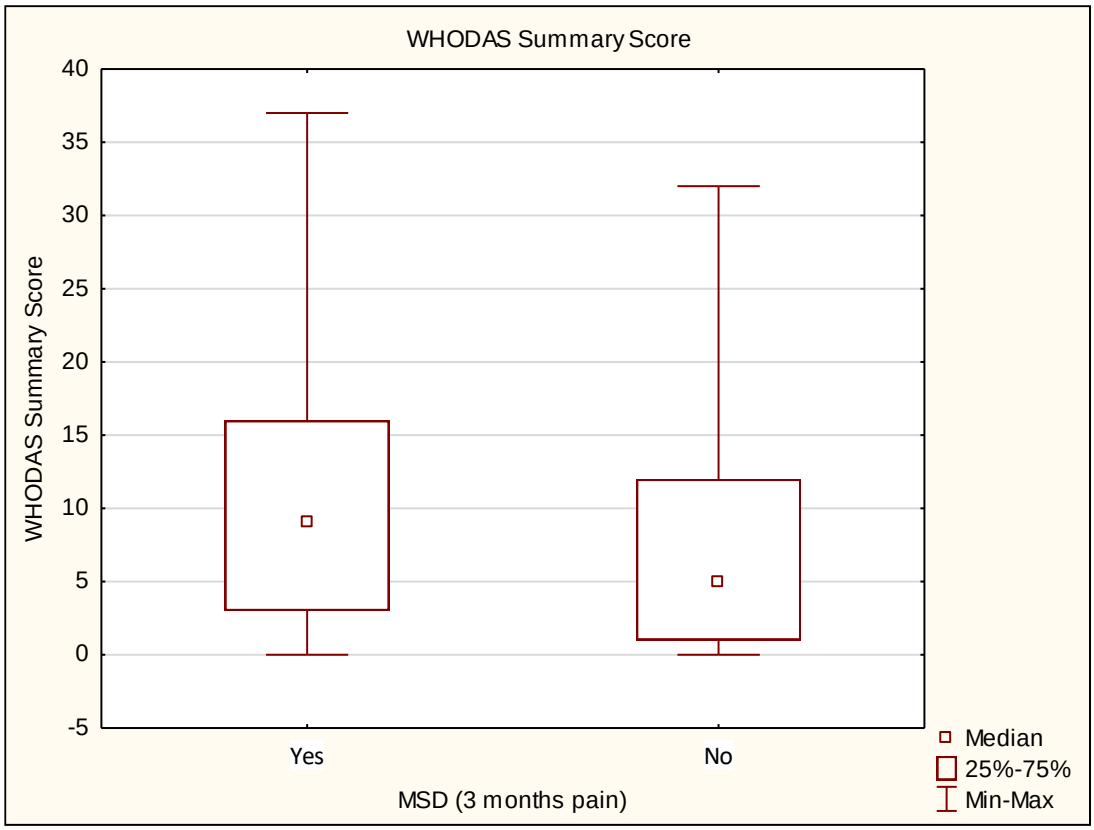


Figure 19: Comparison of median WHODAS 2 scores in women with (n=350) and without MSD (n=422)
Note that a higher score indicates a poorer level of functioning.

Table 30: Comparison of WHODAS 2 scores in women with chronic diseases

Condition	N with condition	Rank sum in those with the condition	N without the condition	Rank sum in those without the condition	Statistic
HPT	412	171160.5	369	134210.5	***Z=3.21; p<0.001***
DM2	179	74302.0	602	231069.0	Z=1.63; p=0.10
CVD	54	27215.5	727	278155.5	***Z=3.83; p<0.001***
HCL	174	75828.5	607	229542.5	***Z=2.98; p<0.001***
MSD	350	151822.0	422	146556.0	***Z=5.38; p<0.001***

In addition, there was a significant negative correlation (rho =-0.160, p<0.001) between WHODAS 2 score and EQ-5D-3L Utility score after the removal of two outliers who reported either very high (50 and 0.9) or very low scores (14 and -0.2) on both measures (N=755) (note that higher scores on the EQ-5D-3L indicate better health-related quality of life whereas higher scores on the WHODAS 2 indicate poorer functioning and disability) (Figure 20).

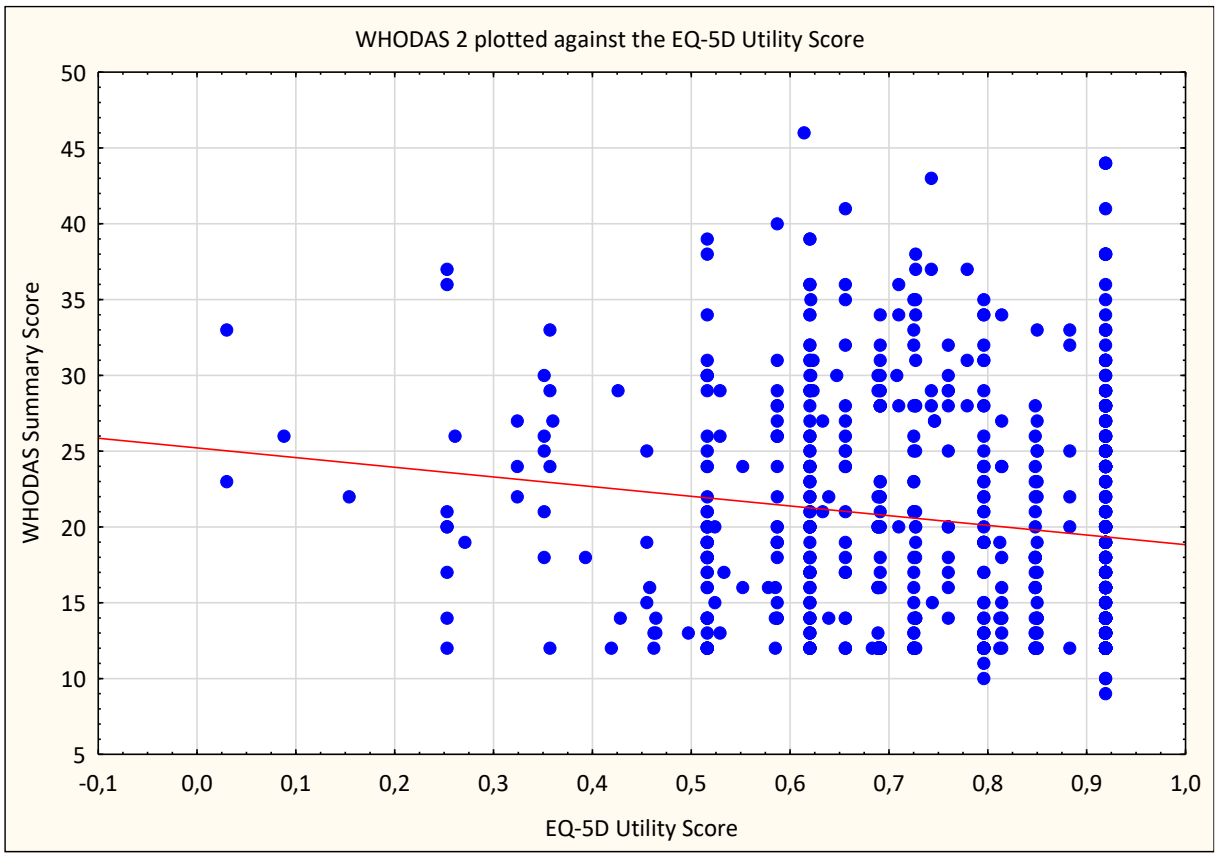


Figure 20: Correlation between WHODAS 2 score and EQ-5D-3L utility score (n=755)

N=755, 2 Outliers removed, 47 missing.

4.4.6 Relationships between MSD, chronic diseases and risk factors

Decision tree analysis (CHAID) was performed to establish possible relationship pathways between the dependent variable, MSD, and independent variables. In the first model MSD and Age, BMI, and PA MET min/week were included. Age (Chi-Sq=133.4, p<0.01) was the only variable that was associated with MSD, with nearly two thirds of the participants older than 42 years of age reporting MSD (Figure 21).

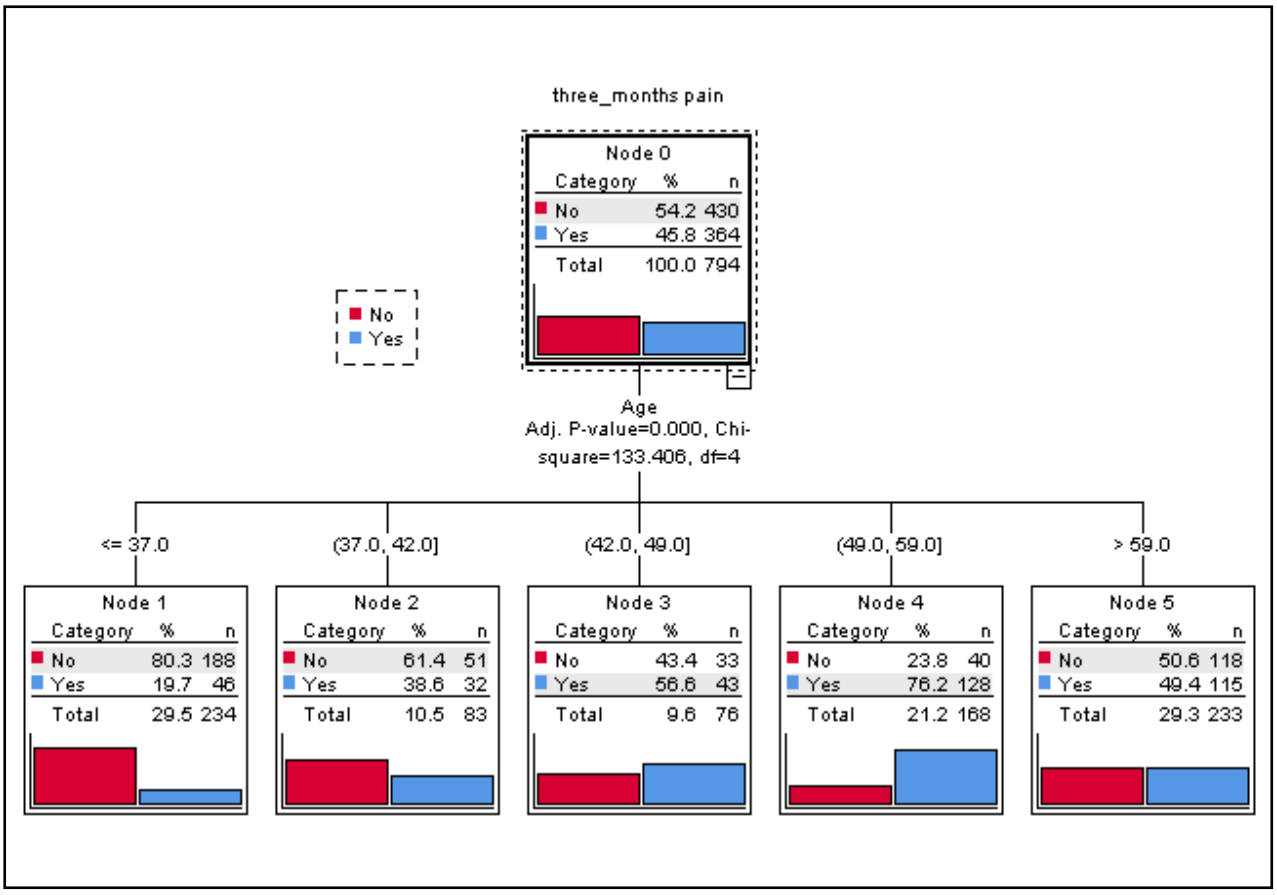


Figure 21: Decision tree analysis of MSD, Age and factors (BMI and PA MET min/week) (n=794)

N=794, 10 missing, Age, BMI and PA entered

After removing Age from the analysis, a significant association was found between MSD and levels of PA MET-min/week (Chi-Sq=11.9, p=0.011). Nearly half (48%) of the women (n=760), who had less than 6918.0 PA MET-min/week, reported having MSD. In those who had lower levels of PA MET-min/week, BMI was associated with MSD (Chi-Sq=11.3, p=0.014). More than half of the women (52.2%), who had low levels of PA MET min/week value and an increased BMI (>30.25kg/m²) reported having MSD (Figure 22).

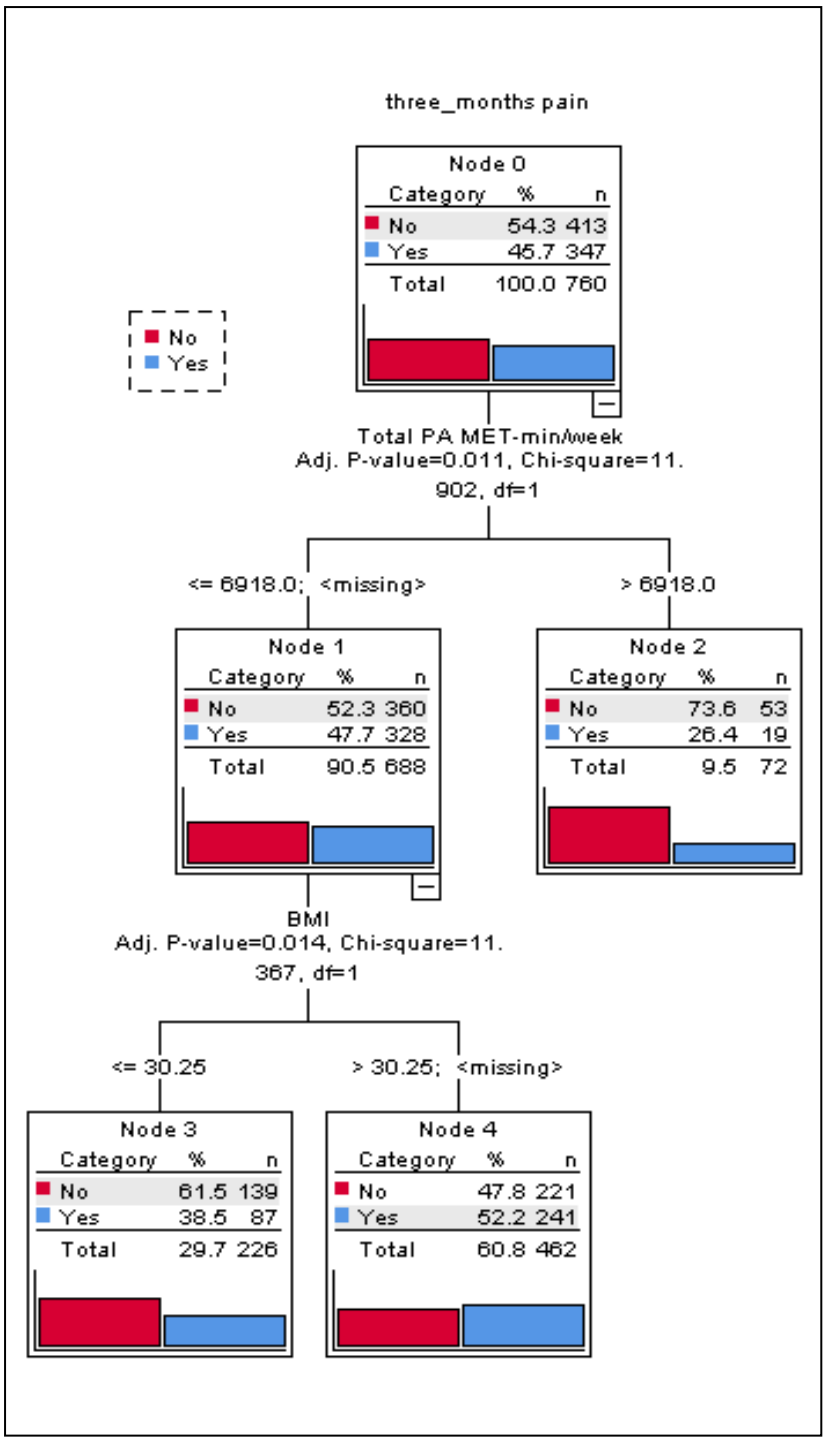


Figure 22: Decision tree analysis of MSD and factors (PA MET-min/week and BMI) (n=760)

N=760, 43 missing, BMI and PA entered

Thereafter, decision tree analysis for MSD and all chronic diseases was performed. A significant association was found between having MSD and HPT (Chi-Sq=59.16, p<0.01), with a higher proportion of women with HPT (59%) reporting MSD (Figure 23).

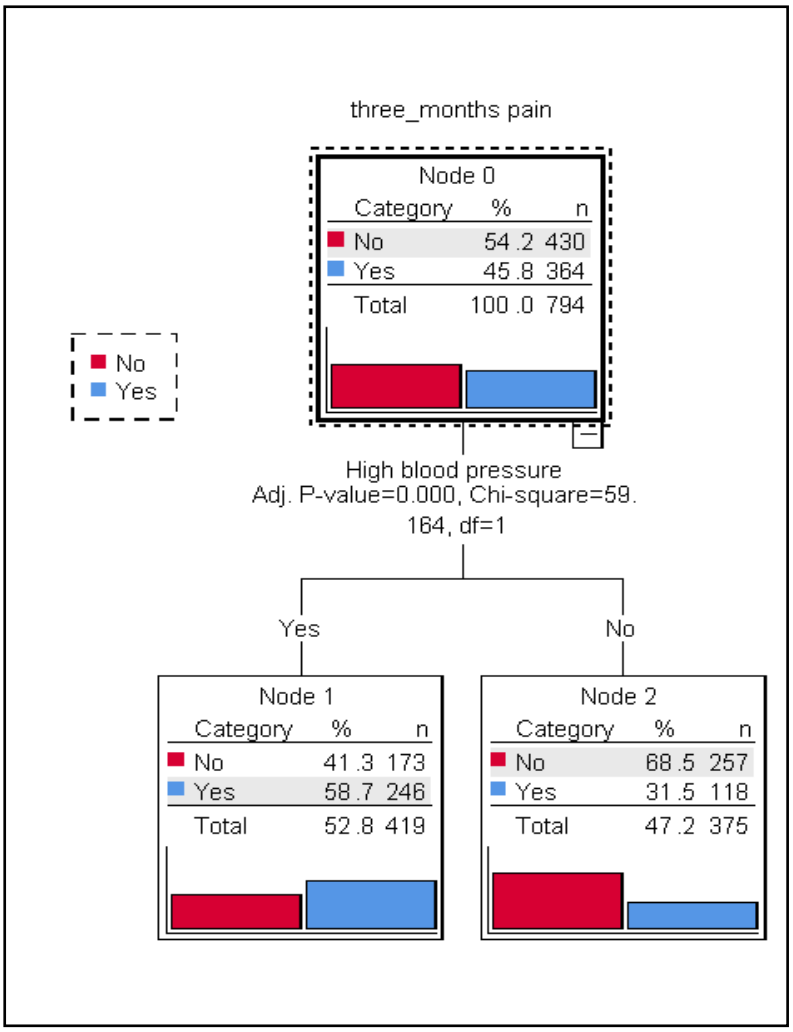


Figure 23: Decision tree analysis of MSD and chronic diseases (n=794)

N=794, 9 missing, HPT, DM2, HCL entered.

Further decision tree analysis (CHAID) was done to establish possible relationship pathways between HPT (dependent variable) and independent variables (Age, MSD, BMI and PA). Age was significantly associated with HPT (Chi-Sq=334.9, p<0.001). Specifically, women in the 30–40-year age category with HPT had a higher likelihood of reporting MSD (Chi-Sq=387.6, p=0.04) (Figure 24).

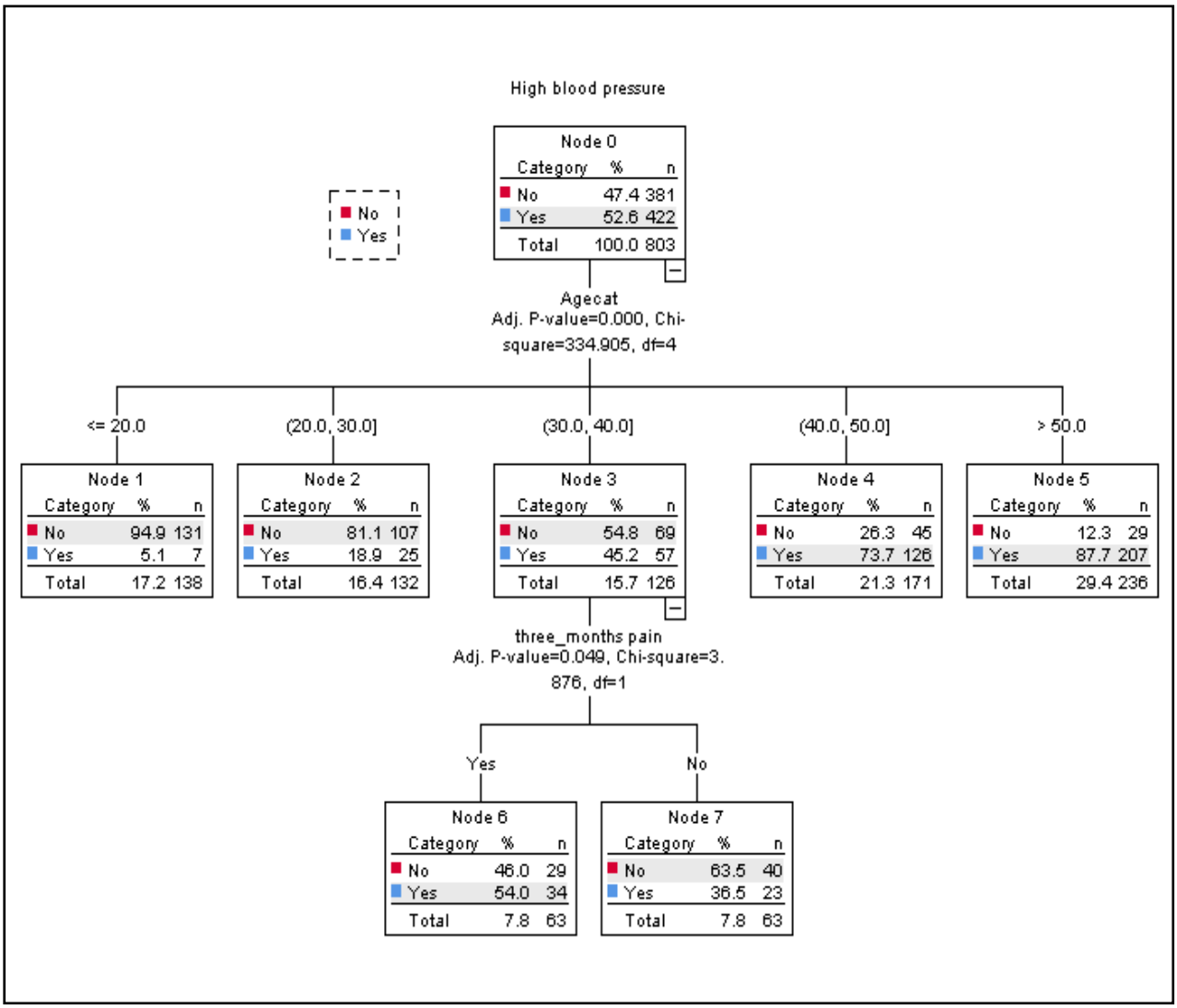


Figure 24: Decision tree analysis of HPT and associated factors (n=803)

N=803 Age, MSD, BMI and PA entered.

4.4.7 Summary of the results

In this phase of the research 803 women with a mean age of 48.4 years from Mitchells Plain CHC in Cape Town were recruited. The typical profile of the participants included speaking Afrikaans, isi-Xhosa or English as a home language, not married, having two or more children and having completed grade 7. Many women were unemployed or were housewives who received government grants with an income of less than R2000 a month. Furthermore, many women (40%) were the heads of their households and never smoked or consumed alcohol.

Hypertension (HPT) was the most common CDL (53%) reported, followed by MSD, which had a prevalence rate of 45%. Almost a third of the women had both conditions. Comorbidity of the three most reported chronic diseases (HPT, MSD and DM2) was reported by 11% of the women. However, CHAID analysis indicated that HPT was the only condition that was significantly associated with MSD. Overall, the prevalence of the different conditions increased with age, however, the prevalence of MSD peaked (76%) at 50 years of age and then decreased to 57% at 60 years and 39% at 70.

In those with MSD, all joints were affected but the most common sites of chronic MSD were the knee, shoulder, lower back, and hand/fingers. Most women with MSD reported onset of pain more than 12 months previously. Morning stiffness was experienced by about two-thirds of the respondents, particularly in the knee, lower back, and shoulder.

Those who had experienced pain (63%, 229 of 364) reported a mean pain severity score (PSS) of 5.34 (SD=1.45), i.e. moderate pain severity. The pain interference score (PIS) was 4.88 (SD=2.26). Pain interfered with general activity, normal work, walking ability, mood, and sleep.

The mean BMI of the sample was 30.8 (SD=7.54), and most of the women were obese (51%). A significant association was found between BMI and MSD with a greater proportion of obese women (nearly half) reporting MSD. The mean BMI was significantly greater in women with MSD and CVD compared to those without these chronic diseases.

The median Total Physical activity MET-min/week (PA MET) was 2499 (IQR: 3363, Range: 13.2-18774). Significant differences in PA MET scores by chronic disease were found in the sample. The sum of ranks for PA MET was significantly lower in women with all diseases (MSD, HPT, DM2, CVD, HCL), indicating lower physical activity levels.

Furthermore, a significant association was found between having MSD and PA level (Chi Sq=18.5, p<0.001) with more women with MSD reporting Low PA levels. Women with HPT also reported Low levels of PA compared to those without the disease (Chi Sq =17.96, p<0.001).

In all domains of the EQ-5D-3L, apart from Self-care, more than a third of the women reported having some problems with Pain/Discomfort, Mobility, Usual activities, and Depression/Anxiety. The mean EQ-5D-3L Health Utility score was 0.76 (SD=0.17) (N=779), and the mean EQ-5D-3L VAS was 69.4 (SD=22.5). More women with MSD reported having some problems in all five domains compared to those without MSD.

The median value of the WHODAS 2 was 7 for the whole sample and 9 for those with MSD, indicating worse functional ability in those with MSD. Areas in which moderate difficulties were reported by approximately one-quarter of all the women included domains primarily concerned with physical functioning, (daily work, household responsibilities, standing and walking) and emotion. At least three-quarters of the women did not report any problems at all with social interaction within the community and with strangers and friends. MSD and HPT were both associated with significantly higher scores on the WHODAS 2 (indicating worse scores). The overall score of the WHODAS 2 was weakly negatively correlated with the EQ-5D-3L Utility Score implying a weak relationship between HRQoL and Functional Ability as measured by the two instruments.

Bivariate analyses for HPT and MSD indicate that the same factors were significantly different in those with each of the conditions than those without, e.g. higher age, lower PA MET, lower Health Utility Score and higher WHODAS 2 scores. However, BMI was significantly higher only in those with MSD (Table 31).

Table 31: Summary table of statistically significant differences between outcome measures in women with either MSD or HPT and those without diseases

Condition	Outcome	Mean ± SD in those with the condition	Mean ± SD in those without the condition	Statistic
HPT	*Age	58.4 ± 12.1	37.4 ± 13.7	t=22.8; p<0.001
	*PA MET	130190.5	138087.5	Z=3.69; p<0.001
	EQ-5D-3L Utility Score	0.72 ± 0.17	0.81 ± 0.61	t=7.16; p<0.001
	** WHODAS	171160.50	134210.50	Z=3.21; p<0.001
MSD	*Age	53.0 ± 13.4	44.5 ± 17.9	t=7.6; p<0.001
	*BMI	31.8 ± 7.8	30.0 ± 7.1	t=2.6; p<0.001
	*PA MET	112909.5	148816.5	Z=2.34; p<0.001
	*EQ-5D-3L Utility Score	0.68 ± 0.17	0.83 ± 0.13	t=13.3; p<0.001
	** WHODAS	151822.00	146556.00	Z=5.38; p<0.001

All conditions were tested with separate variances Tested with Mann-Whitney U*

CHAID revealed that Age was the only factor that was significantly associated with MSD. However, after removing Age, a significant association was found between MSD and low levels of PA (less than 6918.0 PA MET-min/week). A BMI of greater than 30.25 was only associated with MSD in women who had low levels of PA. Furthermore, women with HPT aged 30-40 years were more likely to have MSD.

4.5 Discussion

The aim of this study was to establish the contextual background for the developing and testing of an intervention by describing the prevalence and profile of women with chronic joint pain and comorbidities attending a local CHC in Cape Town. This discussion will review the findings considering current literature and will foreground the implications for the planning of the intervention.

4.5.1 Description of the Sample

The sample included women almost equally spread across the age categories, with a spike in the 50-59 age category. In terms of demographic characteristics, the sample was similar to the population (based on 1.2 million people) of the area as described by the Western Cape Government[275]. Nearly a quarter of the population in the area are unemployed (24.2%), 20% of households have been categorised below the poverty line (<R3500 per month) and 16% of residents have not completed grade 7[275].

Compared to the population reported on in the last National Census of 2011 (37.8%), a higher proportion (44.2%) of women in this study were the sole providers for their families than the population norm [285]. Even though this study was a clinic-based survey and the census was a population-based survey, it highlights that a large proportion of women are responsible for taking care of their families alone without the support of a partner. It is likely that many of these women are required to not only work to provide an income for their families but may also have to care for children and do housework. In addition to their family responsibilities, they may face further challenges with ill health and disability associated with chronic joint pain and comorbidities and are therefore reliant on public health care services[286]. The implication for the development of an intervention Programme for this population, is that the ability to do physical activity may be critical as the participants in the Programme may be breadwinners and caring for children. Their financial and time resources may also be limited making it difficult to find time to attend the clinic regularly.

Most participants reported speaking isiXhosa and Afrikaans and this was expected as the large number of Afrikaans-speaking people were expected at this clinic according to the National Census 2011. The National Census 2011 described the population in Mitchells Plain as predominantly women (51%), who spoke English (47%) or Afrikaans (46%) with less than 5% speaking isiXhosa[2877].

[7] Mitchells Plain Population statistics were obtained from the Census 2011 Community Profile

However, there were more isiXhosa-speaking people than Afrikaans and English-speaking people in this study. This may reflect the census data being out-of-date. It is possible that isiXhosa-speaking people have moved from neighbouring townships to Mitchells Plain, but there is no evidence to support this theory. A further explanation for the large number of isiXhosa speakers is the formation of a new Xhosa informal settlement called "Siqalo" in 2012 in Mitchells Plain. A social survey was conducted in this settlement in 2013 which estimated that approximately 8000 people lived in Siqalo[288]. This new informal settlement could possibly explain the reason for the increased proportions of isiXhosa-speaking people attending the Mitchells Plain CHC.

Another possible explanation for this unexpected finding could be that isiXhosa-speaking people attended the Mitchells Plain CHC for health care services for other diseases such as HIV/AIDS during the data collection period due to the stigma and discrimination against people living with HIV/AIDS experienced at their local clinics. Two local studies, one in Johannesburg and one in Cape Town, conducted qualitative studies about stigma against people with HIV/AIDS reported that some participants with HIV/AIDS would attend neighbouring clinics to access health care for HIV/AIDS to maintain anonymity[289 290]. This could be the case at the Mitchells Plain CHC. The implication for the intervention is that it must take different languages and cultural practices with instructional material appropriate for use in Afrikaans, isiXhosa, and English.

The relatively low levels of formal education also need to be factored into the planning of the intervention Programme as over one quarter of the participants had only completed primary school and three quarters had not completed secondary school. Therefore, the instructional material and presentation should be targeted at participants with a reading age of that of a Grade 7 student or less.

4.5.2 Prevalence of chronic joint pain and comorbidities

The prevalence of chronic joint pain (referred to MSD in tables and figures) experienced in the past 3-months was 45% (CIs 42-49%). The prevalence of chronic joint pain in this study was higher than those reported in some international studies. In other developing countries, prevalence ranges from 30% in Venezuela[10] to 35.4% in Mexico[291]. It is possible that these lower prevalence figures are due to the inclusion of men and women in both studies as opposed to the current study which recruited women only, as women have a higher prevalence of chronic joint problems[16 27 276]. A further reason for the lower prevalence rates in the other studies could be due to the younger participants (43 and 46 years) compared to the older participants in the current study (53 years)[63 52].

However, the prevalence of chronic joint pain in this study was similar to the prevalence of 45.7% recorded in Ecuador[292]. The latter study recruited both men and women with a mean age like the Mexican and Venezuelan studies (42 years). However, there was a higher prevalence of chronic joint pain, similar to that of the current study. The differences in contexts, cultural diversity, geographic location, and methodologies used across the studies may have contributed to the higher prevalence. The studies in Ecuador[292] and in Venezuela[10] were population-based surveys, while in Mexico, the researchers recruited people from community clinics[291]. The use of community clinics (CHC) as research sites for the studies in Mexico and in the current study are the likely reason for the higher prevalence rates. People attending a CHC are more at risk of having OA[276 293 294].

A few studies have been conducted in Africa reporting on the prevalence of MSD in communities. The high prevalence of chronic joint pain (45.3%) and diagnosed arthritis (23.6%) in the current study was similar to the results of a community-based study in Kenya [295] that reported a 42.7% prevalence of chronic joint pain in adults (older than 60 years) and 25.3% of diagnosed arthritis or OA, of which a significantly higher prevalence was found in women (62%) compared to men (39.5%, $p<0.001$)[295]. Even though the Kenyan findings are like the current study, the results should be interpreted with caution as it represents prevalence in a much older population (>60 years of age). The high prevalence of chronic joint pain and arthritis in the Kenyan sample could reflect older age.

The findings of the current study were comparable to a South African study using the same questionnaire to determine the prevalence of chronic joint pain in people attending a CHC[27]. The prevalence of chronic joint pain and diagnosed arthritis in the women (45.3% and 23.6%) in the current study was much higher than the prevalence of chronic joint pain and diagnosed cases (36% and 15%) reported by Parker & Jelsma (2010)[27]. The differences in prevalence rates could be due to the current study recruiting only women, whereas the latter study included both women and men.

Of interest, was that the proportion of women with chronic joint pain in the current study was highest in those between 40 and 60 years of age, rising to 76% of the sample, but then decreased in the older age categories. A possible reason could be due to functional demand, as many of the women are likely to engage in strenuous physical activity related to caring for children/grandchildren, housework and possible employment involving manual work such as domestic and factory work during their middle-aged years. It could be that in the older groups, the demands of physical work are less, resulting in lower reporting. Another possible reason for older women not reporting MSD pain could be that they expect pain to be part of the ageing process and, therefore, do not complain about having pain. The previous study by

Parker & Jelsma (2010)[27] did not report the prevalence according to age categories and therefore patterns in prevalence cannot be compared to this present study.

The results of this study show a high prevalence of chronic joint pain in women attending the Mitchell's Plain CHC and highlight a need for an evidence-based intervention Programme that would address the symptoms such as pain, joint stiffness and muscle weakness leading to functional limitations. The primary target age group, based on the above information, should be those bearing the greatest impairment and functional burden i.e., women between 40 and 60 years of age.

4.5.2.1 Prevalence of comorbidities

Comorbidities were common, as would be anticipated in women attending a primary health care (PHC) clinic or CHC. Of interest to the planning of the intervention is that hypertension (HPT) was reported by about half of the women, and chronic joint pain and HPT were co-morbid in almost one third of the women. There was also an overlap with diabetes mellitus type 2 (DM2) (23%) and 11% had all three of the chronic diseases (MSD, HPT and DM2). The findings of this study are consistent with other local and international studies reporting on middle-aged women with chronic joint pain such as OA[27 177 53 64 36]. As about one third of the women with chronic joint pain also reported HPT and/or DM2 in this study, the original proposition for the development of a combined intervention Programme as a cost-effective use of physiotherapy resources was therefore supported.

4.5.2.2 Nature of chronic joint pain

The chronic joint pain had lasted for more than one year in about a quarter of the women, which could indicate that management had not been successful during this time and alternative interventions should be offered. At least two thirds of the women reported some or all of the symptoms consistent with a diagnosis of OA: pain for longer than three months, pain at night, most symptoms felt in the knees and morning stiffness[296 79]. Other studies in similar settings in South Africa report comparable prevalence of joint stiffness in those with chronic joint pain i.e. 56%[27] and 71%[190] compared to the 73% in this study.

It appears that in individuals living in Mitchell's Plain, the knee joint is most affected by chronic joint pain or OA. The knee is a common site for chronic joint pain or OA in people from several countries including Sweden[18], the UK[297] and in Africa[17]. Impairment in the knee could restrict the affected individual in performing functional activities such as walking, bending, kneeling and climbing stairs in the home or at work. Therefore, it is important to develop appropriate interventions that would include functional

exercises to address the burden of knee joint pain and disability in this sample. Specific strengthening exercises for muscles around the knee joint and lower back, and flexibility exercises to improve mobility in affected joints should be considered when planning the intervention.

In addition to the high proportion of women reporting knee joint pain, shoulder and hand/finger joint pain was highly prevalent. These results are consistent with findings in Korea (Oh et al., 2011) and in England[298]. Oh (2011)[299] found that knee OA and ageing were risk factors for shoulder OA. Similarly, Cushnaghan (1991)[298] found significant associations between knee and hand OA in women. It would seem that women with knee OA could be twice as likely to develop shoulder OA further affecting their functional abilities[299]. These findings suggest that the intervention Programme should also include exercises and functional activities for the upper limb.

4.5.2.3 Pain severity and pain interference

In terms of pain severity, the mean PSS of 5.3 (SD=1.45) indicates that the participants had "moderate" pain[300]. Zelman (2003)[301] reported that reducing pain intensity to less than 5 could increase function and quality of life in patients with osteoarthritis and is a criterion for "a day of manageable pain". This is further supported by Keller (2004)[302] with higher scores indicating more severe pain and more difficulty with activities (pain interference).

The mean PSS in the current study (5.3; SD=1.45) was similar to the PSS from a study of self-management practices in 250 patients with MSD and depression in Indianapolis, USA[303]. While there is limited research available using the BPI in people with chronic joint pain or OA in South Africa, there is some evidence regarding pain severity in patients with OA in South Africa (Saw, 2015). A mean PSS of 6.5 (SD=2.29) was reported in the latter sample (n=42), which is slightly higher than the current study. The possible reason for the differences noted in the PSS scores could be due to the latter study participants' having late-stage OA and suffering with more severe pain, as they were on a waiting list for joint replacement surgery[304]. These results suggest that women with chronic joint diseases such as OA have moderate pain severity and that the proposed intervention should include non-pharmacological pain management strategies such as exercise, self-management and neuroscience education. There is compelling evidence reporting the positive effects of neuroscience education in decreasing pain and catastrophization in patients with chronic musculoskeletal conditions, such as OA [305].

The mean pain interference scores (PIS) indicated moderate interference with all activities (Range: 5.3 [SD=3.38] to 5.9 [SD=2.83]) apart from enjoyment of life (3.7; SD=3.28) and relationships with other people (2.6; SD=3.10). The mean scores are within similar ranges to those reported in respondents with OA in the USA[306]. Participants in the USA study reported a mean pain interference score between 6.0 and 6.7 for nearly all activities, except for mood (5.8) and relationships with other people (4.0) (n=107). The results from both these studies imply that pain interferes substantially with functional-related activities (work, general activity, walking) and interferes less with non-functional (sleep, mood, relationships).

It is important to highlight that both studies reported sleep (a non-functional domain) to be affected by pain. This finding is consistent with results from other studies, as older people with pain related to OA consistently report problems with sleep[307 308]. Therefore, the proposed intervention should include strategies to improve sleep and address the relationship between sleep and chronic pain.

The mean PIS of the current study was considerably lower than the mean PIS (6.70 ± 2.34) reported by patients with knee and hip OA awaiting surgery in a local South African study [153]. The possible reasons for the differences in mean values could be due to the severity of OA as the sample in the previous study were recruited from a hospital waiting list for joint replacement surgery, which is usually recommended for patients with late-stage osteoarthritis[304]. In addition, patients with chronic pain may avoid physical activity due to fear of injury, which in turn could increase pain and the lack of activity could weaken the surrounding muscles and resulting in poor functional abilities[309].

Although the mean PIS score in this study was lower than that of the local studies, the standard deviations were relatively high (over 3) for each item, indicating that there was a large range of responses. The implication for the intervention Programme is that the Programme should cater for those with limited pain interference with activities through to those with severe problems, particularly with activities that require physical functioning, such as walking and work, using a graded approach to exercise.

4.5.2.4 Current Management of chronic joint pain and comorbidities

Most women (70%) in this study were receiving prescribed analgesia and NSAIDS for symptoms related to MSD at the CHC. Although paracetamol and NSAIDS were commonly prescribed as first line treatment for pain in people with OA in the past[310 123], recent evidence shows that the overall efficacy for pain relief is poor and regular use may cause adverse effects[125 311 312 313]. Furthermore, inadequate pain relief has been associated with severe functional problems and poor quality of life in people with OA[314]. Given that people with OA are using prescribed paracetamol and NSAIDS for chronic pain, the safety and

effectiveness of long-term use of these medications should be considered. Hence, the use of effective non-pharmacological treatments for OA should be considered.

It is concerning that, in contrast to the large number of women receiving pharmaceutical intervention for their pain, only 20% of the women with chronic joint pain were referred to physiotherapy and occupational therapy for exercise and even less for other interventions.

As discussed in the literature review, core non-pharmacological treatment clinical guidelines for best practice in managing OA have been formulated by the National Institute for Health and Care Excellence (NICE, 2008)[122], Osteoarthritis Research Society International (OARSI, 2008)[123] and European League Against Rheumatism (EULAR, 2003)[315]. These clinical guidelines all include education (focus on self-management and patient-driven treatments), exercise and activity, and interventions for weight-loss (if obesity is a problem) as first line treatment strategies for OA. Unfortunately, it appears that these women may not have received optimal non-pharmacological management for MSD or OA. These findings support the need to develop and implement non-pharmacological interventions based on the core treatment guidelines (education, exercise, and weight-loss Programmes) at this CHC. This highlights that the health system needs to be optimised to ensure that people with chronic joint pain or OA are referred for appropriate non-pharmacological management.

More than half of the women (422 of 803) in this study reported having hypertension (HPT). These findings are consistent with the results from other local and international studies reporting high prevalence rates of HPT in South Africa and Sub-Saharan Africa[316-319]. Furthermore, 50% of the women with HPT (212 of 422) reported using medication to control the condition. It is not known why the remaining women (50%) were not using medication, as there were no follow-up questions in the survey to explore this. However, a possible reason for the lower proportion of women using medication could be that some of these women were newly diagnosed at the time of data collection and were not prescribed anti-hypertensive medication as they needed to be monitored and were given advice on lifestyle modification as per the South African Hypertensive Treatment Guideline[320]. According to the guideline, patients that have been diagnosed with HPT (BP 140–159/ 90–99 mmHg), and have ≥ 3 risk factors, diabetes mellitus, target-organ damage (TOD) or other complications should receive lifestyle modification for three to six months with counselling regarding diet, low sodium diet, weight loss, exercise, moderation in alcohol consumption and cessation of smoking to help reduce the blood pressure without use of medication.

Should patients have hypertension (BP 140–159/ 90–99 mmHg), have < 3 risk factors, no TOD or complications then lifestyle modification and monotherapy should be implemented with monitoring in 4-6 weeks. If this course of management does not help to reduce the blood pressure, lifestyle modification and fixed-drug combination therapy should be considered for patients with higher blood pressure values (≥ 160/100 mmHg) for better outcomes[320].

While this treatment guideline specifies the criteria for administering anti-hypertensive drugs, it is not known whether all the primary health care centres or CHCs in Cape Town have implemented these guidelines. There seems to be a lack of good quality studies on the outcomes of these management strategies in the country[320]. In any event, the large proportion of women with HPT in this study and the apparent lack of adequate medical treatment indicate that there is a need to explore a non-pharmacological intervention for this group. The findings suggest that the proposed intervention Programme should consider including non-pharmacological strategies for controlling blood pressure with health education, exercise, and self-management strategies as an adjunct management for people with hypertension. It would be logical to provide a single Programme for those with chronic joint pain and HPT, given that the problems experienced are similar. Further exploration of the results relating to risk factors for MSD are worth considering in the design of an intervention Programme.

4.5.3 Risk factors associated with MSD (Obesity and Lack of physical activity)

4.5.3.1 Obesity

Obesity has become a major health problem in many countries across the globe[321-324], and is recognised as a modifiable risk factor for many chronic diseases[104 64 325 326] or is strongly associated with chronic diseases (arthritis, hypertension, angina pectoris, diabetes mellitus, asthma, chronic lung disease)[105 321]. Globally, rates of obesity are higher in women than in men[324]. The rising prevalence of obesity in women is becoming a worldwide epidemic.

In this study, the mean BMI was high (Mean: 30.8, SD=7.5), similar to that reported in the above-mentioned studies and to a multi-country study in adults older than 50 years of age across six Low and Middle income countries (LMIC) (WHO-SAGE wave I) which reported a mean BMI of 30.5 (SD=12.0) in South Africa (SA) (N=4227)[105]. In the South African report of the WHO-SAGE wave I study[286], it was reported that more women (50.6%, n=1 936) were obese compared to men (38.3%, n=1 574). It is apparent that obesity is a major concern, particularly in women living in areas with limited resources.

In addition, in this study BMI was significantly associated with MSD (Chi Sq=5.24, p=.022) with more obese women (48%) reporting MSD compared to those who were not obese (38%). Not surprisingly and as has been reported elsewhere, BMI was significantly associated with MSD[327 328]. Additional analysis showed that BMI was significantly greater in participants with both MSD (3 months) (t=2.6; p<0.001) and cardiovascular diseases (t=2.3; p=0.02). These findings highlight an important need to include appropriate interventions to address obesity to improve their overall health. Weight-loss interventions could help to reduce pain in affected joints, improve physical function and increase overall health and quality of life[327-329].

4.5.3.2 Lack of physical activity

In the current study, the total median energy expenditure, expressed as Total Physical activity MET-min/week (PA MET), in this sample of women was 2499, indicating "Moderate PA" levels [230]. According to international guidelines, moderate-intensity physical activities of at least 150 minutes per week (30 minutes of activity for at least five days per week) is needed to achieve optimal health benefits[330 331]. Furthermore, the current Public Health Guidelines for Physical Activity recommends that adults accumulate a minimum of 150 minutes each week of moderate intensity activity, which is equivalent to 500-1,000 MET-minutes per week for significant health benefits [332]. Although this recommendation has been accepted as a goal, 30 minutes of moderate-intensity activity is low and broadly equivalent to the basal levels of activity that adult individuals would accumulate in a day. It is for this reason that a higher "cutpoint" is required to describe the levels of physical activity associated with health benefits for measures such as IPAQ [230].

Most of the middle-aged women in this study were not engaging in sufficient physical activity and exercise to maintain good health. A possible reason for the decreased levels of physical activity may be due to chronic joint pain, which is supported by the significant association found between chronic joint pain and PA level (Chi sq=18.5, p<0.001) as more women with chronic joint pain had Low PA levels compared to those without. These results are consistent with previous studies describing low levels of physical activity in people with chronic pain in Sweden[333] and with chronic pain in South Africa[266]. Therefore, the findings highlight that the proposed intervention should use graded activity to increase physical activity levels in people with chronic pain related to OA[334]. Furthermore, the intervention should focus on facilitating behaviour change by including graded exposure to feared physical activities through goal setting to empower patients by raising self-efficacy beliefs. Higher levels of self-efficacy in individuals can lead to setting more challenging goals to improve or change unhealthy habits such as exercise or diet but with a stronger commitment to achieving these goals[335].

4.5.4 Impact of MSD and CDL on health-related quality of life and function

4.5.4.1 Health-related quality of life

In this sample of women, 63% of those with MSD had a high prevalence of "some problems" in the Pain/ Discomfort domain of the EQ-5D-3L, similar to the findings in the Dutch population in Netherlands[336]. In addition, this finding is similar to the results of another local study conducted in Bloemfontein, South Africa, in a cohort of women with chronic joint pain[190]. Both local studies found that pain or discomfort was a problem in women with chronic joint pain.

Picavet (2004)[336] and Barnes (2016)[190] both found that people with MSD have worse HRQoL than those with HPT, however, in this study we found similar poor HRQoL in women with and without MSD and /or HPT. Nevertheless, the women in all three studies had poor HRQoL. These poor scores for health-related quality of life are likely more reflective of the socioeconomic environment in which the participants of both the present study and the previous studies live. A community-based survey conducted in the under-resourced suburb of Nyanga in Cape Town found a similar low mean VAS to that of the present study (66.8, SD=20.8)[337]. As all respondents experienced similar day to day challenges, the lack of a difference in perception of global health might be ascribed to the difficulty in separating health factors from socio-economic factors[337]. In a study on perceptions of HRQoL in a neighbouring under-resourced suburb, Khayelitsha, in Cape Town, the authors concluded that "despite being asked specifically to answer the questions in relation to their health status, the participants apparently did not differentiate between general quality of life (QoL) and specific HRQoL. It appears that members of an under-resourced community regard socio-economic and service delivery aspects of their lives as integral to their perceived state of health"[338].

While HRQoL was generally poor, the domain relating to Anxiety/Depression was worse in the women with one of the CDL. The women with chronic joint pain reported that pain had moderately interfered with "Mood" and "Sleep" which may indicate a differential effect of the conditions on emotional functioning. This is to be expected, as chronic pain negatively affects the affected individual's sleeping patterns, and is associated with stress or anxiety and depression[308 63 339 9].

The HRQoL results of this study suggest that the proposed intervention Programme should include health education and exercises incorporating functional activities to help improve the problems with pain, mobility, walking, standing and general activities. In addition, an education component about managing stress or anxiety/ depression and sleep appears indicated.

4.5.4.2 Functional limitations and disability

In terms of functioning and disability, the women with chronic joint pain had a significantly higher mean ranking of the WHODAS 2 score compared to women without chronic joint pain ($z=5.38$, $p<0.001$), indicating a poorer level of functioning and disability. These results are expected as the normative data for the 12-item WHODAS 2 instrument reflects a higher mean (4.3, SD = 6.1, range 0-48) in people with a chronic physical condition (n=4750) compared to the total population (3.1, SD = 5.3, range 0–48)[205].

The instruments used to measure pain, HRQoL and functioning and disability revealed a similar pattern emerging across the domains in the women presenting with the two most common conditions, chronic joint pain and HPT, in the current study. Apart from Pain, physical activities which included General Activity, Walking, and Work in the PIS (BPI), Mobility and Usual Activities in the EQ-5D-3L and the WHODAS 2 domains of Standing, Daily Work and Walking (in chronic joint pain only) were affected and problems were significantly associated with the two health conditions. As with Pain, it was expected that the chronic joint pain group would report a decreased HRQoL and functional limitations compared with those without. Similarly, those with HPT reported a decreased HRQoL and functional limitations. Apart from the high comorbidity with chronic joint pain in this sample, possible reasons for the similarities in the women suffering from these two conditions could be due to age and obesity, as common risk factors for these diseases. This association is further supported by local and international studies[340-343]. This will be further explored in the next section discussing relationships between chronic joint pain, HPT and other risk factors. However, it is therefore evident that women with both chronic joint pain and/or HPT experience more pain, poorer health-related quality of life and functional limitations compared to women without these diseases. It is recommended that the intervention Programme should include education on optimal pain management and exercise (strength-training, flexibility, and functional activities) to improve the health outcomes in this sample of women.

4.5.4.3 Relationships between chronic joint pain and CDL

The Bivariate analyses showed that higher age, low physical activity levels (PA MET), poorer health-related quality of life (lower EQ-5D-3L Health Utility Score) and functional problems (higher WHODAS 2 score) were significantly worse in those with chronic joint pain and HPT compared to those without. To further substantiate these relationships, CHAID analyses confirmed that older Age (50–59-year-old category) was significantly associated with chronic joint pain; PA MET-min/week (less than 6918.0 PA MET-min/week) was associated with chronic joint pain, and BMI (> 30.25 kg/m²) was associated with chronic joint pain in those who had a PA level of less than 6918 METs. In addition, Age was significantly associated with HPT, and 30-39-year age category was associated with chronic joint pain.

These findings are consistent with both local and international studies reporting significant associations between these factors and chronic joint pain and/or HPT[9 110 298 111 103 53 20 295 63 336 10 344]. This finding implies that the intervention should include management strategies (health education on diet, physical activities and exercise) to address the two common health conditions, chronic joint pain and HPT, and associated factors, specifically low physical activity levels and obesity.

4.6 Strengths and Limitations of the study

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement is a checklist of items that was used to critique the current epidemiological study[345]. In Table 32, each item of the STROBE statement is presented with details of where the recommendation has been addressed.

Table 32: Critical evaluation of epidemiological study using the STROBE guideline

Item	Item No	Recommendation	Section where this is addressed
Title and abstract	1	Indicate the study's design with a commonly used term in the title or the abstract. Provide in the abstract an informative and balanced summary of what was done and what was found.	Abstract (Epidemiological study)
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported.	Section 4.1
Objectives	3	State specific objectives, including any pre-specified objectives.	Section 4.2
Methods			
Study Design	4	Present key elements of study design early in the paper.	Section 4.3: Introduction to Methods
Setting	5	Describe the setting, location, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.	Description of setting and location in Section 4.3 AND dates for data collection and recruitment period is reported in Section 4.4: Introduction of results
Participants	6	Give the eligibility criteria, and the sources and methods of selection of participants	Section 4.3.1.1
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Section 4.3.2
Data sources/measurements	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Section 4.3.2 AND Section 4.3.4
Bias	9	Describe any efforts to address potential sources of bias	Section 4.3.4
Study size	10	Explain how the study size was arrived at	Section 4.3.1.2
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Section 4.3.4
Statistical methods	12	Describe all statistical methods including those used to control for confounding	Section 4.3.4
		Describe any methods used to examine subgroups and interactions	Section 4.3.4
		Explain how missing data were addressed	Section 4.3.4, 4.4.3.1 AND 4.4.3.2
		If applicable, describe analytical methods taking account of sampling strategy	N/A
		Describe any sensitivity analyses	N/A
Results			
Participants	13*	Report numbers of individuals at each stage of study – e.g. numbers potentially eligible, examined for eligibility, confirmed eligible,	Section 4.4: Introduction to results

Item	Item No	Recommendation	Section where this is addressed
		included in study, completing follow-up, and analysed	
		Give reasons for non-participation at each stage	Section 4.4
		Consider use of a flow diagram	Section 4.4
Descriptive data	14*	Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders	Section 4.4.1
		Indicate number of participants with missing data for each variable of interest	Number of participants reported for each instrument as n throughout Section 4.4
Outcome data	15*	Report numbers of outcome events or summary measures	Numbers are reported for each instrument as n in Section 4.4
Main results	16	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Section 4.4.2-4.4.6
		Reported category boundaries when continuous variables were categorized	Category boundaries provided
		If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done – e.g. analyses of subgroups and interactions, and sensitivity analyses	Method described in Section 4.3.4
Discussion			
Key results	18	Summarise key results with reference to study objectives	Section 4.4.7 AND 4.5
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	Section 4.6
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from the similar studies, and other relevant evidence	Section 4.5
Generalisability	21	Discuss the generalisability (external validity) of the study results	Section 4.5 AND 4.7
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.	Sources of funding are mentioned under acknowledgements and in the Abstract

A limitation of this study is the use of a cross-sectional research design. This means that no cause-and-effect relationships between variables can be determined. However, valuable information was extracted from this study which describes the characteristics and health profile of women attending a local CHC in an under-resourced area in Cape Town. Even though this study was limited to a single CHC, some aspects of the results appear common to the population in Cape Town as supported by the findings of several other studies[27] [23] [44] [153] and could therefore be generalizable to women attending other CHCs in Cape Town. Furthermore, the information extracted from this CHC was useful as it highlighted a need for evidence-based interventions for women with chronic joint pain or OA and HPT at the Mitchells Plain CHC. The proposed intervention will be designed and implemented at this CHC to improve the health outcomes of these women.

A limitation of the study was the length of time it took for participants to complete the questionnaires and clinical testing. There were many women (n=299) who did not complete the weight and height measurements to calculate BMI due to time constraints to see their respective health professionals. The missing responses for BMI could have contributed to the overall presentation of obesity in the sample, as the results might have been underestimated or overestimated, influencing the reported associations between obesity and MSD and CDL. However, this potential bias was assessed using additional analyses through Chi Square tests to determine if the presence of diagnostic categories were related to having missing responses. Fortunately, the missing responses were not related to the presence or absence of MSD and other chronic diseases indicating that the results presented in the study are accurate and valid.

Another limitation of the study was the self-report of chronic joint pain and CDL. There were no health care professionals involved to diagnose the women who participated in the study, and this could have influenced the prevalence rates of chronic joint pain and comorbidities. However, the women reported on previous diagnoses of arthritis or rheumatism (158 of 364 cases) and CDL, and these reports were confirmed in their medical folders thus reducing risk. The definition of chronic joint pain used in the survey to determine prevalence included the symptoms of arthritis or OA as highlighted and discussed previously in Section 4.5.2, which further reduces the risk of self-report bias.

4.7 Conclusion and Recommendations

4.7.1 Conclusion

The study aimed to determine the prevalence, characteristics, health-related quality of life, functional impact, and physical activity levels of women with chronic joint pain such as OA and chronic diseases of lifestyle attending a local Community Health Centre to establish the contextual background for an intervention. This study found that the typical woman attending the CHC was of middle age (50 years), spoke isiXhosa or Afrikaans, had low levels of formal education (mean grade 8), was married with children, was unemployed or a housewife and receives government funding (state grants) as an income. Some of these women indicated that they smoke cigarettes (22%) and consume alcohol (13%).

There was a high prevalence of chronic joint pain (45.3%; 95% CI: 41.9-48.8), of which 43.4% (158 of 364) had previously been diagnosed with arthritis or OA; with the knee joint being most affected. It was noted that women with chronic joint pain experienced moderate pain severity (PSS=5.3, SD=1.45) and had moderate pain interference with activities particularly requiring physical functioning, such as general activity (PIS=5.8, SD=2.83), normal work (PIS= 5.7, SD=3.09) and walking (PIS=5.4, SD=3.25).

Approximately 70% of the women reported receiving pharmacological treatment (prescribed analgesia and NSAIDS) for treatment of pain and other symptoms related to chronic joint pain at the CHC. Even though a high number of women with chronic joint pain were receiving medical treatment, only a few reported receiving non-pharmacological management with exercise (20%, n=70), massage (7%, n=25) and education (6.6%, n=24) being the most common interventions received. In addition, a few women (14%, n=54) reported that exercise was the best intervention that reduced symptoms. The majority of women were not receiving optimal non-pharmacological management for chronic joint pain at this CHC.

More than half of the women (N=803) reported having hypertension (HPT) and 23% had diabetes mellitus type 2 (DM2). Nearly 70% (n=556) had one of the three chronic diseases, 161 women (20%) had both chronic joint pain and HPT and 85 women (11%) had all three conditions. Women who attended this CHC presented with multimorbidity, negatively impacting their health-related quality of life and physical functioning. Women with chronic joint pain and HPT, had significantly lower health utility scores indicating poorer health-related quality of life. Most women were obese and did not engage in sufficient physical activity or exercise (low levels of physical activity).

On the WHODAS 2, some women reported having moderate difficulty with activities such as walking, standing, household responsibilities, and work. Notably, women with both chronic joint pain and HPT had significantly lower WHODAS scores than those without disease, indicating a poorer level of functioning and disability in affected women.

4.7.2 Clinical and research implications and recommendations

The results of the epidemiological survey highlighted that poor middle-aged women living in an under-resourced urban area attending a local CHC in Cape Town suffer from a high prevalence of chronic joint pain and HPT. Not only do these women suffer from chronic pain associated with these conditions but they have problems with functional activities in and outside the home and experience difficulties with their emotional functioning. Factors such as obesity and lack of physical activity may be contributing to the high prevalence of disease and poor level of functioning, however, no cause-and-effect relationships could be determined from this study. It is evident that women with chronic joint pain and HPT have poor levels of physical and emotional functioning and poor health-related quality of life.

In conclusion, the results of this study emphasize a need for the assessment of chronic joint pain or OA and associated chronic diseases and the need for evidence-based non-pharmacological interventions for these women. Interventions for these women can be optimised by including appropriate health education on chronic joint pain or OA and HPT, weight-loss strategies, exercise with a focus on overall strengthening and functional activities, pain management and stress and anxiety management. The next chapter will discuss the development of an evidence-based intervention Programme for women with osteoarthritis and hypertension based on the results of this survey and thereafter, the results of a clinical trial testing the effectiveness of such an intervention.

5 CHAPTER 5: THE DEVELOPMENT OF A CONTEXTUALLY RELEVANT INTERVENTION FOR OSTEOARTHRITIS

5.1 Introduction

This chapter aimed to describe the process followed in the development of the intervention for the Phase II study (SmArt-Health) in achieving the second aim of the thesis. The aim was to adapt and develop a contextually relevant non-pharmacological intervention Programme based on exercise, health education and self-management principles designed to educate, empower, improve functional status and health-related quality of life of women with OA and comorbidities.

The intervention was developed by addressing the following objectives:

- To determine the best evidence for effective interventions for people with osteoarthritis through a narrative review (Chapter 2, Section 2.6)
- Establishing which topics were relevant to the participants to incorporate in the educational booklet by extracting the results from Aim 1 (Chapter 4, Section 4.4)
- To ensure contextual relevance by including the participants in the decision-making regarding the preferences, nature, and content of the intervention Programme through questionnaires.

Therefore, the purpose of this chapter is to describe the structure and content of each component of the intervention.

5.2 The development of a contextually and relevant non-pharmacological intervention for women with osteoarthritis

In answering the first objective, the review about clinical guidelines (Chapter 2, Section 2.6.2) highlighted that a combination of health education, self-management principles and exercise were the “core” treatments for osteoarthritis of the knee and hip in adults. Randomised controlled trials reviewed in Chapter 2 (Section 2.6.2) which implemented these recommendations in adults with OA, reported that these were effective management strategies for OA providing improvements in pain, physical function, health-related quality of life and other health outcomes.

Based on the review of the literature, it was decided to develop a non-pharmacological management model of care advocating a patient-centred self-management approach by incorporating the "core" treatments of education, self-management, and exercise for women with OA attending a primary health care facility in Cape Town. Furthermore, it was important for the non-pharmacological intervention to be contextually relevant for all the women participating in the study. The intervention had to consider the context that was relevant to the participant[45]. In other words, the current health needs, social environment, and personal preferences of affected women had to be considered through shared decision-making to be able to provide meaningful information and management strategies that were relevant to these women.

5.2.1 Theories and principles underpinning the development of an intervention for osteoarthritis

5.2.1.1 ICF Framework

The ICF framework has been used as the preferred theoretical framework underpinning the rationale and development of an appropriate intervention for people with osteoarthritis and associated chronic diseases of lifestyle (Chapter 1, Section 1.2). This framework provides an understanding of the various factors affecting the individual's functional ability and activities in relation to a health condition[29]. Therefore, the ICF framework was used to conceptualise the intervention by highlighting the impact of OA on women in relation to impairments, activity, and participation restrictions.

5.2.1.2 Principles of Self-management and Self-efficacy

Therapeutic approaches applying cognitive-behavioural principles integrating self-management of pain and exercise have been advocated as appropriate interventions to ameliorate negative behaviours (lack of physical activity and poor diet) and reduce pain, disability and improve quality of life in people with chronic pain[144-146].

The term "self-management" is particularly important to people who are diagnosed with chronic diseases, such as OA, as the affected person should be responsible for the day-to-day management of their illnesses[346]. Self-management education Programmes are specifically designed to help change behaviour by empowering people with chronic diseases to be able to take responsibility and manage their own health problems. The aim of self-management Programmes is not to replace medical care but to embed that care within in a patient-centred interdisciplinary team to improve outcomes for these patients[347 348].

A self-management Programme should consider the patient's needs, concerns and problems and it is important to conduct a needs assessment with each group of patients to determine the appropriate topics for the Programme[346]. There is evidence for the use of self-management education Programmes with people with arthritis and osteoarthritis[349-352]. One of the most commonly reported on self-education Programme is the arthritis self-management Programme (ASMP), developed by the Stanford University School of Medicine chronic disease self-management Programme by Lorig and Sobel (2001)[154]. The ASMP runs for 2.5 hours per week over a 6-week period and is led either by trained peers or health professionals. The content covered throughout the Programme is specific to osteoarthritis and includes how to manage pain and fatigue, the benefits of physical activity or exercise, understanding how to use medication, how to manage anger, fear, and frustration, how to solve health-related problems and how to improve communication with doctors and health professionals.

There are five core self-management skills that are embedded in self-management Programmes including in the ASMP. These core skills are problem-solving, decision-making, utilising resources, developing partnerships with health professionals and taking action[346]. Self-management Programmes should teach basic problem-solving skills to patients through the practical identification of problems, developing solutions for the identified problems, implementing the solutions, and evaluating the results. Decision-making should be facilitated through teaching patients about disease processes, risk factors, symptoms, and skills to manage their condition at home to be equipped to self-manage their illnesses daily. If patients are given appropriate information about their chronic disease, they would be able to make important decisions about whether visiting a doctor is necessary or not.

A self-management Programme should encourage and empower patients to form relationships with their health professionals. Skills for use in health care consultations such as asking questions about their diseases and other illnesses and skills to enable patients to share the decision-making about the best treatments for them should be developed in a self-management Programme. In addition, the Programme should include the skill of taking action. This is related to behaviour change through goal-setting, measuring the patient's confidence levels or self-efficacy and developing an action plan to achieve the goal[346]. Raising self-efficacy can promote the adoption of healthy lifestyles by enabling people with behavioural and coping strategies to assist with personal changes. If people have a stronger perceived self-efficacy, they are more likely to be successful in reducing unhealthy habits and are able to adopt and implement new healthy habits into their daily routine more confidently[335].

To understand the term self-efficacy better, Bandura (1994, p.1)[335] defines self-efficacy as:

"*people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives.*

Self-efficacy beliefs determine how people feel, think, motivate themselves and behave. Such beliefs produce these diverse effects through four major processes. They include cognitive, motivational, affective and selection processes".

Stronger perceived self-efficacy in individuals can lead them setting challenging goals but with a stronger commitment to achieve them. Therefore, self-belief or self-confidence in people, as part of self-efficacy, plays an important function in motivating and leading them to believe what they can and cannot do. A strong self-confidence can help people think ahead of possible outcomes of their proposed actions and to set relevant goals and plan appropriate action plans to produce these outcomes for themselves. People with strong self-confidence levels can manage their behaviours and can develop incentives to help them persevere to attain the challenging or difficult goals. It is for this reason that self-management Programmes should consider self-efficacy and guide people in developing strong self-confidence or self-efficacy to facilitate success in achieving goals to adopting a healthy lifestyle[335].

The SmArt-Health Programme was developed with content like the ASMP but was modified for context. The Programme was developed incorporating the principles of self-management (including the core self-management skills) and self-efficacy highlighted above. These principles were included with the aim of empowering participants through the transfer of knowledge and development of skills to self-manage osteoarthritis.

5.2.1.3 Principles of Adult learning

In facilitating self-management of chronic diseases such as OA and comorbidities in adult patients at primary health care facilities, it is important to consider the principles of adult learning to optimise self-directed learning. The principles of adult learning by Malcolm Knowles, the pioneer of adult learning (1977)[353], as summarised by Lieb (2005)[354] were used to inform the pedagogy of the intervention. The following principles were considered:

Adults should be autonomous and self-directed: Adults should be active participants in the learning process and feel free to direct themselves through group work and discussions about topics that are relevant to them.

Adults have life and work experiences and previous knowledge: Adults should be allowed to draw on their previous experiences and knowledge to help understand the theories and concepts taught to be able to value the learned content.
Adults are driven by goals: Adults are goal-oriented and in an educational workshop, the instructor should state the specific learning objectives of the workshop and how to obtain their specific goals for the intervention.

Adults are interested in concepts that are relevant: Instructors should consider content and concepts that would be applicable and relevant to the group of adults to be taught. The adults would value the learning more if they can relate the learning to their own work or experiences.

Adults are more practically minded: Instructors should consider facilitating knowledge and learning that would be useful to the adults in their homes or work. Adults will appreciate the learning more if they can practically apply it to themselves.

Adults need to be respected: Instructors should create opportunities for adult learners to share their experiences and acknowledge their acquired knowledge and life experiences in the intervention. Adult learners should be able to speak freely about their experiences and should always be respected.

The principles of Adult learning were embedded within the SmArt-Health intervention Programme. The instructor was a qualified physiotherapist and was sufficiently trained to facilitate the SmArt-Health Programme using these principles. Further information about the training and the delivery of the intervention is described in section 5.2.3.2.

5.2.2 Characteristics and profile of women for the intervention

This section will be answering the second and third objectives:

- To determine which topics are relevant to the participants to incorporate in the educational booklet by extracting the results from Aim 1 (Chapter 4, Section 4.4)
- To ensure contextual relevance by including the participants in the decision-making regarding the preferences, nature, and content of the intervention Programme through questionnaires

The results of the Epidemiological study (Phase I) (Chapter 4) were reviewed to identify the characteristics and health needs of the women affected by OA and subsequently highlighting the important topics that should be included in the educational component of the intervention.

Based on the results of the study presented in Chapter 4, it was identified that two chronic diseases, hypertension (HPT) and diabetes mellitus type 2 (DM2), should also be targeted in the intervention, in a single intervention which might be a more cost-effective use of resources. In addition, the intervention would need to target women older than 30 years, be available in Afrikaans, isiXhosa and English with reading materials at a Flesch-Kincaid reading level of grade 8 with a readability score of 60-70, which is understood by 13 to 15 year old learners[355].

Apart from suffering with symptoms related to these chronic diseases (MSD, HPT and DMII), these women reported on the impact of health outcomes. Most of the women reported having moderate levels of joint pain, problems with physical functioning such as walking and mobility in the home and at work, were obese and had low levels of physical activity. All of these may in turn negatively affect their health-related quality of life. Therefore, it would be relevant for the intervention to target these outcomes for positive change.

As approximately 75% of the women in the Phase I study reported being unemployed, housewives or retired, it appeared that it would be acceptable for the intervention to be implemented at a venue within or near the local CHC in Mitchells Plain during the day. In addition, transport costs to and from the CHC should be included in the budget for the delivery of the intervention as more than 77% of the women earned a meagre monthly income of less than R2000[8].

[8] SA R2000 is converted to US $119.62 using the conversion rate of 1 US dollar = R16.72 dated 1 September 2020

5.2.3 The "SmArt-Health" intervention and workbook

The "Self-management for Arthritis and High blood pressure with education, activity and lifestyle modification therapy" (SmArt-Health) intervention Programme comprised of the "core treatment" (education, self-management, and exercise) to manage osteoarthritis in women. The aim of the intervention was to reduce impairments (joint pain, hypertension, obesity) and improve activity and participation restrictions (health-related quality of life, physical activity levels, physical function in walking, climbing steps, sit-stand activities) in women with osteoarthritis and hypertension through empowering patients with self-management skills and increasing self-efficacy.

The intervention was specifically designed for middle-aged women with OA and Hypertension (HPT) attending the Mitchells Plain Community Health Centre (CHC) in Cape Town and who had previously participated in the Phase I study. The intervention Programme was a six-week workshop consisting of facilitated sessions using a workbook with content related to health education, self-management principles and exercise.

5.2.3.1 Description of the Workbook

The SmArt-Health intervention used a workbook (Appendix E-1) that was modified from one previously used in South African studies managing HIV/AIDS[44], end-stage OA in patients on a waiting list for arthroplasty in Cape Town (Western Cape)[151] and in Johannesburg (Gauteng)[304] and OA in adults living in a peri-urban area in Bloemfontein (Free State)[190 356]. These workbooks were developed based on self-efficacy theory[357] and the principles of self-management used in the chronic disease self-management Programme from Stanford University School of Medicine[154 346]. The workbook incorporated health education on the management of the relevant chronic diseases.

Health Education

A lack of knowledge and awareness of poor lifestyle behaviours that contribute to the development of chronic diseases and ill health is a problem in many patients attending primary health care facilities. It is important to provide patients with the knowledge about health risks for chronic diseases to create an awareness of unhealthy lifestyle and practices[358]. The primary emphasis of health education is about understanding unhealthy behaviours and choices related to their health conditions and to changing these behaviours[359]. However, knowledge alone is not sufficient for behaviour change and personal efficacy is needed for success in adopting new healthy lifestyle behaviours[358].

Obesity and lack of physical activity were common risk factors that emerged in the women with OA and HPT who participated in Phase I of this study. Obesity is a primary risk factor for knee OA[328 329]. Although the exact mechanisms linking the two health problems are complex and further research is needed to explore the specific mechanical and metabolic pathway in which obesity may contribute to structural damage in joints[360], there is evidence to support that weight loss reduces pain, improves function and delay disease progression in obese individuals with knee OA[328 329 360 361]. It is, therefore, recommended that obese individuals with knee OA should follow a weight loss intervention, in addition to other core interventions for OA. Not only does weight loss benefit individuals with knee OA, but it can also help reduce hypertension.

There is evidence available on effective strategies for weight loss and reduction of blood pressure in people with hypertension. According to NICE[38], EULAR[40] and OARSI[39 138] clinical guidelines on best management strategies for osteoarthritis, interventions for weight loss should include information about how to plan and eat healthy meals with a focus on reducing calorie intake, reducing fat and sugar, reducing portion size, meal replacements, self-monitoring, weight-loss goals and maintaining body weight in participants who had reached their goals. An example of such a weight loss intervention is documented by Blumenthal et al., (2000)[362] in a study about exercise and weight loss for people with hypertension. The clinical trial included various intervention components for participants including an aerobic exercise class only, a weight loss and exercise programme, and a waiting list control group. The weight loss intervention was based on behavioural modification strategies relating to exercise, nutrition, lifestyle, attitudes, and relationships. The weight loss component of the intervention was a group-based programme of approximately 26 weeks with weekly group sessions. Participants had recorded their weight at the beginning of each session and kept a food diary. Participants started each week with a review of their food diary and weekly goals based on behaviour modification targets. After the group review and feedback session, the facilitator worked through educational topics from a workbook that focused on behaviour change strategies that discussed healthy eating, meal planning, shopping, and coping with stressful situations and relapses. The last few sessions dealt with weight maintenance and individual plans to maintain the weight loss achieved in the past few weeks[362].

The study by Blumenthal et al., (2000)[362] found remarkable results in that both treatment groups had significantly reduced the blood pressure (BP) measures compared to the control group. However, participants in the weight loss intervention had larger reductions in BP compared to the exercise only and control groups. Therefore, combination therapy consisting of aerobic exercise and a behavioural weight loss strategies is recommended to reduce BP measures in overweight and obese individuals[362].

In addition, individuals with hypertension who follow a weight loss programme and exercise, should restrict alcohol consumption and salt intake in their diet[363].

Literature highlighted the need to include health education related to topics about the symptoms and management of OA and HPT, self-management strategies of these chronic diseases, benefits of exercise and how to safely participate in exercise, stress management, healthy eating for weight loss, and medication were included in the SmArt-Health workbook. The trained physiotherapist facilitated health education of these various topics through the workshop and the use of the workbook.

Educational content in the workbook

The workbook played an integral role in the intervention, as a supplement to reinforce knowledge about self-management of osteoarthritis and hypertension in the participants' daily routine. Each participant was encouraged to actively engage with the content of the workbook during the weekly facilitated workshops and afterwards at home to be able to understand, consolidate and apply the new information taught in their daily lives. The workbook was divided into six weekly educational topics (Table 33).

The workbook included action planning forms (Appendix E-1) and exercise diaries (log sheet) (Appendix E-2) for the participants to use. At the end of every educational session, goal setting and action planning for the week was facilitated with the participants. Thereafter, the participants were instructed to record the executed exercises or physical activities that were planned for each week. At the beginning of every session, debriefing with the participants was done to reflect and discuss their experiences of implementing the planned activities over the past week. Furthermore, at the last session, the physiotherapist reviewed the participants' weekly action planning forms and exercise diaries and provided feedback about their new healthy behaviours that were implemented at the start of the workshop and highlighted their achievements.

Table 33: Educational topics in the SmArt-Health workbook

Topic per week	Educational Content	Self-management component
Week 1: Osteoarthritis, High blood pressure, Self-management and Exercise	• What is Osteoarthritis • What is High blood pressure • What can physiotherapy do for high blood pressure • What is Self-management • Benefits of Exercise • Types of exercises • Steps to success with exercise • An exercise routine	Goal setting and Action plan for Exercise
Week 2: Managing common symptoms related to osteoarthritis and high blood pressure	• What is pain • What is stiffness • What is swelling • Difficulties doing certain activities • Pacing and resting • What is fatigue, frustration and depression • What is the cause of headaches • Why do I feel shortness of breath • Resting positions for breathlessness • Why do I get chest pain	Goal setting and Action plan for Managing common symptoms
Week 3: Stress Management	• What is stress • Managing stress • Relaxation skills • Sleep management	Goal setting and Action plan for Stress Management
Week 4: Eating Well	• The diesel diet • Low fat-high carbohydrate diet • High fat-low carbohydrate diet • Food to avoid if you have high blood pressure • Drinking water • Losing weight	Goal setting and Action plan for Nutrition
Week 5: Medication and disease-related problem solving	• Analgesic drugs • Anti-inflammatory drugs • Anti-spasmodic drugs • Anti-depressant drugs • Medication for high blood pressure • Making informed decisions about treatment • Appropriate use of medication • Communicating effectively	Goal setting and Action plans
Week 6: Continuing as a successful self-manager	• Key components of successful self-managing • Action planning for the future • Reflection on behaviour changes	Review of completed Exercise diaries

Exercise

Based on the literature and the characteristics of the participants, the exercise component of this intervention included strengthening exercises, stretching and endurance exercises focusing on muscles of the lower limb. The exercise Programme previously used in the workbook by Parker (2013)[44] was modified using the general principles of exercise prescription by the American College of Sports Medicine (ACSM)[364]. The exercises were selected to improve the functional problems that participants reported in the Phase I study and was tailored for middle-to-older aged women. The cultural diversity of the participants was considered when the exercises were developed. The exercise session was accompanied by appropriate music to encourage participant engagement. The weekly exercise routine is displayed in Table 34.

Table 34: Weekly exercise routine for participants

Exercise routine	**Breakdown of components (25-35 minutes total)**
Start with correct breathing techniques	2 minutes
Postural alignment in standing	1 minute
Warm up: Marching on the spot	2 minutes
Stretching of muscles in spine and lower limbs	5 minutes
Strengthening exercises of hip and knee	5-10 minutes
Functional exercises: Sit to stand from chair Stepping up and down steps Marching on the spot (intermittently)	5-10 minutes
Cool down: Gentle stretches Breathing exercises	5 minutes

Relaxation

Relaxation training is a common non-pharmacological therapy used for managing chronic pain[365]. Relaxation techniques, such as guided imagery with deep breathing and muscle relaxation through body scan methods, have been found to be effective in reducing pain in people with cancer[366], chronic pain[367], chronic musculoskeletal pain[368] and osteoarthritis[369].

Relaxation training has also been found to be effective in managing chronic headaches, improving vitality and sleep[370]. Furthermore, relaxation therapy as part of stress reduction programmes, has been found to be effective in preventing or treating patients with hypertension[371] [372] [373]. Since the intervention was developed for women with OA and Hypertension, who have symptoms of chronic pain, possible headaches and sleep problems, a component of relaxation was included into the workbook as part of the intervention (Appendix E-1).

5.2.3.2 Training and Delivery of the SmArt-Health intervention

Training of the physiotherapist

A qualified physiotherapist was recruited to conduct the SmArt-Health intervention to the participants. The physiotherapist was trained in the content of the SmArt-Health workbook, and the method to facilitate the various components of the intervention (educational workshop, exercise session, relaxation session and the self-management session). The physiotherapist was able to deliver the intervention in English and Afrikaans, with the assistance of an isiXhosa-speaking translator if necessary.

The principles of adult learning were applied in the training of the physiotherapist (instructor) in a form of experiential learning. The physiotherapist adopted these principles of adult learning throughout the intervention programme to optimise participant engagement as active learners to become successful self-managers of their chronic diseases. In addition, the physiotherapist was instructed to address four key elements of learning when facilitating the intervention programme: 1) Motivation, 2) Reinforcement, 3) Retention and 4) Transference[354].

Motivation was an important aspect for the physiotherapist to consider as adult patients (adult learners) learn best when knowing the reasons for participating in the intervention programme and understanding the expected outcome. Therefore, the physiotherapist incorporated motivating strategies by showing the relationship between the intervention programme and the expected outcomes[354].

One strategy was to remind the adult learner about the reason for joining the workshop and the possible outcomes (self-manager of pain and symptoms, improved functional abilities, improved sleep, stress management, improved quality of life) in the weekly sessions to keep the adult learner interested and motivated to complete the intervention. The physiotherapist reinforced the learned content by promoting the benefits of learning to the adult learners and encouraged the adoption of positive behaviours throughout the intervention[354].

Another method of reinforcement was reviewing of weekly goals and feedback on the effects of achieving those goals. Furthermore, a positive reinforcement for completing the intervention was receiving a "certificate" on completion of the intervention.

Retention of the learned content was important and the physiotherapist assisted the adult learner to apply the gained knowledge in their daily lives to be able to value and retain the learning[354]. The weekly demonstrations of the exercise programme and review of the goal-setting tasks were examples of applying the new knowledge gained to help the learners enhance retention.

Transference was the last element of learning whereby the adult learner applied the gained knowledge about managing their chronic diseases and the behavioural changes taught in the lives[354]. In the intervention, the adult learners completed the "Action plan forms" and "Exercise diaries" on a weekly basis and applied the gained knowledge in their daily lives. At the end of the intervention programme, the adult learners reflected on positive behaviour changes made throughout the intervention. Transference could have only occurred if the adult learners could associate with the new knowledge; if the knowledge were similar to what they knew; if the knowledge was beneficial for them; and if the level of original learning was high. The success of the adult learner and ultimately the success of this intervention demanded a great responsibility from the physiotherapist[354]. Hence, it was for this reason that the principles and key elements of adult learning were embedded in the training of the physiotherapist and the intervention programme.

Delivery of the SmArt-Health intervention

The SmArt-Health intervention was conducted in a conference venue in a clinic adjacent to the Mitchells Plain Community Health Centre. The intervention occurred during the day from 12 pm to 2 pm and was delivered in a workshop format with small groups of 10-13 participants each. Furthermore, the participants were randomly assigned to three groups and each group were allocated a specific day of the week (Monday or Tuesday or Wednesday). The SmArt-Health intervention was conducted once a week for two hours for a period of six weeks. The small groups of 10-13 participants and the duration of six weeks in the workshop was supported by similar self-management intervention studies for chronic diseases such as OA[350 154] that used a similar protocol in delivering their interventions. In addition, the six-week duration was adequate to produce significant improvements in health outcomes[350 154].

The first two-hour session comprised of an educational session of one hour, an exercise component of approximately 25 minutes, and a relaxation session of 10 minutes facilitated by the trained physiotherapist. The remaining five intervention sessions started with round table feedback on the participants' goals and achievements for the past week and then followed the same sequence as the first session.

The exercise session was progressed weekly by adding two minutes to the duration of the session and by increasing the frequency and intensity of exercises. The physiotherapist ensured that each participant performed the different exercises safely and correctly and monitored for signs of distress. If there was a participant that reported an increase in pain in the affected joints and laboured during the exercise session, that participant would be told to reduce the intensity of the activity. If symptoms persisted after resting, the participant was escorted to the emergency care unit at the CHC. Fortunately, there were no participants that reported pain during the facilitated exercises sessions and no participant needed emergency care. In addition, each participant was encouraged to record their weekly exercise routines in their exercise diaries.

After the exercise session, the physiotherapist facilitated the relaxation session through using a body scan relaxation audio-recording with the participants in a supine-lying position on a mat, with their eyes closed. The body scan guides and instructs the participant to become aware of their body and facilitated breathing techniques to help relax tight muscles in the body from the head to toes. This relaxation technique was added in the SmArt-Health workbook as part of the "Stress management chapter".

At the end of each intervention session, the group of women were invited to have a light healthy snack and could socialise with each other. Attendance for the intervention was recorded and monitored on a weekly basis. The research manager contacted participants if they had missed a session and encouraged them to attend the next session. Telephone calls and cellphone text-based messages were sent to participants on a weekly basis as a reminder for the workshop the next week. At the final session, we had a small social gathering and awarded all the participants with an attendance certificate. Thereafter, the participants were discharged from the workshop and were encouraged to keep in contact with their small group of peers for added support.

6 CHAPTER 6: THE EFFECT OF THE SMART-HEALTH INTERVENTION ON FUNCTION AND HEALTH OUTCOMES IN WOMEN WITH OSTEOARTHRITIS AND HYPERTENSION: A RANDOMISED CONTROLLED TRIAL

6.1 Introduction

Osteoarthritis (OA) is one of the ten leading causes of functional impairments and severe disability, causing years lived with disability (YLD) in both developed and developing countries[48]. Osteoarthritis has been reported as the most common type of arthritis across the world[101 374 57 60 17]. It is evident that OA is more prevalent in middle-aged women and especially affects those living in impoverished areas in developing and developed countries[9 52 298 19 63 17]. As the burden of osteoarthritis increases with age in these women, so does the burden of comorbidities, such as hypertension (HPT)[343 53 318 20]. Apart from suffering from chronic pain related to osteoarthritis, these women often have poorly controlled hypertension and difficulties with physical functioning (walking, standing and household chores) and may experience related poor health-related quality of life. The implication of these findings is that there is a need for evidence-based management strategies to address these two prevalent chronic diseases in women attending primary health care centres.

As discussed in Chapter 5, the SmArt-Health (self- management for osteoarthritis and hypertension with education, activity, and lifestyle modification therapy) intervention programme was developed for middle-aged women diagnosed with osteoarthritis and hypertension attending a local community health centre (CHC). This intervention programme is a new format of care advocating a patient-centred self-management approach for women with both osteoarthritis (OA) and hypertension (HPT) at a CHC in Cape Town. The primary goal of treatment was to improve physical functioning and health-related quality of life by reducing pain, obesity, blood pressure and blood glucose levels, and increasing physical activity levels.

6.2 Aims and objectives

The aim of this phase of the study was to determine the effect of the SmArt-Health intervention on impairments (joint pain, obesity, hypertension, diabetes mellitus type 2); activity and participation restrictions (physical function in walking, climbing steps, sit-stand activities, health-related quality of life, physical activity levels,) and personal factors (self-efficacy in managing chronic diseases) in women with both osteoarthritis and hypertension.

6.2.1 Hypothesis

Women with osteoarthritis (OA) and hypertension (HPT) will have improvement in self-reported and performance-based physical function, pain, blood pressure, blood glucose, obesity, physical activity levels, health-related quality of life and self-efficacy after participating in the six-week SmArt-Health intervention supervised by a physiotherapist.

6.2.1.1 Null hypothesis

Therefore, the null hypothesis for this study is that women with osteoarthritis (OA) and hypertension (HPT) will not have any statistically significant improvements in self-reported and performance-based physical function, pain, blood pressure, blood glucose, obesity, physical activity levels, health-related quality of life and self-efficacy compared to women who did not participate in the physiotherapist led six-week SmArt-Health intervention.

6.2.2 Objectives

To establish, in a sample of women attending a CHC with both OA and HPT, whether there was a significant difference between those receiving the SmArt-Health intervention and those receiving usual care in:

- Self-reported physical function (WHODAS 2 12-item)
- Performance-based physical function (walking, climbing steps, sit-stand activities) (ALF)
- Pain (BPI)

- Blood pressure
- Blood glucose levels
- Obesity (BMI)
- Physical activity (IPAQ)
- Health-related quality of life (EQ-5D-3L)
- Self-efficacy levels in ability to self-manage chronic diseases (Self-efficacy for Managing Chronic Disease 6-item Scale)

The primary outcome measure was self-reported physical function assessed by the WHODAS 2 and objectively assessed with the Aggregated Locomotor Functional (ALF) test.

6.3 Methodology

6.3.1 Research design

A pragmatic randomised controlled trial (RCT); single blinded, pre-test-post-test design was used. It is acknowledged that the confounding variables of physiotherapy treatment and medication might have impacted on the results. However, due to the random allocation, these effects were equally distributed across both the control and the experimental groups. The inclusion criteria stipulated that the participants had to attend the relevant Physiotherapy OA and Chronic disease clubs for one month or more prior to being recruited to the study, in the expectation that the immediate effect of either physiotherapy or pharmacological intervention would have already resulted in changes in their functional status.

6.3.2 Participants

Participants were recruited from the sample of women who participated in the Epidemiological study (Phase I) in 2014 at the Mitchells Plain CHC. Women aged 30 years and older that had a previous diagnosis of OA and who attended the chronic care clubs for the management of hypertension at the CHC were invited to participate in the study. Therefore, all women who had both OA and HPT were included in this study.

6.3.3 Inclusion criteria

The following criteria were used to select participants for the study:

- Diagnosed with OA and HPT at the CHC
- Previously attended the OA “group” at the physiotherapy department or attended the chronic care “club” for CDL management at the CHC
- Attended the management “group or club” for one month or more
- Read and write in English, Afrikaans, or isiXhosa.

The participants were contacted telephonically and recruited sequentially until the target enrolment was met.

6.3.4 Exclusion criteria

Women were excluded if they:

- Did not meet the minimum standards for safe participation in exercise as established through the use of the American College of Sports Medicine (ACSM) Risk stratification categories for cardiovascular disease[364] (Appendix D-7)
- Had acute HIV disease manifestations such as flu-like symptoms, weight-loss, neurological symptoms (peripheral neuropathy), visceral pain and chronic musculoskeletal pain as recorded in their medical folders
- Started on Anti-retroviral medication or TB treatment within the last three months as recorded in their medical folders
- Had acute traumatic joint injuries, or were immobilized in a cast/external fixation or had surgery after the initial screening phase
- Were pregnant
- Had communication difficulties due to cognitive impairments
- Had received any kind of 'hands on' physiotherapy treatment

6.3.5 Sample size calculation

At the time of the intervention, there were no data from clinical trials using the WHODAS 2 or ALF test (physical function) available to gain the means and standard deviations to determine the sample size for this study. Therefore, the EQ-5D-3L health-related quality of life instrument was used to calculate the sample size as data from a different sample of respondents, similar in cultural background and socio-economic status to the participants of the current study were available[375]. Statistica data analysis software system was used to calculate the sample size for this study[376]. According to the EQ-5D-3L results in the study by Jelsma et al., (2004)[375], the expected baseline mean for the VAS was 74.7 with a standard deviation of 14.9. A sample of 74 was calculated to detect the predicted difference of 11.4 in the VAS scores between the means of control and experimental groups with a power level of 90% and the significance level set to 0.05.

Therefore, the calculated sample size required was 37 participants in each group. To allow for attrition, a sample size of 40 participants was required for the control and the experimental group.

6.3.6 Recruitment of participants for randomisation

Telephonic interviews were done to recruit eligible participants for randomisation in this study. The inclusion and exclusion criteria were asked to each participant in the interview. Once the participant passed all the criteria, the ACSM screening tool was used to determine if participants were eligible and physically fit to perform exercises safely. The flow chart below (Figure 25) describes the process of recruitment.

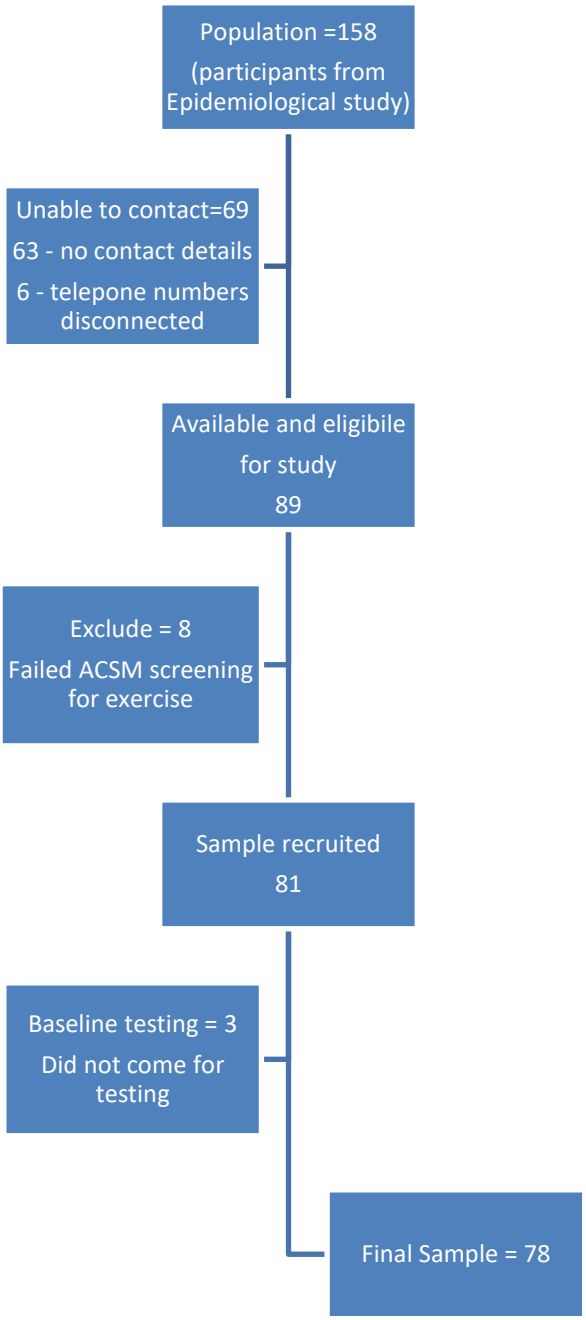


Figure 25: Recruitment of participants for the intervention study

6.3.7 Sampling and randomisation

Random allocation was done using Microsoft Excel randomisation function to help minimize the effect of possible confounders. The sampling frame was all women who had OA and HPT and who participated in the Epidemiological study in 2014.

The names of all women who met the inclusion criteria, passed the ACSM screening tool and agreed to participate in the study were eligible for random allocation into the study.

6.3.8 Intervention and Instrumentation

6.3.8.1 The intervention

The SmArt-Health intervention described in Chapter 5 was used in the RCT. The women in the experimental group participated in the intervention Programme. The women in the control group participated in usual care treatment at the CHC. The usual care treatment for OA at the CHC was a weekly OA educational group class conducted by the Occupational Therapist and Physiotherapist working at the CHC. The group class consisted of 15 to 20 people who had OA or were beginning to develop the disease. There was an attendance register that monitored who attended the weekly classes. The content of the educational class contained information about OA, the signs and symptoms of OA, healthy eating, and information on pain management. All participants underwent testing at weeks 0, 6, and 12 for comparison between groups.

6.3.8.2 Instrumentation

Standardised outcome measures described in Chapter 3 and that were used for the Epidemiological study (Chapter 4) were also used in the intervention study with additional outcome measures. These additional outcome measures are discussed below. All the instruments were available in English, Afrikaans, and isiXhosa languages.

The primary outcome for the intervention study was functional ability assessed by the WHODAS 2 (Appendix D-2) and the additional performance-based outcome measure, the Aggregated Locomotor Function test (Appendix D-4).

The data were collected using the following outcome measures:

- Demographic, social, occupational, medical, pharmacological and rehabilitation history: Using the adapted and validated COPCORD questionnaire[167] (Appendix D-8)

- Functional ability: Self-report using the WHODAS 2 12-item version[203], and the Aggregated Locomotor Function test[213]
- Pain: Brief Pain Inventory (BPI)[183] (Appendix D-1)
- Anthropometric measures: Weight, height and calculated BMI[193] (Appendix D-5)
- Physical activity levels: IPAQ short form[227] (Appendix D-9)
- Health-related quality of life: EQ-5D-3L[215] [214] (Appendix D-3)
- Blood pressure: Using automatic digital blood pressure monitors[377]
- Blood glucose levels: Using out-patient glucometers[378]
- Confidence levels in managing chronic diseases: Self-efficacy for Managing Chronic Disease 6-item Scale[379] [154] (Appendix D-6)

The following additional outcome measures were used for the intervention study (RCT):

- Exercise diary to document weekly exercise to determine rate of attendance and compliance (Appendix E-2)
- Acceptability questionnaire (Appendix E-3)

The acceptability questionnaire was used to determine the attitude of the participants in the intervention group towards the programme. This tool was previously used in a local study on the effectiveness of the Positive Living intervention to manage pain in HIV[44]. Five questions were asked to establish what participants liked most/least about the programme, what they would change or add to the programme and whether they liked the self-management booklet.

The following questions were asked:

1. *What did you like the most about the programme?*
2. *What did you like the least about the programme?*
3. *What would you change about the programme?*
4. *What would you add to the programme?*

5. *What did you think about the self-management book?*

6.3.9 Procedure

Ethical approval was obtained from the Faculty of Health Sciences Human Research Ethics Committee, University of Cape Town (HREC Ref: 093/2014) (Appendix A-1). Approval was obtained from the Western Cape Department of Health before commencement of the epidemiological study and the implementation of the intervention study (RP 030/2014) (Appendix A-2). The intervention study (RCT) was registered as a clinical trial on the Pan African Clinical Trial Registry (PACTR201403000774191). The study conformed to the principles of the Declaration of Helsinki[284]. Permission was gained from the facility managers, sisters in charge and the physiotherapists in charge at the CHC. The sister and physiotherapist in charge received a calendar indicating the dates and times for baseline measurements and for the six-week intervention.

Participants who attended the OA group classes and chronic care club for treatment of HPT at the CHC and that participated in the epidemiological study were contacted telephonically by research assistants until 89 women indicated their willingness and provided verbal consent to participate in the intervention study. However, 81 women met the inclusion criteria and were recruited for the study. Each participant had a unique code that was used for the intervention study to link data of the same participant at every follow-up evaluation session. The participants were given a date to meet at the CHC to explain the purpose and procedures of the study, obtain written informed consent, conduct the baseline testing, and thereafter were randomised into groups (week 0).

Prior to the commencement of the intervention, final year (4th year) physiotherapy students from the University of Cape Town were recruited as research assistants and were trained by the PI on the aims and objectives about the RCT, methodology and outcome measures, the intervention, and data collection procedures. The research team comprising of the study co-ordinator, the intervention physiotherapist, research assistants and the PI were available for all the testing periods and the PI checked that all procedures were conducted in a standardised manner according to the protocol. Furthermore, the PI, study co-ordinator and physiotherapist was available at each intervention session. The physiotherapist had facilitated the intervention with the experimental group, while the PI and study co-ordinator checked that the intervention session was conducted according to the protocol and was consistent with the planned intervention. At the end of each session, the three researchers had a debriefing session discussing any challenges that were experienced in a session. These debriefing meetings were very helpful to ensure treatment fidelity and quality control to ensure that the intervention study adhered to the highest quality standards possible.

During data collection, five stations were created at the research venue for various outcome measures for testing. There were stations for participant interviews; clinical testing using the ALF test; blood pressure and blood glucose testing; height and weight measures and a station to speak to the principal investigator (PI) about the intervention. One research assistant was placed at each station and explained the procedures of the baseline testing and obtained written consent from the participants before gathering the data. At baseline testing, only 78 women completed the outcome measures (questionnaires and clinical tests). Once data collection was completed, the codes of the participants were used to generate a random number using Microsoft Excel 2010 for random allocation into the experimental (EXP) and control (CON) groups.

Treatment allocation was concealed using sequentially numbered, opaque, sealed envelopes to ensure a non-biased estimate of treatment effect. The principal investigator (PI) managed this randomization process. All the research assistants were blinded as to group allocation. The experimental group was further randomly allocated to three groups of 10-13 participants, to ensure adequate numbers of participants for the small group intervention. The PI contacted all the participants in the experimental group to return to the research venue at the CHC the following week to participate in the six-week intervention programme.

The experimental group received a calendar indicating the time and dates for the intervention. The intervention was a two-hour session workshop, facilitated by a different physiotherapist who was trained in using the SmArt-Health workbook, once a week for six weeks. The intervention was implemented over three days (Monday to Wednesday) per week to accommodate the three groups of women for the duration of six weeks. The women allocated to each group could only attend the intervention on the specific day that they were allocated. The experimental group received weekly text-based messages and phone calls as a reminder to attend the intervention programme. The follow-up and reminder system has been found to be useful for encouragement and adherence to interventions in studies[380].

The participants of the control group were called and received dates for repeat measurements only. The control group were expected to visit the CHC for the 6- and 12-week follow-up tests. The control group was instructed to continue with their weekly usual care, in the form of educational group classes at the CHC and received reminder text-based messages to maintain participation and adherence throughout the intervention.

After the six-week intervention programme, the participants in the experimental group were discharged and were encouraged to continue the adopted health lifestyle programme at home. All participants in the study had measurements at baseline (week 0), at the end of intervention (week 6) and at 12 weeks (6 weeks after the intervention). Comparison of data was done to determine the effectiveness of the intervention on primary and secondary outcomes. Refer to Figure 26 for the study procedure.

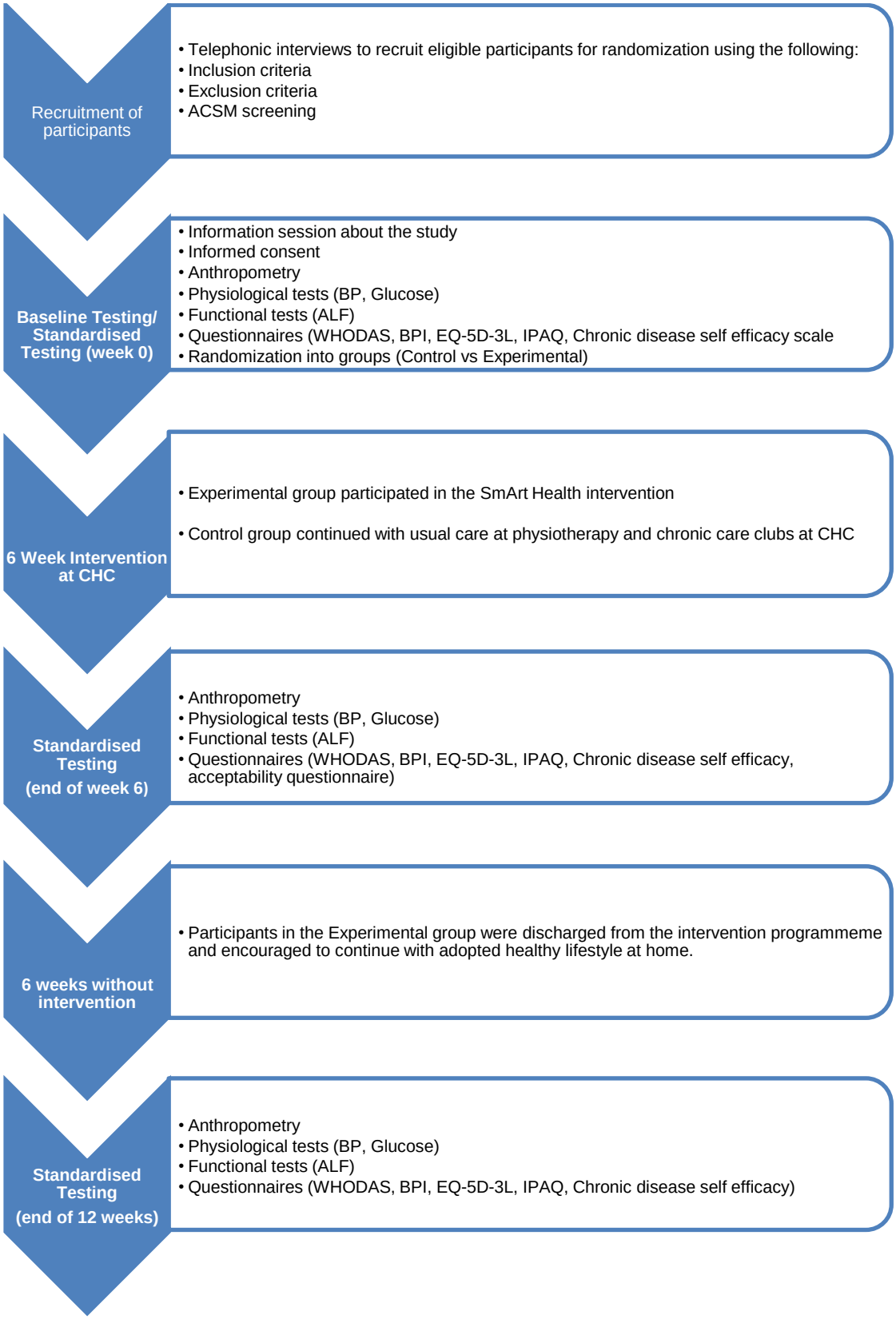


Figure 26: Testing procedure

6.3.10 Data management and Analyses

Descriptive statistics were used to describe the demographic characteristics of the participants. As the sample size was greater than 30, the Central Limits Theorem (CLT) applies and parametric statistics were used for numerical data in most cases[280]. According to the CLT, if you have a large enough sample (>30), the distribution of the sample mean would approach the standard normal distribution of the population. However, if data on histograms were grossly abnormally distributed, non-parametric statistics were used.

An Independent t-test (parametric data) or Mann-Whitney U test (non-parametric data), in cases with abnormal distribution, were used to establish equivalence between the groups on admission to the study. Repeated measures ANOVA tests were done to compare the scores across time between the two groups. This test was chosen as the Central Limits theorem applies to the data sets as the number of participants in each group was more than 30. The ANOVA has been found to be a robust test, even in the presence of non-normally distributed data[381]. The parametric data are presented as the mean ± standard deviation. Statistical significance was accepted as $p \leq 0.05$. The Kruskal Wallis ANOVA test was used for comparison of scores between groups for grossly abnormally distributed data (non-parametric) and the data are presented as median with interquartile range (IQR).

As there were two cases, one in the control and one in the experimental group who were unable to participate in the six-week post-intervention testing session, a decision had to be made regarding the management of the missing data. The most used methods were either to do complete case analysis or to impute the final scores[382-384]. Based on published recommendations, it was decided to do complete case analysis, a method used in the majority of studies[382 384]. The reasons for this were that the missing data were missing at random according to the definition, "Missing at random (MAR) can be assumed if the missingness is related to observed data (outcome or other collected data)"[382]. In our case, the experimental group participant did not attend as she become ill with a disease unrelated to the conditions under study. The control group participant was unable to attend as her spouse passed away. Regarding the 12-week testing session, there were eight missing responses in total (experimental n=3; control n=5). In this case, the missingness may not have been random, but we were not able to ascertain this as we could not contact these participants.

The option of imputing data and using the six weeks measures as place holders for the 12-week measures was rejected as the purpose of the comparison between the six and 12-week measures was to ascertain whether the participants had maintained their functional levels. Imputation would thus have inflated the number of participants who had maintained their six-weeks status. Consequently complete-case analysis was used for this analysis as well.

6.3.11 Ethical considerations

Ethical considerations were analysed according to the bioethical principles of autonomy, beneficence, non-maleficence, risks, and justice.

6.3.11.1 Autonomy

Participants were made aware that participation was voluntary, and it would not affect their scheduled visit or services at the Community Health Centre. Participants were informed that they could withdraw from the study at any stage without being penalised in any way. An information sheet was given to the participant in their preferred language. An informed consent form of the study was read by or read to the participants and signed before completing the questionnaires or participating in the intervention study. Demographic and personal information of participants remained confidential and were used purely for the purpose of the research study. The master list containing the names and contact details of participants who participated in the intervention, were stored on an external hard drive with password protection and a hard copy of the document was kept in a secure and locked cabinet.

6.3.11.2 Beneficence

Participants engaging in the intervention study received light healthy meals every week but no remuneration, other than reimbursement for travel costs to attend the measurement and intervention sessions. Participants in the control group will be offered the intervention programme at the end of the study, should the intervention be found to be effective. participants who screened positive for pain due to OA, diabetes mellitus type II, hypertension, and obesity, but did not want to participate in the intervention and those who were not randomly selected for the intervention were referred for further management at the nearest CHC/hospital.

6.3.11.3 Non-maleficence and Risks

Although great care was taken to minimize the risk of participants sustaining an injury during the exercise programme, in the event of such an incident taking place, the participant would have received immediate post-injury care by referral to the nearest hospital for management. Therefore, participants in the intervention group were screened using ACSM exercise guidelines by a physiotherapist to exclude any person with risk factors in participating in an exercise programme. The physiotherapist who conducted the intervention sessions, was trained in cardio-pulmonary resuscitation, and had first aid kits available for any unforeseen event. In addition, the intervention was conducted in a room in a clinic with both medical nurses and paramedics available. If any participant felt unwell during the exercise session, she would have been referred immediately to the clinic sister for appropriate assessment and management. However, there were no participants who reported feeling unwell during the exercise sessions in this intervention and did not need any further medical interventions.

Delayed onset muscle soreness (DOMS) or muscle ache, which is a common consequence of unaccustomed exercise, could have occurred. Fortunately, none of the participants experienced DOMS during the intervention. Should any participant have experienced some discomfort of any kind, the exercise Programme would have been altered to accommodate the discomfort experienced. Participants would have been provided with information on how to manage any minor muscle aches or pain.

6.3.11.4 Justice

The intention of the research was to improve functional ability, physical activity, and the health-related quality of life of some of the most marginalized members of society. This group of participants has been chosen particularly because they lived in areas with poor infrastructure and inadequate resources. Middle-aged women have been targeted as they are often the primary breadwinners and are responsible for both earning an income and holding families together. Participants were made aware that the results of the study might be published in an accredited medical/health care journal to create an awareness of the profile of disadvantaged women with osteoarthritis and co-morbid CDL.

6.3.11.5 Insurance

The University of Cape Town offers a no-fault insurance which covered all the participants if something may have gone wrong. Participants had the right to claim compensation for an injury in the event of negligence of the researchers.

6.4 Results

6.4.1 Recruitment and follow-up of participants

The recruitment, baseline testing and follow up testing is presented in the flow chart below (

Figure 27). At six weeks testing, 71 participants attended and completed post-testing. One participant from the experimental (EXP) group did not attend as she was ill and one participant from the control (CON) group did not attend as her husband had died.

At 12 weeks post-testing, 63 participants attended the testing. Four participants from the EXP group did not attend as one participant was ill and three could not be contacted. Five participants from the CON group did not attend and were lost to follow up.

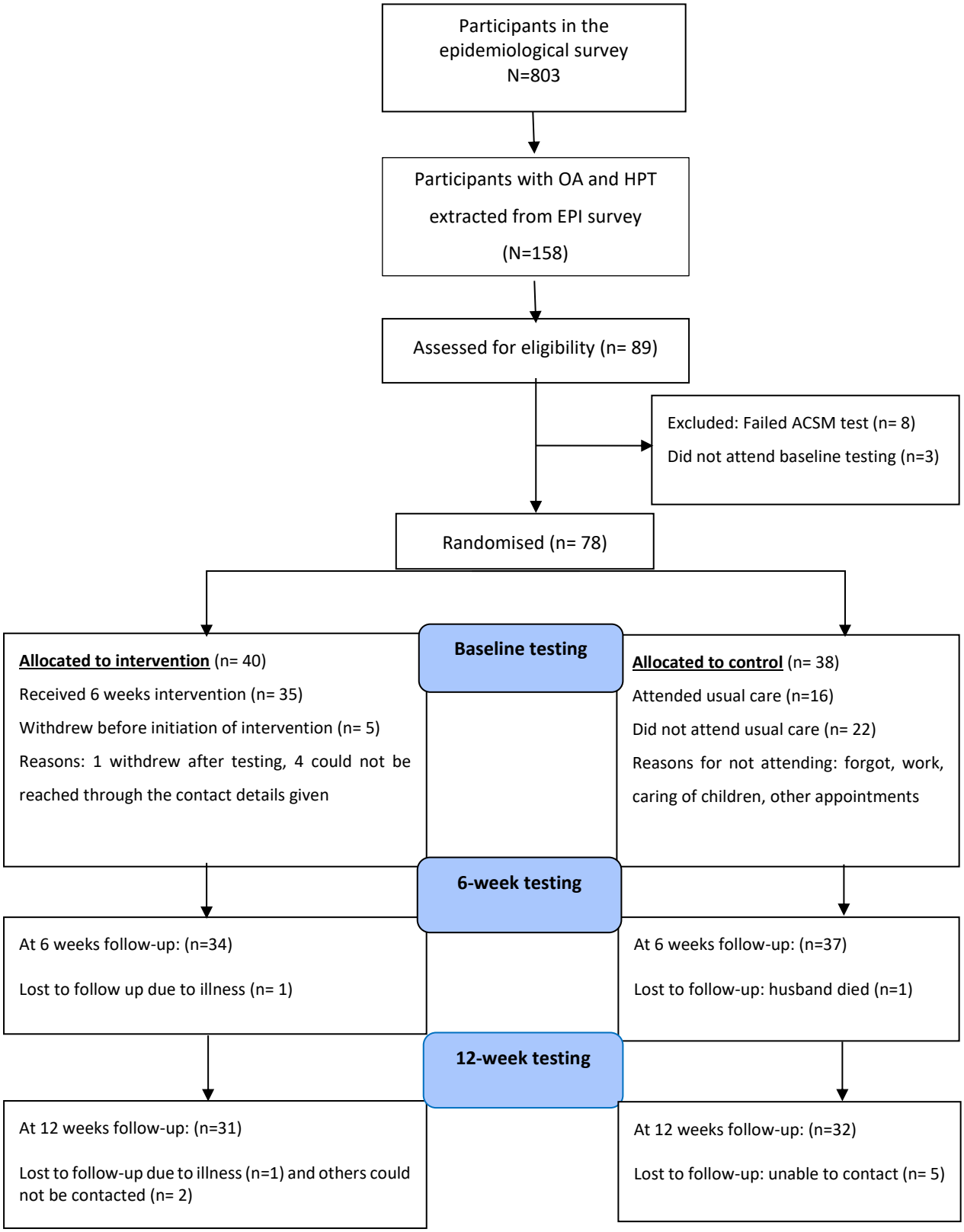


Figure 27: Consort Flow diagram reporting the recruitment and allocation of the participants for the intervention

6.4.2 Attendance of participants in the intervention and usual care Programmes

The programme started with an attendance rate in week 1 of 62% for the total group (N=73) with 94% attendance by the EXP group (33 of 35) and only 32% by the CON group (12 of 38). The number of attendees subsequently decreased every week after week 1. Week 4 had the least number of attendees (n=30) compared to the other weeks. Furthermore, no participants from the CON group attended usual care sessions beyond week 3. A significant association ($p<0.01$) was found between groups across all weeks, whereby the EXP group had a higher percentage of attendees than the CON group throughout (Figure 28).

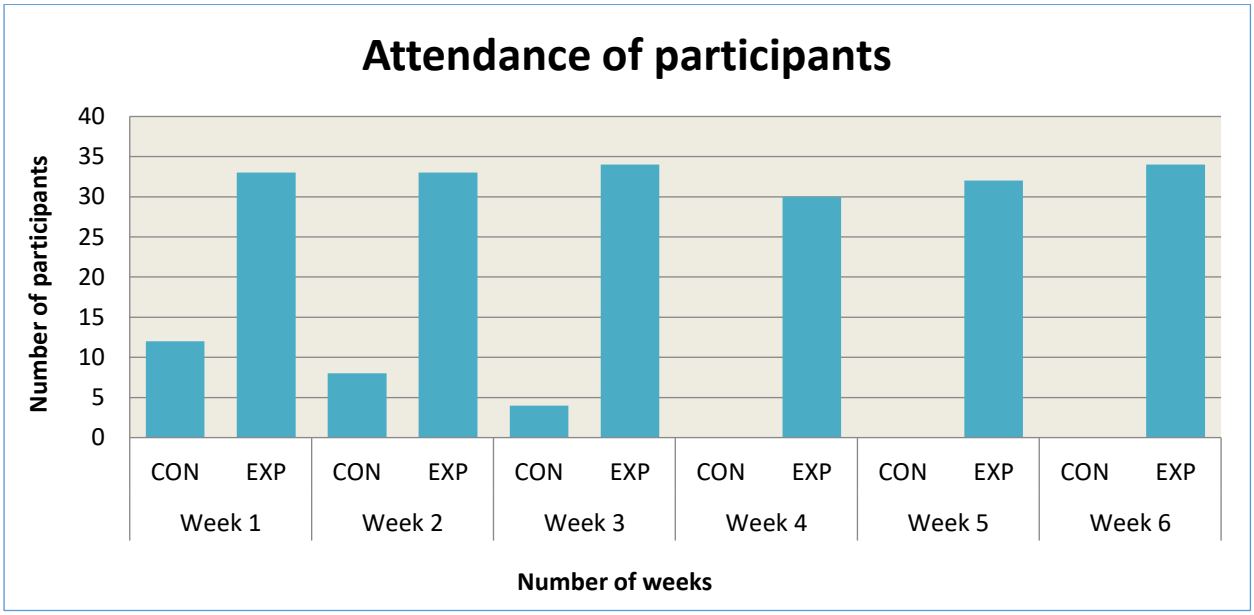


Figure 28: Attendance of participants in the Control (CON) and Experimental (EXP) groups

A total of 23 participants of the CON group did not attend any session at all, compared to the 24 participants of the EXP group who attended all 6 sessions of the intervention (Figure 28).

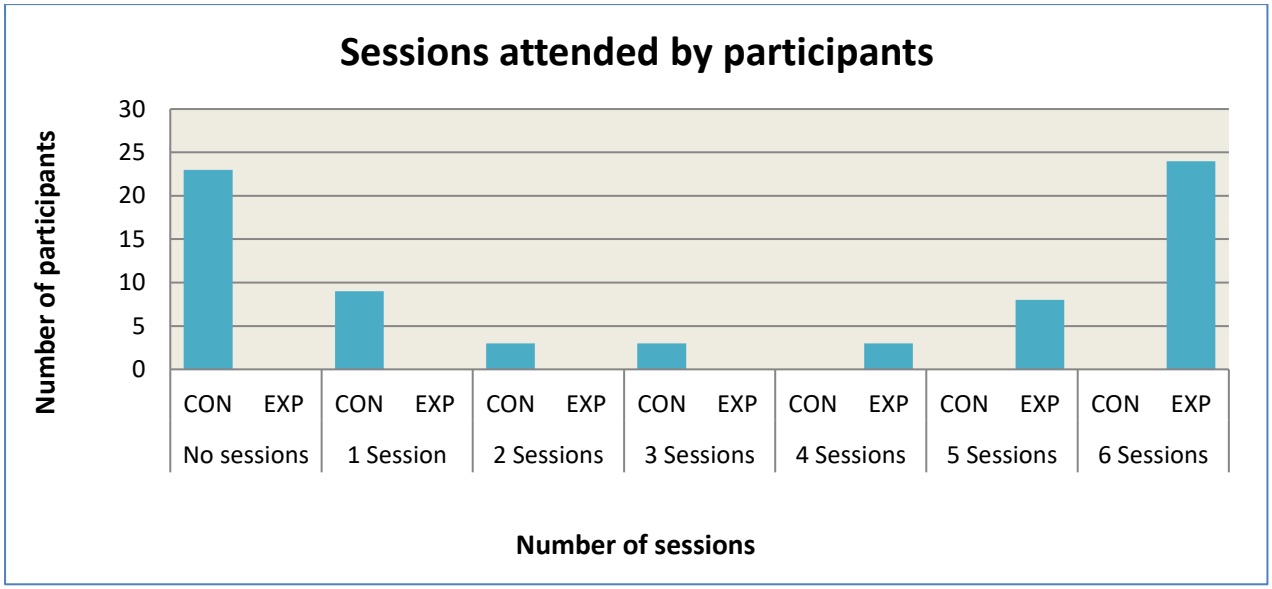


Figure 29: Number of sessions attended by participants in the Control (CON) and Experimental (EXP) groups

6.4.3 Comparison between participants in epidemiological survey and intervention

6.4.3.1 Demographic characteristics

The participants in the intervention study (n=73) (RCT sample) were compared to the 85 participants from the epidemiological survey (EPI sample) who were not recruited for the intervention. The mean ages of the RCT sample (n=73) and the EPI sample (n=85) were 55.5 years (SD=7.6) and 59.9 years (SD=11.1) respectively (Figure 30). There was a significant difference in age between the two groups (t=2.8, p=0.042), with the EPI sample being older.

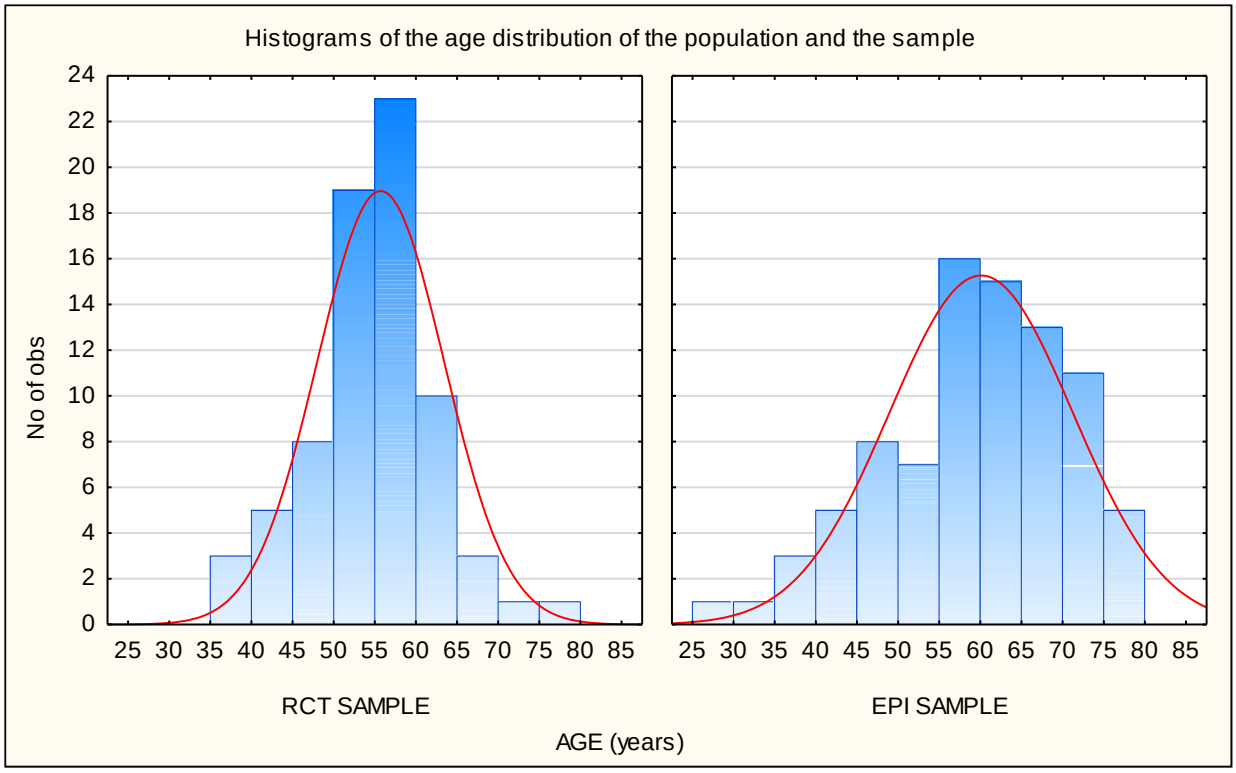


Figure 30: Comparison of Histograms of age distribution between the sample in the intervention and the sample in the epidemiology study

No significant differences were found between the two groups with regards to: educational level (t=0.08; p=0.278) and number of children (t=1.46; p=0.144) (Table 35). A higher proportion (63%) of participants spoke Afrikaans in the RCT sample group compared to the EPI sample group (47%) and no isiXhosa speaking participants were in the RCT sample group. In the job category variable, a higher proportion of participants were unemployed (54.9%) in the RCT sample group, whereas a higher proportion of participants were retired (22.3%) and housewives (27%) in the EPI sample group. Participants reported on their monthly income according to categories and most participants in the EPI sample group (71.7%) and in the RCT sample group (42.4%) reported having an income of R1001-R2000 per month. Therefore, the RCT sample were younger; more likely to be married with children; the majority were Afrikaans speaking; unemployed (earning R1001-R2000 per month)[9]; and never smoked cigarettes or used alcohol.

[9] Conversion of SA Rand (R1000-R2000) to US dollar ($70.28-$140.56) calculated on 10 January 2020

Table 35: Comparison of demographics of EPI sample (n=85) and RCT sample (n=73)

Variable	Category	EPI (n=85)	%	RCT (n=73)	%	Statistics	P-value (≤0.05)
Age	Mean (SD)	59.9 (11.1)		55.5 (7.6)		t=2.88	***.001***
Children	Mean (SD)	3.4 (1.7)		3.0 (1.5)		t=1.46	.144
Education (grade)	Mean (SD)	8.0 (2.1)		8.5 (2.2)		t=0.08	.278
Language	Afrikaans	40	47	46	63	χ^2=9.12	.010
	isiXhosa	8	9.4	0	0		
	English	37	43.5	27	36.9		
Marital status	Married	40	47	36	49.3	χ^2=160.06	.000
	Widowed	23	27	17	23.2		
	Single	16	18.8	12	16.4		
	Divorced	6	7	8	10.9		
Job category	Unemployed	32	37.6	39	53.4	χ^2=171.85	.000
	Retired	19	22.3	5	6.8		
	Manual	5	5.8	3	4.1		
	Housewife	23	27	16	21.9		
	Admin	2	2.3	5	6.8		
	Professional	0	0	2	2.7		
	Security	1	1.1	0	0		
	Other	3	3.5	1	1.3		
Monthly Income	0-1000	10	11.7	21	28.7	χ^2=163.94	.000
	1001-2000	61	71.7	31	42.4		
	2001-3000	8	9.4	5	6.8		
	3001-5000	2	2.3	6	8.2		
	>5001	0	0	2	2.6		
Smoking	Never	45	52.9	37	50.6	χ^2=160.25	.000
	Stopped	17	20	11	15		
	Currently	23	27	25	34.2		
Alcohol	Never	67	78.8	57	78	χ^2=162.07	.000
	Stopped	7	8.2	11	15		
	Currently	11	12.9	5	6.8		

Abbreviations for statistical tests: T-test = t, Chi-square = χ^2

6.4.3.2 Medical information of participants in EPI sample and RCT sample

All Participants reported on the presence of chronic diseases of lifestyle (CDL), in addition to having three-month joint pain and hypertension. Most of the women (52%) in the sample group indicated having hypercholesterolaemia, and a lower proportion of women reported having diabetes mellitus (36%) and other CDL (38%). There were no significant differences noted in the proportions of women in the RCT sample that had chronic diseases compared to women in the EPI sample (Table 36). Therefore, the RCT sample matched the EPI sample.

Table 36: Comparison of medical information between EPI sample (N=85) and RCT sample (N=73)

Variable	**Categories**	**EPI (n=85)**	**%**	**RCT (n=73)**	**%**	**Statistics**	**P value (≤0.05)**
Diabetes mellitus II		30	35.2	27	36.9	χ^2=0.04	.825
HCL		41	48.2	38	52	χ^2=0.22	.632
CVD		9	10.5	11	15	χ^2=0.71	.398
Respiratory disease		13	15.2	15	20.5	χ^2=0.74	.388
Mental illness		1	1.1	0	0	χ^2=0.86	.352
Other CDL		20	23.5	21	28.7	χ^2=0.14	.700
Weight (kg)*	Mean (SD)	81.2 (20.3)		80.2 (16.8)		t=0.306	.760
Height (m)*	Mean (SD)	1.57 (0.06)		1.55 (0.06)		t=1.241	.217
**BMI (kg/m^2)*	Mean (SD)	32.9 (8.8)		32.9 (6.5)		t=0.004	.996
BMI categories*	Underweight	1	1.6	0	0	χ^2=4.44	.216
	Normal	9	15.2	8	12.5		
	Overweight	15	25.4	9	14.0		
	Obese	34	57.6	47	73.4		

**Only 59 women of the EPI sample and 64 of the RCT sample group had weight, height and BMI measures taken, percentage is based on these numbers **Tested with separate variances. HCL- Hypercholesterolaemia, CVD - Cardiovascular disease, CDL – Chronic diseases of lifestyle*

6.4.4 Comparison between experimental (EXP) and control (CON) group of participants

6.4.4.1 Demographic information of experimental and control groups

Ages of the participants in both the experimental and control groups were normally distributed with no significant differences between groups (Figure 31). There were no significant differences between the demographic characteristics of the participants in each group (Table 37).

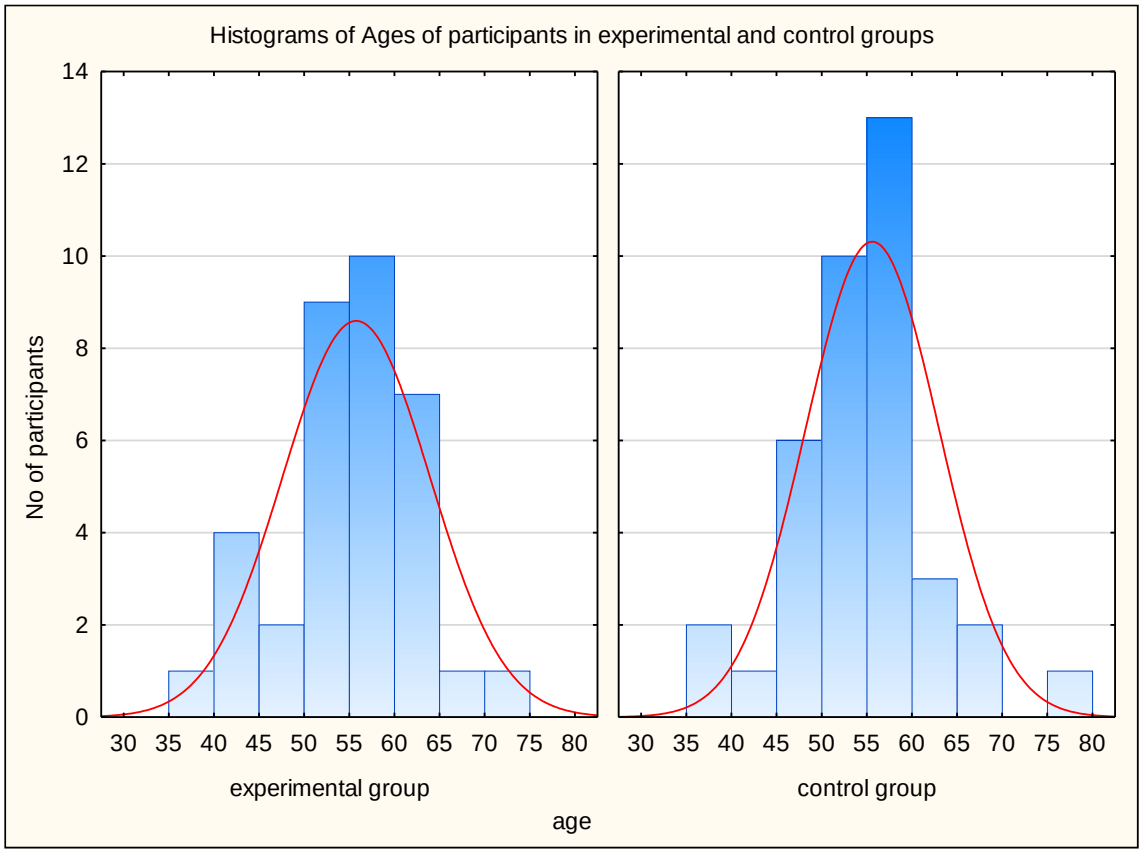


Figure 31: Histograms of Ages of participants in experimental and control groups

Table 37: Comparison of demographic information of experimental (n=35) and control groups (n=38) at baseline testing

Variable	**Category**	**Experimental (n=35)**	**Control (n=38)**	**Statistic**	**P-value (≤0.05)**
Age	Mean (SD)	55.6 (8.1)	55.5 (7.3)	t= .086	0.932
Language	English	12	17	χ^2 =.83	0.362
	Afrikaans	23	21		
Marital Status	Single	5	7	χ^2 =.41	0.939
	Married	16	17		
	Separated/ Divorced	4	5		
	Widowed	10	9		
Income	0-1000	10	15	χ^2 =1.60	0.808
	1001-2000	19	16		
	2001-3000	3	2		
	3001-5000	2	3		
	5001-7000	1	1		
Breadwinner	No	19	23	χ^2 = .29	0.590
	Yes	16	15		
Current job	Housewife	19	13	χ^2=3.28	0.193
	Unemployed	11	15		
	Other	5	10		
Children	Mean (SD)	3.1 (1.4)	2.6 (1.5)	t=1.247	0.216
Education (grade)	Mean (SD)	8.3 (2.4)	8.0 (2.5)	t=.456	0.650

6.4.4.2 Medical conditions of participants in experimental and control groups

There were no significant differences between groups in history of smoking or alcohol use, or the presence of health conditions (Table 38). A higher number of participants in the CON group had mild hypertension compared to the EXP group (χ^2 =12.1, p=0.01).

Table 38: Comparison of lifestyle habits and medical conditions between experimental and control groups at baseline

Variable	**Category**	**Experimental (n=35)**	**Control (n=38)**	**Chi-square (χ^2)**	**P-value (≤0.05)**
Smoking	Currently	11	14	.57	.751
	Never	14	12		
	Stopped	10	12		
Alcohol	Currently	2	9	4.96	.084
	Never	24	23		
	Stopped	9	6		
Health conditions	Diabetes mellitus II	8	10	.12	.732
	HCL	21	26	.56	.453
	CVD	6	6	.02	.876
	Respiratory disease	11	7	1.66	.198
	Mental illness	1	3	.89	.345
	Other CDL	12	14	.05	.820
Blood pressure*	Normal	6	2	12.1	0.017
	High normal	9	3		
	Mild HPT	6	18		
	Moderate HPT	11	9		
	Severe HPT	3	6		

HCL- Hypercholesterolaemia, CVD - Cardiovascular disease, CDL – Chronic diseases of lifestyle, HPT- Hypertension

**Values for categories of blood pressure: Normal= SP= 120-129, DP= 80-84; High normal= SP=130-139, DP= 85-89; Mild hypertension= SP-140-159, DP=90-99; Moderate hypertension SP=160-179, DP=100-109; Severe hypertension= SP=>180, DP>110*

Participants reported on the use of medication for their chronic diseases identified in the above table. There were no significant differences in medication use between groups (Table 39).

Table 39: Use of medication for chronic diseases in experimental and control groups

Medication	Experimental (n=35)	Control (n=38)	Chi-square	P-value (≤0.05)
Hydrochlorothiazide	19	28	2.98	p=.083
Simvastatin	20	21	0.02	p=.871
Enalapril	17	17	0.10	p=.742
Aspirin	11	18	1.93	p=.164
Atenolol	9	12	0.30	p=.580
Metformin	10	9	0.22	p=.634
Insulin	1	6	3.51	p=.060

6.4.5 Comparison of outcomes over time (week 0, 6 and 12) between groups

6.4.5.1 WHODAS: Function and disability

There were significant differences in the median WHODAS 2 scores between groups over the 12 weeks of the study. The median scores were the same for both groups at week 0, however, a significant improvement was evident at week 12 in the EXP (Median=6, IQR=2-14) compared with the CON group (Median=14, IQR=11-19.5; KW-H (1.63)=7.846, p=0.005). The median score for the EXP group decreased from 14 (IQR=7-20) at week 0, to 10 (IQR=5-18) at week 6 and further decreased to 6 (IQR=2-14) at week 12, with the within group differences approaching significance (Chi Sq=5.596, p=0.060). No changes were evident within the CON group over the 12 weeks (Chi Sq=2.638, p=0.267) (Figure 32) (Appendix F-4).

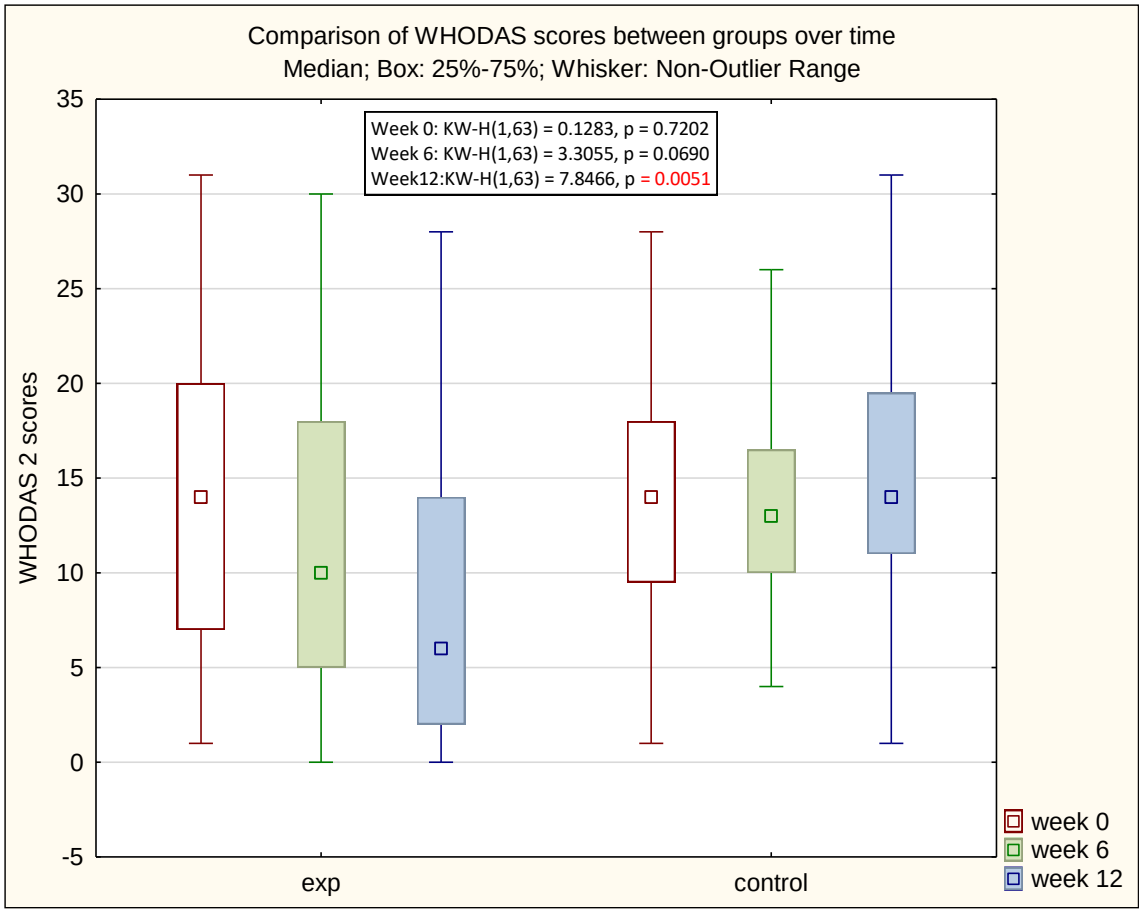


Figure 32: Comparison of WHODAS 2 scores between groups at each time point (week 0, 6, 12)

6.4.5.2 Aggregated Locomotor function: Functional ability

There were significant differences in the median ALF scores between groups over the 12 weeks of the study. The median scores were the same for both groups at week 0. At week 6, a significant difference was evident between the EXP (median=17.4, IQR=15.9-19.8) and CON groups (median=19.4, IQR=17.7-22.7; KW-H (1.63)=6.9317, p=0.008) (Figure 33). Significant improvements were noted within the EXP group between week 0 and week 6 (Chi Sq=42.000, p=0.000). However, significant improvements were also noted within the CON group between week 0 and week 6 (Chi Sq= 24.937, p = 0.000) (Appendix F-4).

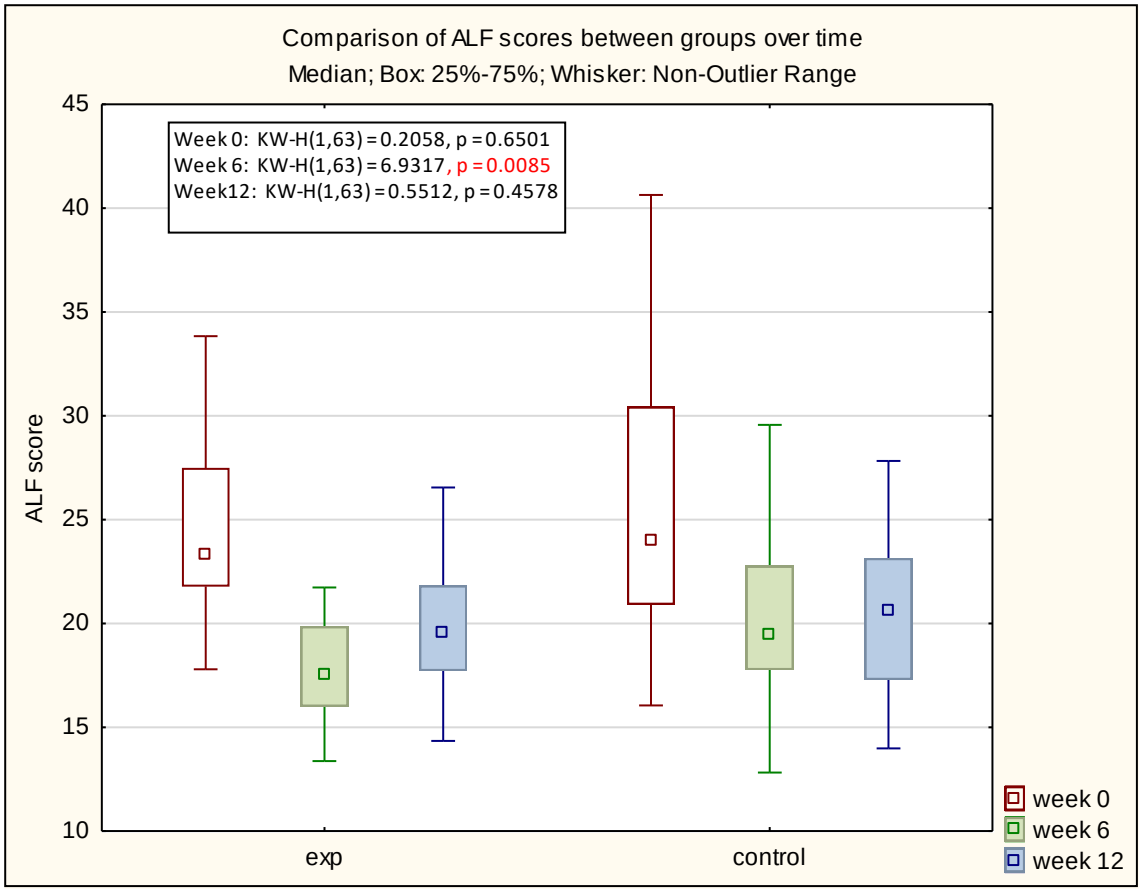


Figure 33: Comparison of ALF scores between groups at each time point (week 0, 6, 12)

6.4.5.3 Brief pain inventory: Pain severity and Pain interference

There were significant differences in the mean Pain Severity Scores (PSS) between groups over the 12 weeks of the study. A repeated measures ANOVA indicated that there was a significant improvement in the mean PSS over the 12 weeks with the EXP group having significantly lower pain severity scores at week 12 than the CON group ($F_{(2,122)} = 3.68$; p=0.02) (Figure 34). A significant improvement in PSS were noted within the EXP group between week 0 to week 6 (p=0.048) and between week 0 and week 12 (p=0.040). In other words, participants in the six-week intervention had significantly reduce mean pain severity scores over time. No changes were evident within the CON group (Appendix F-4).

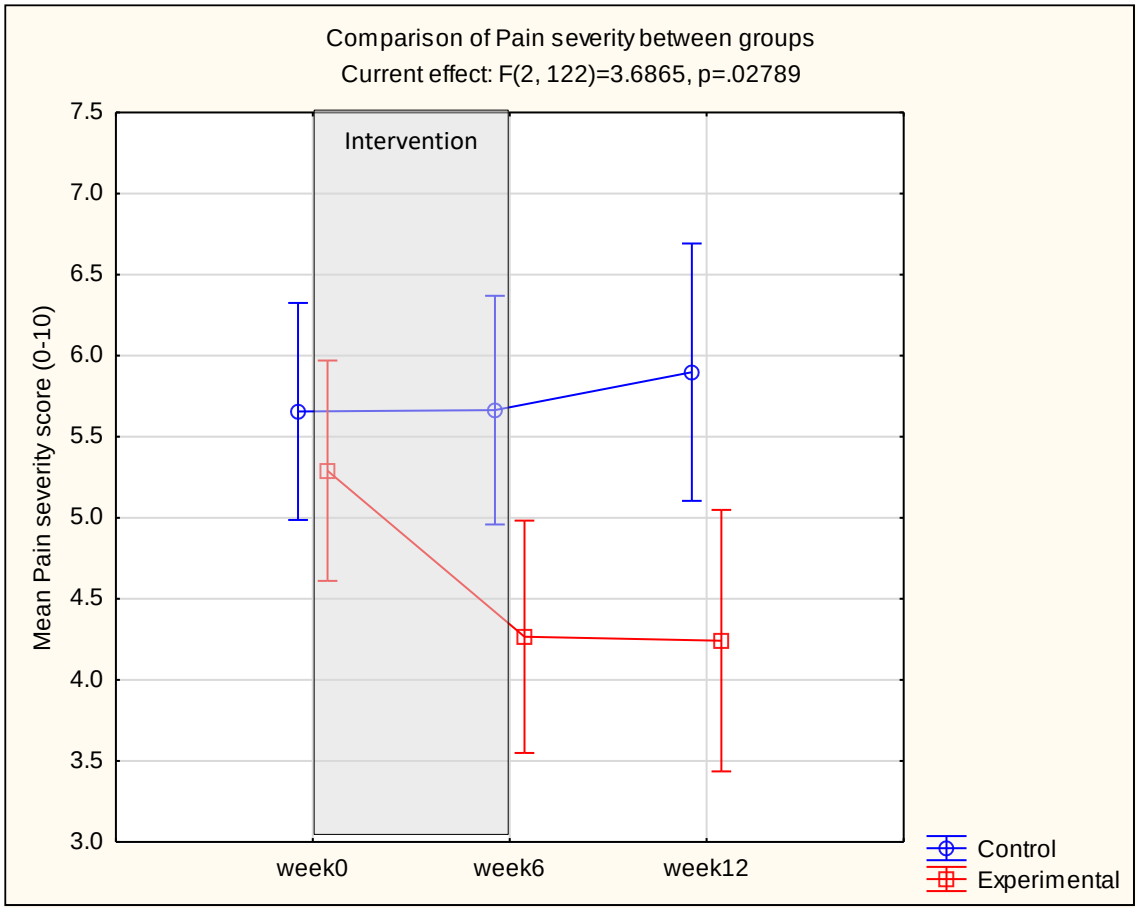


Figure 34: Comparison of pain severity scores between groups over time

There were significant differences in the mean Pain Interference Scores (PIS) between groups over the 12 weeks. As the ANOVA indicated a significant difference in mean PIS scores over time ($F_{(2,122)} = 7.71$; $p<0.01$) (Figure 35), a Post-hoc Tukey test was done to identify where the differences lay. The Post hoc Tukey test indicated that participants in the EXP group had significantly lower PIS score than the CON group (3.8, SD=2.5 vs. 6.2, SD=1.6) at week 6 ($p=0.001$). In addition, significant differences were noted within the EXP group between week 0 and week 6 ($p<0.001$) and between week 0 and week 12 ($p=0.022$). In other words, participants in the six-week intervention had significantly reduced the mean PIS. The PIS of the participants in the CON group did not change over time.

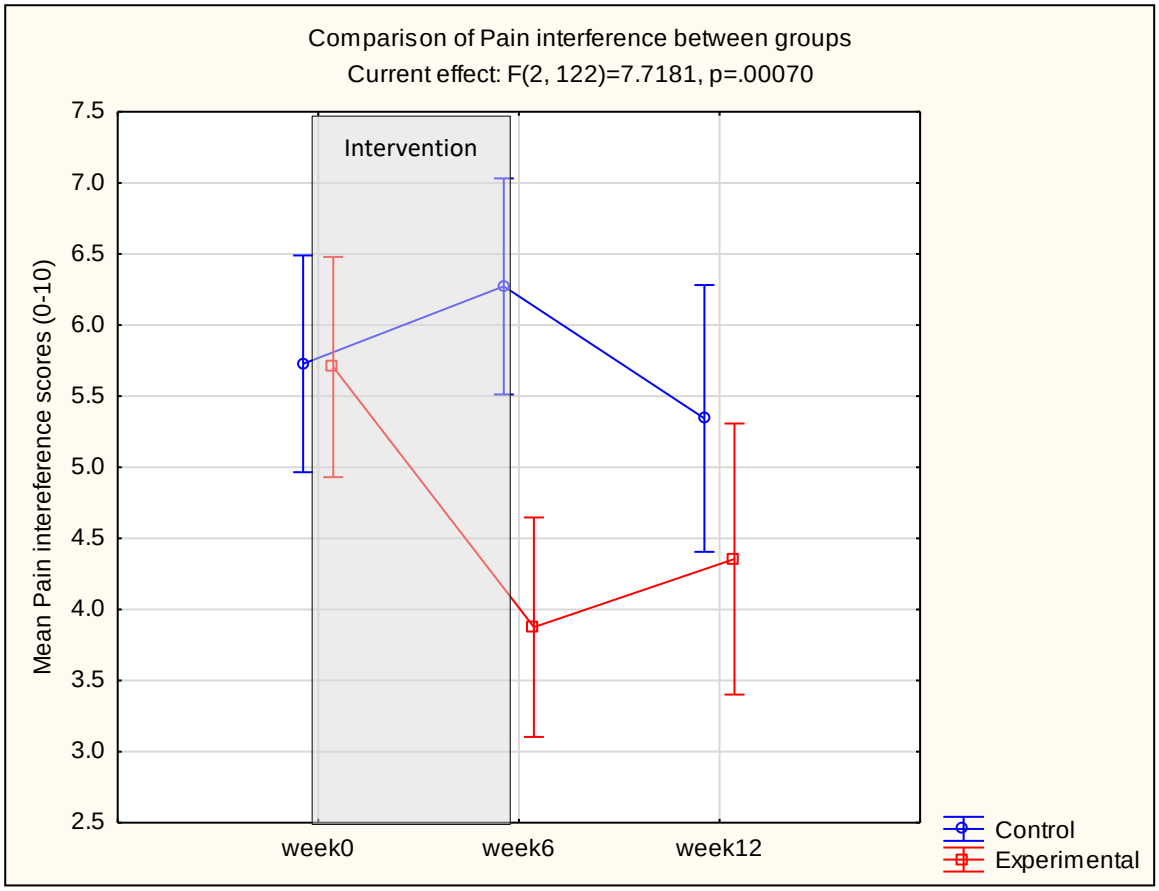


Figure 35: Comparison of pain interference scores between groups over time

6.4.5.4 Chronic diseases of lifestyle

The blood pressure and blood glucose values between the EXP and CON groups over the 12-week intervention will be presented next.

Blood pressure: systolic and diastolic pressure

The mean Systolic pressure (Mean=149.9, SD= 20.6) and Diastolic pressure (Mean=88.7, SD= 13.4) of the EXP group was lower than the CON group (Systolic Mean= 157.8, SD= 21.7; Diastolic Mean= 91.4, SD=13.1) at week 0. In other words, the two groups differed slightly at baseline before the intervention was implemented (Table 40). The repeated measures ANOVA indicated that there were no significant changes in the mean Systolic ($F(2, 122) = 0.32023$, $p = 0.726$) and Diastolic pressure scores ($F(2, 122) = 0.01801$, $p= 0.982$) over the 12 weeks of the study (Appendix F-4).

Table 40: Comparison of systolic and diastolic blood pressure values between experimental and control groups at each time point (week 0, 6, 12)

	Experimental Group (n=31)		**Control Group (n=32)**	
Blood pressure values	**Mean**	**SD**	**Mean**	**SD**
Week 0				
Systolic Pressure	149.9	20.6	157.8	21.7
Diastolic Pressure	88.7	13.4	91.4	13.1
Week 6				
Systolic Pressure	152.7	19.8	157.4	27.5
Diastolic Pressure	90.2	12.4	92.3	16.7
Week 12				
Systolic Pressure	143.2	23.9	152.5	22.4
Diastolic Pressure	87.1	13.6	89.4	12.6

Blood glucose levels

There were significant differences noted in the median Blood glucose levels between groups over the 12 weeks of the study. The median blood glucose score in the EXP group was significantly lower (5.2 mmol/l) than the score in the CON group (6.0 mmol/l) at week 6 (KW-H (1,63) = 3.7368, p = 0.053) (Figure 36). In addition, the median Blood glucose score within the EXP group significantly decreased from 6.3 mmol/l at week 0 to 5.2 mmol/l at week 6 (Chi Sq= 11.6198, p=0.003) compared to the CON group who had very little change over the 12 weeks (Appendix F-4).

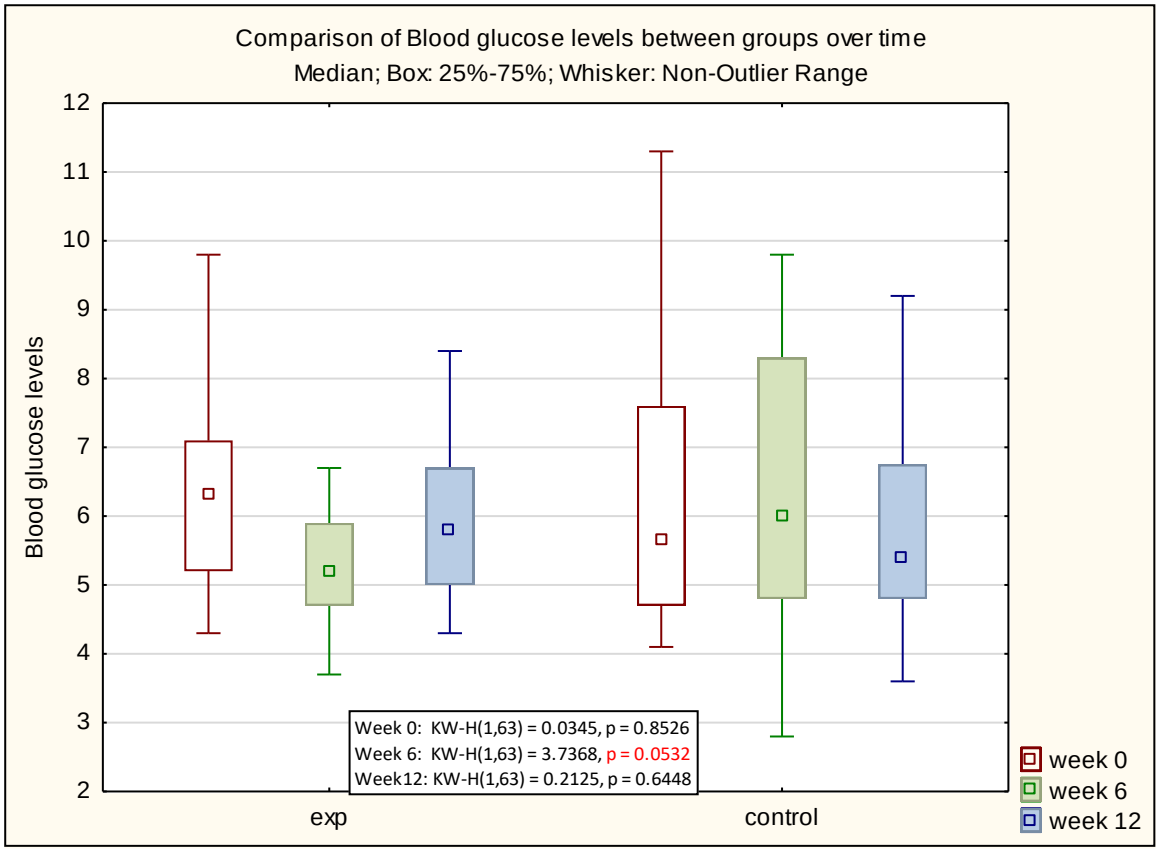


Figure 36: Comparison of Blood glucose scores between groups at each time point (week 0, 6, 12)

6.4.5.5 Body Mass Index

The mean body mass index (BMI) scores between the experimental and control groups are presented in (Table 41). There were no significant differences noted in the mean BMI scores between the groups or within groups over the 12 weeks (Appendix for F-4).

Table 41: Comparison of BMI between experimental and control groups at each time point (week 0, 6, 12)

	Experimental Group (n=31)		**Control Group (n=32)**	
BMI (kg/m^2)	**Mean**	**SD**	**Mean**	**SD**
Week 0	35.6	6.9	37.1	7.6
Week 6	35.6	7.4	37.3	7.4
Week 12	35.7	7.6	37.5	9.3

6.4.5.6 IPAQ: Physical activity

There were no statistically significant differences noted in the median MET-min/week scores between groups over the 12 weeks of the study (see Appendix G). The median scores were quite similar for both groups at week 0, near the 2000 MET-min/week mark. There were no significant differences evident at week 6 between groups. However, the median MET-min/week score within the EXP group increased significantly from 1782 at week 0 to 3828 at week 6 (Chi Sq= 13.612, p=0.001) compared to the CON group who had minor changes at week 6 (Table 42).

Table 42: Comparison in physical activity scores between experimental and control groups at each time point (week 0, 6, 12)

	Experimental Group (n=31)		**Control Group (n=32)**	
Physical activity (MET/min-week)	**Median**	**IQR**	**Median**	**IQR**
Week 0	1782	346-5139	2021	494-4618
Week 6	3828	1584-5970	2614	651-5331
Week 12	980	495-2012	813	274-1840

6.4.5.7 EQ-5D-3L: Health-related quality of life

There were significant differences in the median EQ-5D-3L VAS scores between groups over the 12 weeks of the study (Figure 37). The median scores were similar at week 0, however, a significant difference was evident at week 6 between the EXP (Median=80, IQR=50-100) and CON (Median=60, IQR=50-80) groups (KW-H (1.63) =6.2534, p=0.012). The median score within the EXP group improved from 60 (IQR=50-70) at week 0 to 80 (IQR=50-100) at week 6 and week 12 (IQR=60-90) respectively, approaching significance (Chi Sq= 5.366, p=0.068) (see Appendix G). For the EQ-5D-3L Index, a significant difference was evident at week 6 between the EXP (Median=0.74, IQR=0.68-0.85) and CON (Median=0.62, IQR=0.51-0.77) groups (KW-H (1.63) =5.7329, p=0.0167), (Figure 38). The median Index score within the EXP group improved from 0.62 (IQR=0.19-0.72) at week 0 to 0.74 (IQR=0.68-0.85) at week 6 (Chi Sq=8.300, p=0.015) compared to the CON group who had no changes over time (Figure 38).

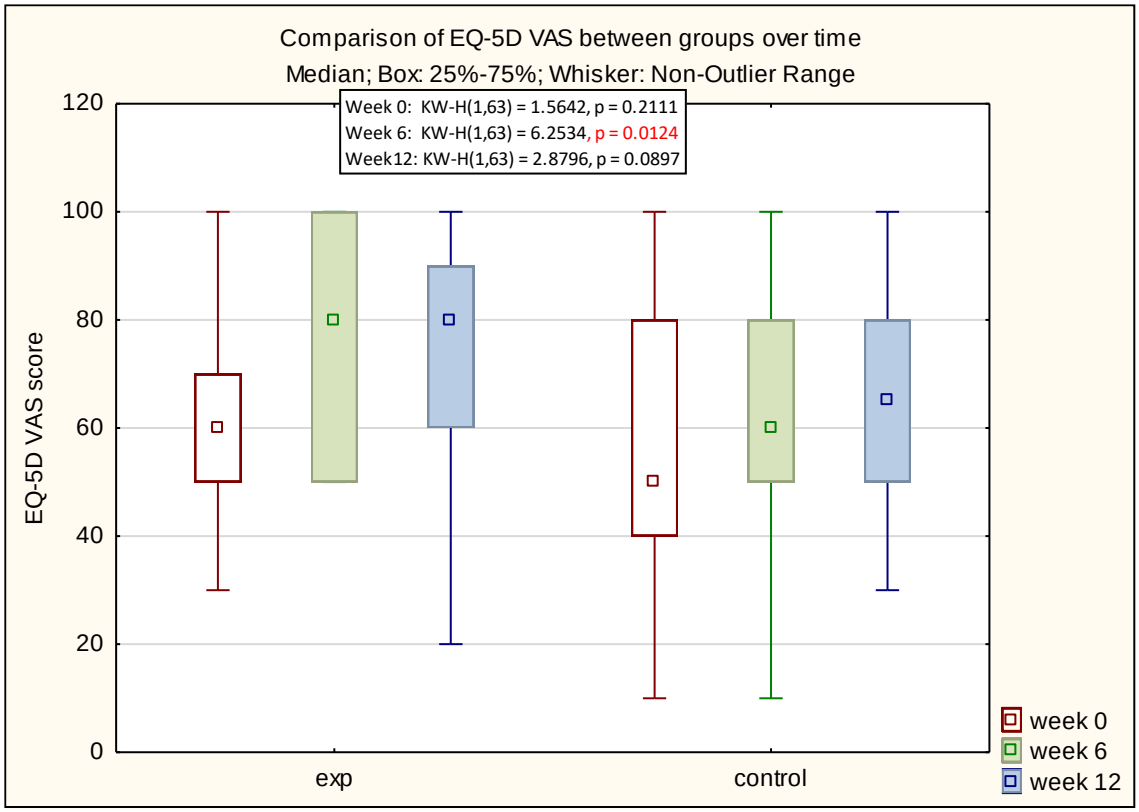


Figure 37: Comparison of EQ-5D-3L VAS scores between groups at each time point (week 0, 6, 12)

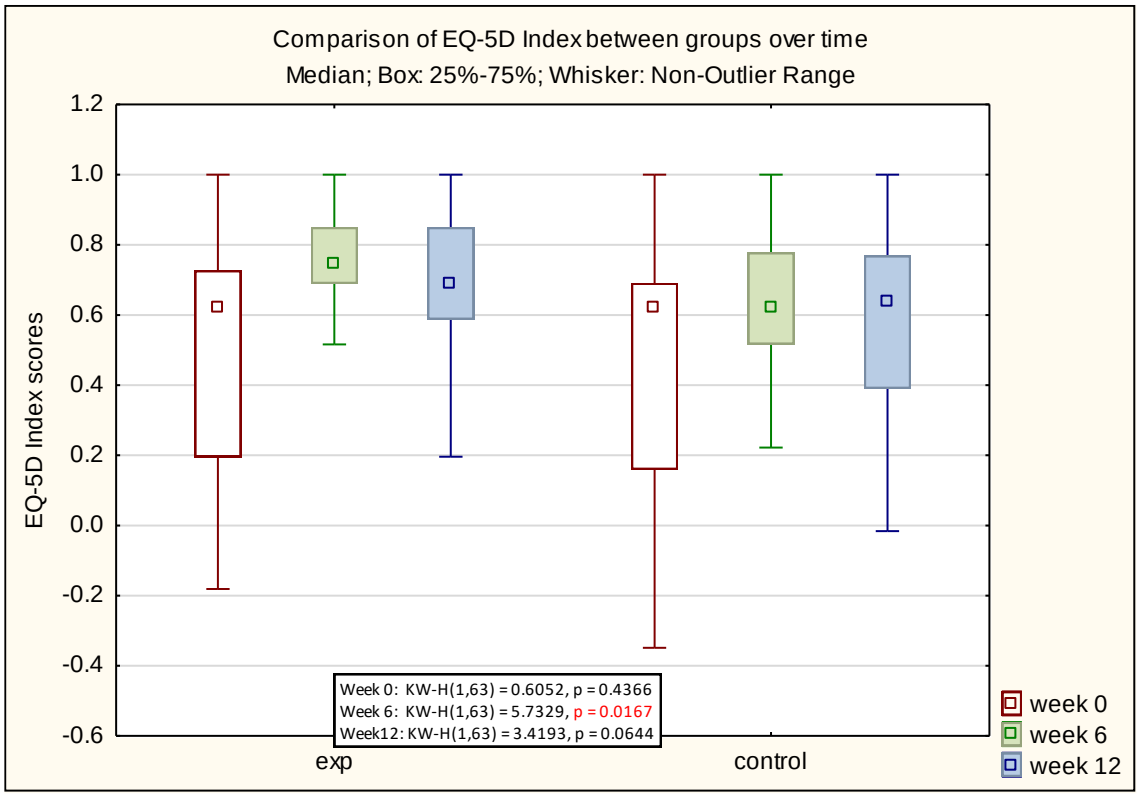


Figure 38: Comparison of EQ-5D-3L Index scores between groups at each time point (week 0, 6, 12)

6.4.5.8 Self-efficacy: Confidence in managing chronic diseases

There was a significant difference in the mean Self-efficacy scores over the 12 weeks between groups ($F_{(2,122)} = 5.11$; p=0.007) (Figure 39). Furthermore, the EXP group had significant improvements in mean scores between week 0 and 6 (p=0.002) and, week 0 and 12 (p=0.001) respectively (Figure 39). No significant differences were noted within the CON group.

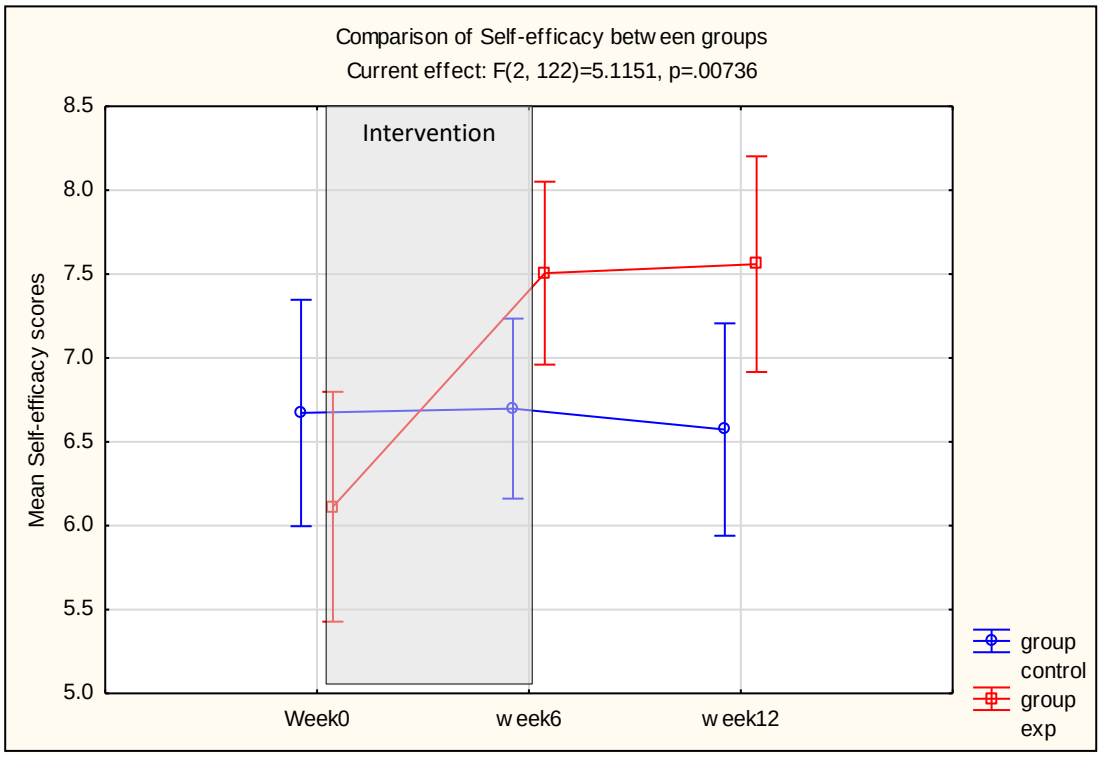


Figure 39: Comparison of self-efficacy scores between groups over time

6.4.5.9 Acceptability Questionnaire

In response to the first question, "*what did you like the most about the programme?", m*ost of the participants (42%, n=13) responded that they liked the exercises the most about the intervention and 35% (n=11) liked both the exercises and education on the various topics and how to self-manage their own health (Table 43). For the second question, "*what did you like least about the programme?",* 35% (n=11) of the participants responded that there was nothing that they did not like about the intervention. However, 27% (n=9) responded that the time was too short and that they would like the intervention to be implemented more than once a week and that they wanted more time for the exercises (Table 44).

In response to the third question "*what would you change about the programme?"*, 32 % (n=10) said that they did not want to change anything about the intervention. However, 10 other participants said that they would want to change the intervention to the morning and would want more time for exercises and relaxation (Table 45). Most of the participants (67%, n=21) reported that they would add nothing more to the intervention as it is a good intervention already (Table 46). For the last question, "*what did you think about the self-management book?",* more than half of the participants responded that the self-management book was very helpful and informative (

Table 47).

Overall, it seems that most of the participants found the SmArt-Health intervention and workbook to be useful and informative. Positive feedback was given about the entire programme, especially the active exercise component and the relaxation session. In general, this programme was acceptable for these women with OA and comorbidities.

Table 43: What did you like the most about the programme?

Count	Theme	Participant (P)	Example of responses
13	**Exercise**	P3	"I liked the exercises because I feel great. It really helps me a lot because now I can do things that I could not do before"
		P6	"I liked the exercises because I never thought that it was so important. I became very aware of my body for the future and my posture was also a problem. I really improved myself in my daily routine"
		P12	"I loved the exercises, it helped me to decrease my pain. It really helps a lot"
4	**Education**	P19	"It gave me courage to help myself, to decrease my medication, to help doctor my husband, let me feel human again to help others"
		P22	"I liked when we talked about the problems that we are having"
11	**Exercise and Education**	P7	"It was very good and did me a lot of good, made life much better. Did more walking and other exercises and it is a great help to self-manage my own life and health. It really did me so much good and I'm happy"
		P10	"I liked the exercises and how I must strengthen my muscles. I learned how to eat healthy and how to handle my arthritis"
		P25	"The communication and knowledge about how to use medication and the exercises"
1	**Self-manage And self-confidence**	P29	"How to self-manage myself and manage my stress levels, this stood out for me and to apply these to my own daily life and things weren't that difficult as they seemed, gave me self-confidence"

Table 44: What did you like the least about the programme?

Count	Theme	Participant (P)	Example of responses
11	**No problems**	P1	"Had no problems, I was looking forward to the reminder on a Sunday"
		P12	"There's nothing I did not like about the Programme"
		P26	"I had no problem with the intervention"
9	**Time was too Short**	P5	"The time was short, but everything else was good. We need more in life and the Programme helped us to relax. It was only done once a week and patients need this more frequently, then maybe we will get better and the hospital won't be so full"
		P11	"Time was too short and would have loved more exercise. The exercise was painful to do in the beginning, but it got better"
4	**Must be in the morning**	P6	"The time was too late; the intervention can be done in the morning in the summer"
2	**Time was too short and too much content**	P2	"Time was too short and too much in our book to learn"
1	**Session on medication was too long**	P7	"The talk about medication was a bit too long"

Table 45: What would you like to change about the programme?

Count	Theme	Participant (P)	Example of responses
10	**Nothing**	P27 P31	"I wouldn't like to change the Programme" "The intervention helped me more, I would not change anything"
2	**More exercise**	P7	"Would prefer more exercise"
10	**Time**	P20 P24	"Perhaps more time for the exercises and relaxation" "Maybe change to the morning"
4	**Nothing but intervention could be longer**	P25	"Nothing. Would have loved the Programme to happen on more days"
2	**Nothing but change the order of sessions**	P18	"No changes needed. The topic of medication can only be changed to the second week so that we can understand how to use our meds"
1	**This Programme must explode**	P19	"I would like this Programme to explode"

Table 46: What would you add to the programme?

Count	Theme	Participant (P)	Example of responses
21	**Nothing**	P4 P8 P14 P25	"There is nothing to add to the intervention" "There is nothing to add to the intervention" "There is nothing I want to add to the Programme" "Nothing. The Programme is good as it is, very resourceful"
5	**More exercises**	P19 P24	"More exercises and walking around the hospital" "A group walk"
1	**Group must meet once a week for exercise**	P17	"We as a group must continue with this Programme and meet once a week to exercise"
1	**Demonstrate exercises on last day**	P20	"Perhaps on the last day ask the group to show what they learned about the exercises"

Table 47: What do you think about the self-management book?

Count	Theme	Participant (P)	Example of responses
17	**Very helpful**	P4	"The self-management book is really a help with a lot that I didn't know and I'm grateful for the book"
		P11	"The information was very relevant, it really helped me a lot. Things I did not know was made known to me by the self-management book"
		P30	"The information was helpful. I learned a lot of things from the book and shared it with other people"
7	**Very informative and good**	P20	"Very informative, learned much about the way the medication affects the body. You always hear about diets and medication but never implement it until now"
		P28	"I think this is a wonderful experience to have this information. So if I need advice in future then I can go back to the book"
2	**Learned a lot**	P26	"I learned a lot from the book"
2	**It refreshed my mind and health**	P17	"It is something that not even the doctor's did for us. This book did refresh my mind and health"

6.4.5.10 Summary of results:

This study compared the effects of the SmArt-Health intervention on physical function and other health outcomes in women with osteoarthritis and hypertension. A total of 73 women participated in the study, with 35 women in the experimental group (received the intervention) and 38 women in the control group (received the standard care consisting of a support group). Only 63 women completed (EXP=31, CON=32) the week 12 follow-up testing.

The groups were similar in terms of demographic and socioeconomic profile at baseline testing (week 0). There were no significant differences in smoking, alcohol, and medical conditions between groups. However, a higher number of participants in the CON group (n=18) had mild hypertension compared to the EXP group (n=6) (Chi-Sq= 12.1, p= 0.017).

The groups were equivalent at baseline (week 0) with no significant differences in self-reported physical function (WHODAS) and performance-based physical function (ALF), pain severity, pain interference, BMI, physical activity levels, blood pressure, blood glucose, health-related quality of life and self-efficacy.

For the primary outcome measure, function, and disability according to WHODAS, the EXP group had a significantly better score than the CON group at week 12 ($p<0.01$). For the performance-based functional test according to ALF, the EXP group had significantly improved scores compared with the CON group at week 6 ($p<0.01$) and the EXP group had significant improvements over time ($p<0.01$).

There was a significant effect over the 12 weeks with improvements evident in scores for PSS ($p=0.02$), PIS ($p<0.01$) and Self-efficacy ($p<0.01$) in the EXP group compared to the CON group. The EXP group had significant improvements over time in PSS (6 weeks: $p=0.048$, 12 weeks: $p=0.040$); PIS (6 weeks: $p<0.001$, 12 weeks: $p=0.022$); and Self-efficacy (6 weeks: $p=0.002$, 12 weeks: $p<0.001$).

Significant differences between groups were found for HRQoL EQ-5D-3L VAS at week 6 ($p=0.012$); EQ-5D-3L Index at week 6 ($p=0.016$); and blood glucose at week 6 ($p=0.053$). The EXP group had significant within group improvements in EQ-5D-3L VAS ($p=0.01$), EQ-5D-3L Index ($p=0.015$) and blood glucose ($p=0.003$).

There were no significant differences in systolic and diastolic blood pressure, BMI, and physical activity (MET-min/week) over the 12-week study between groups. However, there was a significant improvement in median MET-min/week scores within the EXP group at week 6 ($p=0.001$).

In summary, the women that participated (EXP group) in the SmArt-Health six-week intervention had significantly improved scores in physical functioning, pain severity and pain interference, health-related quality of life, blood glucose levels and self-efficacy compared to the women who received usual care (CON group). Furthermore, upon feedback from the participants, this intervention was found to be acceptable by all the participants as an appropriate intervention for OA and comorbidities.

6.5 Discussion

The aim of this study was to determine the effect of the six-week SmArt-Health non-pharmacological intervention using exercise, education and self-management principles on physical function, pain severity and pain interference with function, hypertension, diabetes mellitus type 2, BMI, physical activity levels, health-related quality of life, and self-efficacy levels in managing women with osteoarthritis and comorbidities. The main results of this study indicate that the women who participated in the SmArt-Health intervention had significant improvements in the primary outcome measure of physical function (measured subjectively by WHODAS 2) and lower limb function (walking, climbing up and down steps, sit to stand, measured by the ALF). There were significant improvements in the secondary outcomes of pain, health-related quality of life, blood glucose levels and self-efficacy.

The demographic and socio-economic profile of the participants will be discussed first. Thereafter, the effect of the six-week intervention on physical function, pain, BMI, physical activity levels, health-related quality of life, hypertension, diabetes mellitus type 2, and self-efficacy will be discussed. The feedback on the intervention programme from the participants, limitations of the study and recommendations for future research and clinical implications will conclude this section.

6.5.1 Demographic and socio-economic characteristics of participants at Baseline

Comparisons in demographic and socio-economic characteristics were made between the women recruited for this study (RCT sample) and those in the Epidemiological study (EPI sample) in Chapter 4. Although the groups had similar characteristics in marital status (majority was married), number of children (majority had 3 children), level of education (majority had grade 8), there were some differences noted. The women in the RCT sample were younger (mean age: 55 years) than EPI sample (mean age: 60 years), more women from the RCT sample spoke Afrikaans (63%) and were unemployed (29%). These women earned a meagre income between R0-R1000 per month in comparison to the population. These findings suggest that the women in the RCT sample were struggling financially as their income fell below the South African National Poverty line, commonly referred to as the "extreme poverty line"[385]. These women are similar to the majority of women living in the disadvantaged area of Mitchells Plain in Cape Town[386]. Given the evidence linking relationship between poverty and disability, it is reasonable to suggest that these women are more vulnerable to disability due to poverty intensifying their health problems and physical disabilities related to their chronic diseases which in turn magnifies their experiences of poverty[387].

6.5.2 Function and Disability

6.5.2.1 Self-reported function - WHODAS

As the primary outcome of this study, function and disability were assessed subjectively across six adult life tasks namely: 1) Understanding and communication; 2) Self-care; 3) Mobility (getting around); 4) Interpersonal relationships (getting along with others); 5) Work and household roles (life activities); and 6) Community and civic roles (participation) using the WHODAS 2 12 item questionnaire. The summary score of the WHODAS ranges from 0 to 48 with higher scores indicating complete disability[205]. In this study, the median WHODAS scores for both groups were 14 (IQR) at baseline, which falls within the scoring bracket of 10-48 suggesting they are likely to have a clinically significant disability[205].

The significant improvements in WHODAS scores for the EXP group suggests that the SmArt Health intervention was effective in improving function in performing daily tasks in women with OA. There were no comparative data available from other studies which had implemented an exercise and education intervention for osteoarthritis using the WHODAS instrument. For this reason, a comparison of studies that used similar outcome measures to detect changes in function after engaging in an exercise and education interventions were made.

The findings of the current study are like those of other studies reporting on the effect of a combination intervention using exercise and education to improve physical function in people with osteoarthritis. A South African study by Saw (2015)[153] reported similar findings to the current study. They demonstrated significant improvements in self-reported function measured by the Health Assessment Questionnaire (HAQ) at week 6 (post intervention), week 12 and month 6 ($p<0.01$) for the experimental group, with no changes in their control group.

While the HAQ is a different instrument to the WHODAS, the findings are noteworthy and comparable as the HAQ was originally developed to determine functional disability in people with rheumatic diseases including osteoarthritis[388-390]. The HAQ assessed functional domains such as dressing, hygiene, arising, walking, reaching, eating, and gripping; all activities like the domains specific to mobility, self-care and life activities assessed by the WHODAS. Both instruments are similar in scoring these domains according to the level of difficulty in performing these tasks and functional activities[204].

Bennell and colleagues (2016)[391] conducted an RCT in Australia to determine if a 12-week combined intervention with exercise and pain coping skills based on self-management principles was more effective than exercise or pain coping skills alone in people with knee osteoarthritis. This study found that the combined exercise and pain coping skills intervention yielded significant improvements in function, measured by the WOMAC, compared with exercise alone (mean difference: 3.7 units [95% CI 0.4, 7.0]) and compared with the pain coping skills intervention (7.9 units [95% CI 4.7, 11.2]). In addition, most participants who engaged in the combined intervention (80%) reported global improvements in function compared with the pain coping skills intervention (62%). While the results seem to be comparable to the findings of the current study, it is important to understand whether the intervention was similar or not. The intervention consisted of 10 individual sessions over a 12-week period and consisted of any one of three treatment arms namely: (1) 45-minute sessions of the pain coping skills training, (2) 25-minute sessions of exercise, and (3) 70-minute sessions of the combined exercise and pain coping skills. The pain coping skills intervention covered topics on pain education and cognitive and behavioural pain coping skills. The exercise intervention consisted of six resistive exercises of the lower limb (strengthening of the quadriceps, hamstrings, and hip abductor muscles), performed four times weekly for 12 weeks and three times weekly thereafter[391]. It appears that the components of the exercise and pain coping strategy arms of the intervention were different to the current study.

The latter study had a longer intervention period, included resistive strengthening exercises for muscles surrounding the knee, had different dosage parameters for exercises, and had specific information about how to cope with chronic pain. While this study used a three-arm intervention based on exercise and pain coping strategies that was different to the current study implemented, it reported positive outcomes in function in people with OA. Perhaps the findings suggest that combined interventions consisting of any form of exercise, education and self-management could yield significant improvements in physical function in people with OA.

6.5.2.2 Function measured by performance-based tests

People affected with osteoarthritis often complain about difficulties with functional activities such as walking and standing up from a seated position[392] [393]. Therefore, interventions for OA should include strategies to improve the ability to perform these fundamental daily tasks. In addition to measuring function and disability with the WHODAS 2, physical performance outcome measures such as walking, climbing stairs and sit-to-stand were included as outcome measures.

In terms of physical performance measures, the women in the EXP group had significant improvements in the three physical functional tests (walking, climbing stairs and sit-to-stand) of the ALF compared to the women in the CON group. There were no other intervention studies available at the time of writing this discussion that used a similar intervention for OA and that used the ALF score as an outcome measure. Therefore, comparisons to international studies and South African studies were made which used similar interventions and comparable performance-based measures.

In the study conducted in Australia discussed previously, Bennell (2016)[391] found that a 12-week combined exercise and pain coping skills intervention was significantly more effective in improving walking, sit-to stand and step test measures compared to the exercise or pain coping skills treatment arms alone. Participants who engaged in the combination intervention had significant improvements in performing the 20-meter walking, 30 second sit-to-stand and step tests at week 12. A higher proportion of participants (80%) who engaged in the combination intervention reported a global improvement in function compared to the other treatments [391].

In South Africa, Saw et al. (2015)[226] found that the combined six-week intervention based on exercise and education significantly improved walking 15 meters at fastest speed. For normal walking time, the current study had similar findings to Saw et al. (2015)[226] in that the exercise and education intervention improved the walking time (reduction in time) in the EXP group compared to the CON group.

The other South African study by Barnes (2016)[190] reported that the six-week exercise and education intervention showed no benefit over usual care as the participants in both groups had improvements in walking time. These findings of no difference between groups contrast with the improvements noted in the current study and those of Bennell et al. (2016) and Saw et al. (2015) However, the improvements over time in both groups recorded by Barnes may reflect those of the current study, where both the EXP and CON groups had significant improvements between week 0 and week 6.

It is interesting to note that all three South African studies used similar outcomes and similar methodologies for the interventions and yet had different results. The current study had similar findings to Saw et al. (2015)[226] with improved normal walking time after the six-week exercise and education intervention.

The similarity in the results may be due to both studies being conducted in urban areas of Cape Town and having participants with the same condition within similar age ranges and similar socio-economic backgrounds.

Another reason could be that the interventions were led by qualified physiotherapists and had the same components of exercise, education, and self-management. Furthermore, both studies had small groups of 10-12 participants which allowed the physiotherapists to monitor the participants and provide personal attention to participants who needed assistance in performing the exercises accurately. Saw et al. (2015)[226] also only found improvements in walking time and not in other functional parameters as was the case in the current study. The possible reason for the improvements in all three activities in the current study could be that the sample was younger, less sick and did not have end-stage OA, which was the case for the participants in the Saw (2015) study[226].

Many factors could have influenced the differences found between the Barnes (2016)[190]study and the current study. One possible reason for the differences between groups in the two studies could be due to the large size (more than 20) of the experimental group participating in the intervention in the Barnes (2016) study[190]. Smaller groups of 12-16 participants are usually better for workshops, such as the CDSMP workshops for chronic diseases[394]. Another reason could be the type of exercises used in the intervention. Research has shown that exercises should be task and function specific to be able to improve the functional ability[395]. Barnes (2016)[190] study did not specify if specific functional tasks such as walking and climbing steps were included in the exercise programme, but included aerobics, half squats, lunges, dancing and ball activities. Another reason could be the exercise dosage or inadequate increase in exercise dosage over the six-week intervention period. Finally, the differences could be due to geographical and contextual differences between the two studies, as the Barnes (2016)[190] study was conducted in a rural town, approximately 1004 kilometres away from Cape Town with participants from different sociocultural backgrounds.

Both the participants in the current study CON group and those in the Barnes (2016)[190] study control group had improvements in physical activity tasks. These improvements could be due to familiarisation with the task. Repetition of functional tests at follow-up testing sessions creates familiarity with the task and this leads to an improvement in performance[396]. Another possible explanation could be that people, who are generally physically inactive and are untrained, may experience an increase in neuromuscular activation and develop intra-muscular co-ordination by learning new skills and tasks[397 398].

To avoid the effects of adaptation in future studies, researchers should consider having longer intervention programmes with regular follow-up assessments to be able to measure adaptation responses, as adaptations usually occur early in people involved in exercise-based interventions[396].

The similarities between the results of the current study and the studies of Barnes (2016)[190], Saw (2015)[226] and Bennell (2016)[391] on measures of physical function are encouraging. Improvements in the primary outcomes of physical function are significant as improved function is an important outcome for patients with OA as it directly relates to disability[399 400]. Furthermore, improvements in function have the potential to reduce the need for joint replacement surgeries and possibly reduce the negative impact on work productivity and improve overall health-related quality of life[401 402].

6.5.3 Chronic pain related to osteoarthritis

The reduction in pain severity (PSS) and pain interference scores (PIS) within and between groups and favouring the EXP group, suggests that engaging in the six-week exercise, education and self-management intervention reduces pain in women with OA compared to usual care at the CHC. The findings of this study concur with two South African studies conducted in similar settings in Cape Town[44 153]. Parker (2013)[44] used a similar 6-week intervention with exercise, education and self-management for patients with chronic pain living with HIV/AIDS in Cape Town. The intervention for pain in women living with HIV was associated with significantly reduced pain severity and pain interference scores, like the findings of the current study.

As previously mentioned, Saw (2015)[153] used a similar intervention with exercise, education and self-management on people with osteoarthritis of the knee and hip awaiting joint replacement surgeries. Saw (2015)[153] reported that the combination intervention had significantly reduced pain severity scores within the EXP group (n=20) from baseline to week six ($p < 0.01$) with a significant difference between groups at six months ($p=0.02$), favouring the EXP group. In addition, a significant reduction in pain interference scores were noticed within the EXP group from baseline to week six ($p<0.01$). The current study had similar findings to Saw (2015) with significant improvements in pain severity and pain interference scores between groups and within groups, favouring the EXP group, at both week 6 and week 12 post intervention. Saw (2015)[153] recruited participants that were older, were on a waiting list for joint replacement surgery for more than three months compared to the sample of the current study.

This increased age and potentially more severe OA could explain why those participants took longer to respond to the combination intervention compared to the usual care available at South African primary health care clinics.

The significant improvements evident in physical functioning and in pain severity and pain interference immediately after the intervention (short term) within the EXP group and between the groups of women with OA in the current study is remarkable. It demonstrates that the six-week exercise, education and self-management intervention appears to be an effective management strategy in comparison to usual care offered at the CHC.

One of the mechanisms by which the intervention influenced pain and function could be due to the patient-centred self-management empowering model of care of the SmArt-Health intervention. This model of care is aimed to impact on self-efficacy. A similar study by Hurley (2007)[43] using a cluster randomised trial to compare the effect of exercise, self-management and active coping strategies (ESCAPE-knee pain) in people with chronic knee pain with usual care at primary health care found similar results to the current study with significant improvements in the WOMAC-function scale (Effect size=0.29, 95% CI: 0.07, 0.520; p=0.010) and WOMAC-pain scale in the rehabilitation groups compared to the usual care group at six months (Effect size=0.27, 95% CI: 0.05, 0.50; p=0.016). The ESCAPE-knee pain intervention was conducted twice a week over a six-week period and involved discussions on topics related to self-management and coping strategies and a progressive exercise routine. This intervention was facilitated to both individuals and a group of participants and was delivered by the same physiotherapist.

This improvement in function and pain was seen in individual participants and in group participants that received the supervised ESCAPE-knee pain intervention. The intervention of this study was like the current study as the intervention combined education, exercise and self-management strategies and was led by a qualified physiotherapist. Thus, providing further supporting evidence that the combination of exercise, education, and active coping strategies (or self-management strategies) for OA are more effective and cost effective compared to the usual care available at primary health care clinics[43 152].

6.5.4 Chronic diseases

6.5.4.1 Blood pressure

As stated previously in this chapter, low levels of physical activity and obesity are common risk factors associated with osteoarthritis, hypertension (HPT), and diabetes mellitus type II (DMII)[403 404 104 405 24]. Therefore, it was recommended to include the management of both osteoarthritis and hypertension in the combined intervention to possibly mitigate the impact of these conditions on functional activities and pain. This study found no significant differences in the mean systolic ($F^{(2, 122)}$ = 0.230, p= 0.726) and diastolic pressure scores ($F^{(2, 122)}$ = 0.018, p= 0.982) over the 12 weeks of the study. The six-week intervention did not reduce the mean scores within the EXP group or between groups as expected but increased the mean systolic pressure from 149.9 mmHg (week 0) to 152.7 mmHg and the mean diastolic pressure from 88.7 mmHg (week 0) to 90.2 mmHg at week 6 in the EXP group. However, this was not surprising as exercise usually increases systolic pressure and similar results were reported by Laukkanen (2004)[406].

Furthermore, the mean systolic pressure in the EXP group decreased from 149.9 mmHg (week 0) to 143.2 mmHg (difference of 6.7 mmHg) compared to the CON group at week 12 (difference of 5.3 mmHg). This difference is within the recommendations of a reduction of 2 mmHg to 5 mmHg in systolic pressure to reduce the risk of stroke and coronary heart disease, and to effectively reduce hypertension[200 407 408]. Even though there was a clinical difference noted in systolic pressure in the EXP group at 12 weeks, the CON group seemed to have reduced systolic scores at this time point as well, which could possibly be due to effect of the anti-hypertensive medication. Therefore, the findings related to the impact of the intervention on hypertension are questionable in this sample.

Even though the intervention included components of exercise and education about adopting healthy lifestyles specifically related to diet for hypertension, perhaps the exercise and educational sessions were not adequate to bring about any significant changes to the blood pressure values between groups and within the EXP group. Therefore, the results of the six-week intervention relating to blood pressure should be taken with caution as there were potential limitations highlighted with the intervention. It is recommended to adapt the workbook and exercise component of the intervention to include specific moderate-intensity physical activities of at least 150 minutes per week (30 minutes of activity for at least five days per week) to be able to achieve optimal health benefits, according to international guidelines[330 331]. A further emphasis could be placed on the use of regular walking and resistive exercises as these activities have been shown to reduce blood pressure values[409-411].

Another possible limitation of the intervention was having blood pressure measurements at the three time points (week 0, 6 and 12) only. The use of weekly measurements, before and after each intervention session, may have more accurately measured the acute effect of the exercise session-the post-exercise hypotension (PEH) response[412]. The PEH is usually measured by comparing the blood pressure scores before and after each exercise training session[412]. It is said that the greatest reduction in blood pressure occurs during the first few hours after an exercise session, with high blood pressure values (hypertension) returning to normal blood pressure ranges[408]. With this said, this is the most likely reason for not finding any positive effects on blood pressure. Therefore, future studies exploring the effects of the intervention on hypertension should include blood pressure measurements before and after each exercise session to determine accurate changes in blood pressure.

6.5.4.2 Blood glucose levels

Significant differences were noted between groups over the 12 weeks of the study with reduced median blood glucose scores in the EXP group (5.2 mmol/l) compared to the CON group (6.0 mmol/l) at week 6 (KW-H (1,63) = 3.7368, p = 0.053). In addition, there were significant differences in the median blood glucose score within EXP group from 6.3 mmol/l (week 0) to 5.2 mmol/l (week 6) compared to the CON group who had very little changes over the 12 weeks. It appears that the SmArt-Health intervention had significant improvements in the median blood glucose scores. This was an unexpected finding as the intervention was not directly aimed at managing diabetes mellitus type II (DM2) but rather hypertension. This study's findings concur with other studies who reported that regular physical activity and exercise improves blood glucose levels in people with DM2[413 414 330].

The SmArt-Health intervention was aimed at women with osteoarthritis and hypertension associated comorbidities such as diabetes mellitus type II. It was assumed that this intervention would significantly reduce blood pressure scores in this sample; however, this study failed to reject null hypothesis. Instead, the intervention caused significant changes in blood glucose levels in women in the EXP group and could imply that this appears to be an effective intervention strategy. A possible reason for this effect on blood glucose could be due to the proposed relationship between OA and diabetes mellitus (DM2). In a meta-analysis done by Louati et al., (2015)[415], a high prevalence of OA in people with DM2 and an association between these two diseases were found, indicating a Diabetes mellitus-related OA, highlighting a metabolic osteoarthritis phenotype. Thus, treatment and prevention strategies for OA may be an effective treatment for patients with DM2 as well[415].

Another plausible reason for the positive effects on blood glucose levels in this study could be due to the self-management programme which aimed to empower people with knowledge and skills to take responsibility for their own health. The Chronic Disease Self-Management Programme (CDSMP) implemented by Lorig et al., (2001)[154] in people with chronic diseases of the heart, lungs, diabetes and arthritis, had similar results to the current study. The CDSMP is a 7-week self-management programme based on self-efficacy theory to improve the confidence of an individual to be able to manage and take control of their own health and well-being. This programme was like the SmArt-Health intervention of the current study, using small groups of 10 to 16 participants and weekly sessions of 2.5 hours each. The CDSMP uses a manual or workbook and includes goal-setting, problem-solving, action planning and feedback on a weekly basis, similar to the current study's SmArt-Health intervention. The CDSMP used similar topics as the current study (how to manage chronic diseases, exercise, healthy eating, communication, medication, making appropriate treatment decisions, stress and depression, relaxation and self-management principles). The CDSMP study found that the participants who engaged in this intervention experienced significant improvements in health behaviours, health status, self-efficacy scores and reported less visits to the clinic[154].

Furthermore, studies in Korea[416], Thailand and Sub-Saharan Africa[417], implementing self-management interventions specifically for people with DM2 (similarly structured to the SmArt-Health intervention) found positive results in all health outcomes providing supporting evidence for the use of self-management programmes in people with DM2. These interventions ranged from six weeks to six months; consisted of small groups and focused on education on diabetes self-care and medication, nutrition, exercise, coping with stress and self-management principles. The studies reported on a range of outcomes such as self-efficacy in DM2, heath related quality of life, blood glucose levels, blood pressure levels and BMI.

There is substantial evidence showing the relationship between OA and DM2 and that self-management interventions are appropriate treatment and prevention strategies for both these chronic diseases. In addition, these interventions advocate for behavioural changes improving the overall health status, health-related quality of life and metabolic control in patients with OA and DM2. Therefore, these results can be used to support the use of appropriate non-pharmacological prevention and management strategies such as SmArt-Health for both osteoarthritis and diabetes mellitus type II.

6.5.5 Modifiable risk factors

6.5.5.1 Body mass index

The current study found no significant differences or changes in the mean BMI scores between groups or within groups over the 12-week period. The results of this study concur with both Barnes (2016)[190] and Saw (2015)[153]. The possible reasons for having no changes in BMI in this sample could be due to the 6-week intervention not being specifically targeted at weight loss strategies but rather including information about healthy eating habits. According to Foright et al., (2018)[418], reduced calorie intake in diet is more effective than exercise for weight reduction. However, there is supporting evidence demonstrating that exercise is an effective strategy for weight loss maintenance in individuals who are able to maintain a regular exercise programme, provided that certain behaviours are avoided. In addition, for exercise to be used as an effective strategy for weight loss, researchers should aim to address issues around adherence, molecular mechanisms related to weight gain and variability in individuals [418]. Another possible reason attributed to no BMI changes in participants, is that the study was conducted during winter season. Participating in outdoor physical activity is challenging in these conditions and the low resource community in which the study was conducted does not have facilities for exercise to be done indoors. Sedentary behaviours could contribute towards weight gain[419].

The high BMI found in people with OA in all three of the above studies are supported by studies reporting strong relationships between obesity and OA[419-421] and depicts the current obesity problem in people living in Sub-Saharan Africa[422]. This high prevalence of obesity in sub-Saharan Africa could further aggravate pain and functional problems related to OA and worsen the burden of chronic diseases. Appropriate public health strategies may be more effective to address factors such as healthy diet, physical activity and weight reduction to help reduce the burden of obesity and associated health problems in sub-Saharan African countries[422].

6.5.5.2 Physical activity

This study found no statistically significant difference in the median MET-min/week scores between groups over the 12 weeks of the study. Participants in both groups had the minimum level of physical activity of 600 MET-min/week at baseline, classified as moderate levels of physical activity. However, after the six-week intervention, the MET-min/week within the EXP group changed to the high physical activity category[227]. The results imply that the six-week intervention improved the median Total MET-min/week (physical activity levels) of the EXP group and subsequently shifted them to the high physical activity category (p=0.001).

At the time of writing, there was a lack of local studies available that used combination exercise and education interventions to improve self-reported physical activity levels (MET-min/week) in people with OA. Therefore, comparisons to other studies that used a similar metric to assess physical activity were done. Rosemann (2008)[423] explored the predictors of physical activity in patients with OA of the hip and knee joints in Germany and reported a mean MET-min/week of 2108.3 (SD=1879.6) in women. This was comparable to the current study findings of a median total MET-min/week at baseline from 1782 to 2012.

Barwais et al., (2013)[424] implemented a 4-week personal activity-monitored intervention to increase physical activity levels in sedentary adults to improve total wellness and measured MET-min/week. This RCT found no significant differences within the CON group from baseline to week 4, (the CON group were not using the activity monitors and were informed to continue with their normal day-to-day activities). However, the EXP group had significant differences in MET-min/week for walking ($p< 0.001$), moderate-intensity ($p< 0.001$) and vigorous-intensity activities ($p< 0.001$) at week 4 compared to the CON group. The calculated difference in Total MET-min/week scores (summation of MET-min/week for walking, moderate-intensity and vigorous-intensity)[227] was 1954 MET-min/week post intervention. The difference of 1954 MET-min/week at week 4 (post intervention) was very similar to the difference found within the EXP group (2046 MET-min/week) at the end of the six-week intervention in the current study.

The possible reason for the similarities noted within the EXP groups across the two studies could be due to improved patient adherence by using various aids such as the activity monitoring system, and the self-management exercise and education (SmArt-Health) intervention, motivating behavioural change through goal-setting[425]. In the current study, weekly reminders were sent to the EXP group via email or text messages to increase motivation levels and adherence to the interventions[425].

A few plausible reasons for the insignificant changes in physical activity between groups in this study could be that the SmArt-Health intervention was only conducted once a week, and this could have been the only exercise session for the participants for the week. Perhaps some of the participants did not feel safe in their environment to engage in physical activity alone and could have benefitted more if they had met with their groups more frequently (more than once a week). Another reason could be that most of the participants in both EXP and CON groups engaged in walking daily as they were dependent on public transport to move around from one place to another. This daily physical activity could have already increased their physical activity levels and could be the reason for the increased MET-min/week after the intervention. However, this type and intensity of physical activity was not adequate to yield significant results between groups. Finally, as mentioned earlier, the fact that the study took place during the colder winter months may have prevented some participants from engaging in regular physical activity.

While there were no statistically significant differences in Total MET-min/week scores (physical activity levels) between groups in the current study, it appears that the self-management exercise and education intervention produced a clinical improvement in physical activity levels within the EXP group. Furthermore, the tool was not the most appropriate to measure and detect significant changes in this study as it was originally developed as a surveillance tool[227]. Therefore, it is recommended that future studies should include an objective measurement of physical activity using validated monitors such as accelerometers to provide a more accurate measurement of activity.

6.5.6 Health-related quality of life (HRQoL)

It appears that the SmArt-Health intervention contributed to a significant improvement in the participants' perceived health-related quality of life in the EXP group compared to those in the CON group. In addition, in support of the improvement in the VAS scores, there were also improvements in the Index scores. The results of this study were different to those of Saw (2015)[153] who reported no significant differences in the EQ-5D-3L VAS or Index scores within or between groups. Even though both groups in Saw's study[153] had reported very low HRQoL values (EXP: Mean=0.31, SD=0.34 and CON: Mean=0.35, SD= 0.32) at baseline and had slightly increased scores after the intervention (EXP: Mean=0.58, SD= 0.36 and CON: Mean=0.55, SD=0.26), the scores were still lower than the current study's scores in EQ-5D-3L. The possible reason for the difference in findings could be due to Saw's (2015)[153] sample being different to the current study's sample as they were older, had late stage OA, had more severe pain at baseline, and were placed on a long waiting list for joint replacement surgery and could have experienced poorer health-related quality of life.

However, the findings of the current study were similar to those of Barnes (2016)[190] whose participants were women of a similar age and with similar disease profiles being managed at primary health care clinics. Barnes reported a significant difference in the median EQ-5D-3L Index scores between groups at week 6, favouring the EXP group ($p = 0.019$). The six-week combination intervention (both used by Barnes and the SmArt-Health intervention) were effective in contributing to an improvement in the EQ-5D-3L index scores. These findings emphasise that women with OA engaging in a combination exercise and education intervention based on self-management principles at a primary health care level have improved their physical function, pain, and health-related quality of life.

6.5.7 Self-efficacy

Participants in the EXP group had significant improvements in self-efficacy scores compared with the CON group. There is sufficient evidence showing that people with chronic diseases have lower self-efficacy (SE) scores than people without disease, and that is it an important theory to include in self-management interventions to be able to change an individual's behaviour[426 427]. The results of the current study contrast with the studies of Saw (2015)[153] and Barnes (2016)[190] who found no significant differences in self-efficacy (SE) scores between groups post intervention. However, Barnes (2016)[190] found significant improvements within the EXP group, which was not the case for Saw (2015)[153]. Even though all three studies used similar interventions in similar populations, there are apparent differences.

Once again, the lack of improvement in SE in Saw's study could be due to an older sample, having late-stage OA and having more severe pain than the current participants. Another possible reason could be due to the low educational levels of the participants, which could have resulted in difficulty in understanding and completing the SE questionnaire appropriately[428].

The similarities between Barnes (2016)[190] and the current study could be due to the similarities in the samples, middle-aged women, with similar chronic conditions, attending primary health clinics, and having shared risk factors. In both studies, the significant improvements in SE could be associated with the positive results found in the EQ-5D-3L VAS and Index scores. By including an active exercise component in the intervention, the participants were able to experience that performing exercise did not aggravate the pain levels which may have further increased SE. In addition, the other components of the intervention that emphasised coping strategies for pain and how to self-manage their chronic diseases reinforced their positive experiences and restored self-confidence in performing their daily functional activities[152].

The results of this study demonstrate that the SmArt-Health combined exercise with education intervention based on self-management principles was effective in improving the overall self-efficacy scores in women with osteoarthritis and comorbidities. Moreover, this study substantiates that self-efficacy is an important component to be included in management strategies for chronic diseases such as osteoarthritis and diabetes mellitus in primary care clinics[429-431].

6.5.8 Acceptability of the intervention

The acceptability questionnaire provided useful feedback about the experiences of the participants. All the responses from the participants were positive and the benefits of engaging in this intervention were evident in the responses and in the significant improvements in the health outcomes discussed previously. It is interesting to note that a few participants mentioned that they would use the acquired knowledge and skills obtained through this intervention to educate and empower other people diagnosed with similar health conditions. This is quite remarkable as it reflects the level of self-confidence gained from engaging in this intervention. Furthermore, the positive feedback reinforces the need for physiotherapists to implement combined self-management interventions, such as the SmArt-Health intervention, in women with OA and comorbidities at primary health care level.

6.6 Conclusion

The main aim of this phase of the study was to develop, implement and evaluate an evidence-based intervention advocating a patient-centred self-management approach for women with OA and CDL at primary health care facilities in Cape Town. This study found that the six-week SmArt-Health intervention led by a physiotherapist was effective, resulting in significant improvements in the primary outcome: physical functioning, and related secondary outcomes namely: pain severity, pain interference, health-related quality of life, blood glucose levels and self-efficacy in women with osteoarthritis and comorbidities attending a primary health care clinic in a disadvantaged area in Cape Town. The SmArt-Health intervention appears to be effective and feasible for implementation in similar primary health care settings as it is a relatively low-cost intervention that requires minimal resources. The findings of this study demonstrate the feasibility and efficacy of a self-management intervention for women with OA and CDL at a primary health care clinic in Cape Town, South Africa.

6.6.1 Strengths

The main strength of this study was the research study design, as it was a pragmatic randomised controlled trial (RCT) with single blinding and using pre-test-post-test design. This was the best research study design to be able to evaluate the effect of the intervention on health outcomes. Furthermore, the RCT complied with the CONSORT statement on how to report randomised trials[432]. Lastly, the study was appropriately powered and had an adequate sample size to yield positive results in the health outcomes.

6.6.2 Limitations

This study had a few limitations. The study only made use of self-reporting questionnaires to measure physical activity levels, which could have resulted in inaccurate data due to self-reporting bias. This study did not repeat blood pressure monitoring before and after every intervention session, which could have resulted in the lack of change recorded in blood pressure values. This study had a short duration (six-weeks) of the intervention and short follow-up testing period (ended at 12 weeks which was 6 weeks post intervention). If the intervention was over a longer period (approximately 12 weeks) and the follow-up testing was longer (perhaps included follow-up testing at 12 months post intervention), it could have yielded significant improvements in reducing high BMI in the participants[433].

Another limitation is that the programme was delivered by one physiotherapist, thus we cannot determine whether the impact of the intervention was due to that person's "charisma" or to the programme content.

Furthermore, it is important to determine the cost utility of this combined treatment for OA compared to other treatments in terms of Quality Adjusted Life Year (QALY), however, this was beyond the scope of the current study and a limitation in terms of recommending the intervention as a cost-effective treatment approach. A further limitation is the assumption that the questionnaires used measured what participants most value in an approach to managing their OA. Adding a qualitative research method (mixed methods) would have strengthened this study immensely and may have altered the outcomes. Lastly, this study did not include discussions on minimally clinically important differences in outcome scores and calculating this would be a very useful addition as it reflects what matters to participants (their experience of change), rather than statistical significance.

7 CHAPTER 7: CONCLUSION

7.1 Osteoarthritis- a disabling condition

It is clear that osteoarthritis (OA) is the most common chronic musculoskeletal disease contributing to the increased burden of disability globally and locally[7-9 17]. Osteoarthritis is the most common type of arthritis in people older than 35 years of age in Africa[17] with a high prevalence in middle-aged women in South Africa[17]. Furthermore, OA is significantly associated with obesity[19 52 53] and low levels of physical activity[52]. Thus, women, particularly those who are obese and have low levels of physical activity, are at higher risk for developing OA and developing related disability.

Apart from suffering with the functional limitations and physical disabilities consequent from the chronic pain and joint stiffness associated with OA, affected women often have other chronic diseases of lifestyle (CDL) or comorbidities such as hypertension and diabetes mellitus type 2[343 9 329 48]. This dual burden of OA and comorbidities in South African women places a strain on the those diagnosed and on the over-burdened public health system, creating new challenges for comprehensive health care and rehabilitation services at the primary health care level or in community health centres (CHCs)[434]. A lack of evidence-based non-pharmacological interventions for women with OA and comorbidities which can be implemented at local CHCs is evident, highlighting the need for effective patient-centred non-pharmacological interventions using a biopsychosocial model to improve health outcomes in this population.

As osteoarthritis (OA) can affect an individual's physical function, health-related quality of life and overall wellbeing through multiple interacting mechanisms, the ICF was used as the underpinning theoretical framework for this research[28]. The ICF is based on the biopsychosocial model incorporating the biological, individual and social factors of health and environmental factors together to classify an individual's level of functioning and disability[29]. By using the ICF framework, a better understanding of the interactions between changes in bodily function and structures in women with OA was developed, with knowledge on how these women can function and execute activities in their home and usual environment (community and work) with the condition. The ICF provided a framework to explore possible associations between OA and comorbidities through shared risk factor and facilitated the development of an appropriate, contextually relevant intervention.

7.2 The need for non-pharmacological interventions at primary health care level

Recognising the need for evidence-based non-pharmacological interventions for use with women with OA and comorbidities being managed at CHC level, several research questions relating to the burden of OA in a South African context were identified. The research studies presented in this thesis aimed to address these research questions.

The research questions were:

- *What are the characteristics, comorbidities, health-related quality of life, functional impact and contributing factors to OA in women with OA attending CHCs in Cape Town?*
- *What would the components of a contextually relevant non-pharmacological intervention programme be for women with OA and comorbidities in Cape Town?*
- *How effective would this intervention programme be in addressing the impairments, activity limitations and participation restrictions of these participants?*

The findings of the research studies are summarised below according to the specific aim and objectives. At the outset, the main aim of this research was to develop or adapt, implement, and evaluate a new rehabilitation model of care advocating a patient-centred self-management approach for women with OA and comorbidities at the CHC level in Cape Town.

7.3 Chapter 2: Causes and impact of osteoarthritis: literature review

The objective of Chapter 2 was to review the literature describing the prevalence and characteristics of OA; the possible risk factors and chronic diseases of lifestyle (CDL) associated with OA and the impact of OA on women's health and well-being. Furthermore, the objective was to review the evidence from intervention studies for the most effective non-pharmacological interventions for OA using combined exercise and education approaches.

The prevalence of OA ranged from 14% to 66% for developed countries[9 18 19]; 10.5% to 29% for developing countries[51 50 52]; 1.5% to 10% in Africa[54 53]; and 2.2% to 55% in SA[36 27 17]. It was evident that the prevalence of OA increased with ageing[18 19 17]. Women reported the highest prevalence of OA in developed and developing countries[9 52 63 17]. In addition, women, who were obese and had low levels of physical activity were at higher risk of OA[52 54 53 19]. Studies from both developed and developing countries, including SA, reported that OA was significantly associated with comorbidities such as hypertension (HPT), diabetes mellitus type 2, depression, asthma and chronic obstructive pulmonary disease (COPD)[9 53 54 36 27]. The risk factors of obesity and lack of physical activity for OA appear to overlap with hypertension and diabetes mellitus type 2, suggesting a possible relationship between OA and CDL.

OA has a negative impact on women with comorbidities, as they are deprived of optimal health, suffer with chronic pain, and cannot optimally perform their functional activities in the home or at work. The increased burden of OA with comorbidities could negatively impact the affected individual, family and community[120]. If these chronic diseases are not managed effectively, the affected individual may be vulnerable to experiencing a cycle of impairments (pain, hypertension, diabetes mellitus type 2), activity limitations (poor daily functional activities) and participation restrictions (difficulty or cannot do work and extra-mural activities), leading to continuing worsening health status and health-related quality of life.

According to international clinical guidelines for managing OA[38 40 39] and randomised controlled trials testing the efficacy of exercise, education or self-management approaches for OA[42 43 148 150 151], there is strong evidence advocating for combination interventions consisting of exercise, health education and self-management as effective and affordable non-pharmacological interventions targeting physical function, pain and other health outcomes in people with OA.

This chapter highlighted a high prevalence of OA in women attending primary health care clinics in SA, with significant numbers of these women with OA suffering from additional comorbidities. These women often suffer from chronic pain, joint stiffness, impaired functional ability, obesity, low levels of physical activity and have poor health-related quality of life and may become an increased burden on the public health care system. Unfortunately, there is no evidence available to support the use of non-pharmacological interventions using exercise, education, and self-management in South African clinics to mitigate the negative impact of OA and its associated comorbidities. Therefore, highlighting a need to develop and test non-pharmacological exercise, education, and self-management interventions for women with OA and comorbidities.

7.4 Chapter 3: Instrumentation - The use, selection, translation, and validation of instruments

The first objective of the studies reported on in Chapter 3 was to identify and select the most appropriate outcome measurement instruments to explore the various health outcomes highlighted in the aim of the research study. Furthermore, the selected instruments should be valid and reliable to be able to use in women with OA in the South African context.

Based on the literature review, the following outcome measurement instruments were selected as appropriate:

- World Health Organisation Disability Assessment Schedule 2.0 (WHODAS 2) (Functional limitations and disability)
- Aggregated Locomotor Functional test (ALF) (Physical performance measure of walking, sit-to-stand and climbing steps)
- Community Oriented Programme for Control of Rheumatic Diseases (COPCORD) (Characteristics of people with rheumatology)
- Brief Pain Inventory (BPI) (Prevalence of OA, Pain severity and Pain interference)
- Rossmax automatic digital blood pressure monitor (model-CF155F) (Measure blood pressure)
- Accu-Chek Active (Model GU) glucometer (Measure blood glucose)
- Body mass index (Obesity)
- International Physical Activity Questionnaire-long version (IPAQ) (Physical activity levels)
- The 5-dimension EuroQol (EQ-5D-3L) (Health-related quality of life)
- Self-efficacy for managing chronic disease 6-item scale (SE-6) (Confidence levels)

To conduct the epidemiological study to achieve the objectives for Aim 1, the most instruments were available in the Xhosa, Afrikaans, and English languages. However, there were two instruments, the COPCORD and IPAQ questionnaires that needed to be translated into isiXhosa and Afrikaans. Therefore, the second objective of Chapter 3 was to adapt, translate and validate the COPCORD and IPAQ for use in these languages.

The adapted COPCORD (phase I and II) was successfully validated by a panel of experts for content, clarity, and acceptability for screening of OA and chronic diseases of lifestyle in South Africa.

Thereafter, the adapted COPCORD and IPAQ questionnaires were translated into isiXhosa and Afrikaans to ensure cross-cultural adaptation. The cross-cultural translation process (forward-translation, back-translation process, panel of experts with pre-testing and cognitive debriefing session)[244] was followed to ensure semantic, linguistic, operational and functional equivalence in the two translated questionnaires. Both outcome measures were successfully translated into isiXhosa and Afrikaans. However, some issues were highlighted during the translation process which were addressed by the panel of translators. The main aim of the synthesised translated outcome measures (COPCORD and IPAQ) was to be able to convey the same intended information as the original questionnaires to women speaking either isiXhosa or Afrikaans.

The feasibility and validity of the translated COPCORD and IPAQ questionnaires were evaluated in a sample of 92 participants. This sample was representative of the target sample for the epidemiological and intervention studies. The responses of the translated COPCORD questionnaire were compared to the previously validated BPI and showed acceptable agreement, demonstrating acceptable criterion validity. However, the mode of administration of the questionnaires was problematic and the recommendation was made to change from self-report to interviewer administration.

For the translated IPAQ questionnaire, known group validity was evaluated by comparing the responses to the COPCORD and BMI. Unfortunately, known group validity could not be determined as there were no relationships or significant differences found between groups. Hence, the validity of the IPAQ long form is questionable in this sample. In addition, some participants had challenges with their responses to the long form and thus recommendations were made to consider using the IPAQ short form to eliminate comprehension problems. Finally, both translated questionnaires successfully met the feasibility criteria of this sub-study and were recommended as feasible instruments for use in the epidemiological and intervention studies to follow.

7.5 Chapter 4: The characteristics and functional impact of chronic musculoskeletal disease and comorbidities in women attending a community health centre in Cape Town

The aim of this study was to determine the characteristics, physical activity levels, obesity, health-related quality of life and functional impact in women with chronic joint pain and comorbidities attending a Community Health Centre to establish the contextual background for an appropriate intervention. The specific objectives were to obtain this information using valid and reliable outcome measures discussed in Chapter 3; to identify the prevalence of OA or chronic MSD, identify possible clusters of chronic diseases in women with OA; and to establish relationships between OA, comorbidities, and other risk factors (age, obesity, and lack of physical activity).

In this study, 803 women were recruited and interviewed. The typical woman in this sample was of middle age, not currently married but had children, was unemployed, had low levels of income (state grants) and low education levels. More than forty percent (44.2%) reported being the sole providers for their families, even though many reported being unemployed. The prevalence of chronic joint pain was 45% (95% CI: 42-49%). This included women (158 of 364) who were diagnosed with arthritis such as OA. In addition, nearly half of the women reported having hypertension (HPT), and 23% had diabetes mellitus type 2 (DM2). Notably, OA and HPT were co-morbid in almost one third of the women.

The women with chronic joint pain experienced moderate pain severity and pain interference (mean score >5) especially with activities requiring physical functioning, such as walking and work. Approximately 70% of the women reported receiving pharmacological treatment (prescribed analgesia and NSAIDS) for treatment of pain and very few reported receiving non-pharmacological management (exercise, massage, and education). In those who had reported receiving non-pharmacological treatment, 14% reported that exercise was the best intervention that reduced their symptoms.

Most of the women were obese and had low levels of physical activity (Low PA). There were significant associations between having a high BMI and chronic joint pain, and between having Low PA levels and chronic joint pain. A significant association was found between HPT and Low PA level. Nearly half of the women (43%) reported having some problems with pain according to the EQ-5D-3L, supporting the results from the BPI. In addition, the mean EQ-5D-3L health utility (HU) score was high (0.76, SD=0.17) indicating good health-related quality of life.

However, there were significantly lower HU scores in women with chronic joint pain and HPT compared to those without diseases, indicating poorer health-related quality of life in those with chronic joint pain and HPT.

On the WHODAS 2 instrument, many women reported moderate difficulty with functional activities (walking daily, standing, household responsibilities, and work) and 209 (26%) women reported being moderately emotionally affected by their health problems. The median score of women with chronic joint pain was 9 (IQR: 13) versus 5 (IQR: 11) in those without joint pain, indicating a poorer level of functioning and greater disability. Furthermore, women with chronic joint pain and HPT had significantly higher WHODAS scores, compared to those without these diseases.

This study highlighted the prevalence of both chronic joint pain and HPT independently and as co-morbid conditions in women at a primary health care clinic (CHC) in Mitchells Plain, Cape Town. These findings are important for physiotherapists and all health professionals working in health promotion at CHCs. Physiotherapists should include the assessment of HPT and other chronic diseases, physical activity levels and screen for obesity in the initial assessment of a patient with symptoms of chronic joint pain such as OA. Thereafter, referral to the doctor or health promoters would be indicated for appropriate management. The nurse or health promoters should do the same with patients at the chronic care clubs and screen for OA and refer to physiotherapy for treatment. Furthermore, the lack of appropriate rehabilitation treatment for these women was identified highlighting the need to explore an evidence-based non-pharmacological intervention that would target both chronic diseases in this group of women at the clinic.

7.6 Chapter 5: The development of a contextually relevant intervention for osteoarthritis

The aim of this chapter was to describe the development of an evidence-based contextually relevant intervention Programme, and to describe the structure and content of each component of the intervention. The intervention Programme comprised of the "core treatment" (exercise, education, and self-management) to manage osteoarthritis and comorbidities in women at primary health care level. Since most women in the study in Chapter 4 had chronic joint pain/OA and HPT, it was recommended to include management for both these chronic diseases with the aim of reducing the impact of these conditions on functional activities and pain.

The developed intervention was called "Self- management for Arthritis and High blood pressure with Education, Activity and Lifestyle modification therapy" with the acronym: "SmArt-Health". The characteristics and profile of the women presented in Chapter 4 was used to develop this contextually relevant intervention. A workbook modified from those previously used by South African researchers in studies in HIV/AIDS[44], end-stage OA in patients waiting for arthroplasty[153] and in chronic joint pain in women living in a peri-urban area[190] was developed. All these workbooks were based on self-efficacy theory, theories of social learning[357], and the principles of self-management used in chronic disease self-management programmes[154]. The SmArt-Health workbook was used as part of the intervention as a supplement to reinforce the principles of self-management of osteoarthritis and hypertension in the participants' daily routine.

The intervention programme developed was a six-week workshop facilitated by a physiotherapist that would be delivered in a small group format of 10-13 participants, once a week for two hours. The intervention was structured into an interactive educational session on a relevant topic, an active exercise component and a relaxation session. The last 30 minutes of each session was designed to be used for round table discussions and feedback about participants' goals, action-planning, and achievements. Participants would be encouraged to track their exercise in weekly exercise diaries to evaluate the successes and failures of their exercise goals. At the end of each session, the group were encouraged to socialise with each other while having healthy refreshments.

7.7 Chapter 6: The effects of a six-week non-pharmacological intervention on function and health outcomes in women with osteoarthritis and hypertension: a randomised controlled trial

The aim of this chapter was to determine the effect of the developed six-week SmArt-Health intervention based on exercise, education, and self-management on impairments (osteoarthritis and hypertension); activity and participation restrictions (health-related quality of life, physical activity levels, physical function in walking, climbing steps, sit-stand activities) and other factors (obesity and self-efficacy in managing chronic diseases) in women with osteoarthritis and hypertension.

The physiotherapist-led intervention was tested in a single-blind pragmatic randomised controlled trial (RCT) that used a pre-test-post-test design over a 12-week follow-up period. The main findings of this study indicated that women (EXP group) in the SmArt-Health intervention had significant improvements in the primary outcome of function and disability measured on the WHODAS 2 and lower limb functional tests (ALF). There were significant improvements in the secondary health outcomes, specifically in pain severity and pain interference (BPI), blood glucose levels (DM2), health-related quality of life (EQ-5D-3L) and self-efficacy (SE-6) in the women who participated in the intervention compared to the women in the control group, who had received usual care at the clinic. The six-week intervention did not yield significant improvements in BMI, physical activity levels and blood pressure scores over the three months of the study.

At the end of the six-week SmArt-Health intervention, the women who had participated in the intervention completed an acceptability questionnaire. The responses were positive throughout. All the women reported that the intervention was appropriate and that they enjoyed being part of it, suggesting that the intervention was well accepted by these participants.

In conclusion, the SmArt-Health non-pharmacological intervention appeared to be successful in improving physical function and the secondary outcomes discussed above in women with osteoarthritis and comorbidities. Furthermore, this study provides preliminary evidence that interventions which target self-efficacy and self-management are effective when included in management strategies for osteoarthritis in the primary health care clinic in Mitchells Plain, in Cape Town.

7.8 Recommendations

7.8.1 Clinical

The main findings of this thesis suggest that the SmArt-Health intervention is an effective non-pharmacological management strategy that improves functional limitations, pain, health-related quality of life, blood glucose levels and self-efficacy in women with osteoarthritis and comorbidities at a CHC in Mitchells Plain. Furthermore, combination intervention (exercise, education, and self-management) seems to be an effective intervention for women diagnosed with multiple chronic diseases. The group format used in this intervention appears to be an appropriate and acceptable format to conduct such interventions at primary health care clinics.

The clinical recommendations arising from the two main studies presented in this thesis include:

- A protocol for the assessment and treatment of OA and comorbidities in women attending CHCs in Cape Town should be developed for use in the clinics by the physiotherapists and other health professionals. This protocol should provide specific guidelines for the assessment of OA and associated comorbidities using appropriate and reliable standardised outcome measures to be used for baseline and follow-up measurements for effectiveness of treatment. In addition, this protocol should emphasise the importance of self-management, stress management, nutrition and diet, and pharmacological interventions in managing OA and comorbidities.
- Physiotherapists employed at the primary health care clinics in Cape Town should be trained in using the developed protocol for OA and should consider assessing and managing women with OA and comorbidities, specifically diabetes mellitus type 2, with the group-based intervention of exercise, education, and self-management strategies. The physiotherapist should be trained to screen if eligible patients may safely engage in exercise with OA and comorbidities and provide each patient with a printed SmArt-Health workbook as part of management. The trained physiotherapist should monitor the patients' attendance for six weeks and evaluate their outcomes at the beginning and end of the six-week intervention to be able to report on the patient's progress.
- Doctors and Nurses involved in chronic care clubs at these CHCs should be made aware of the developed protocol for OA and comorbidities through workshops and should be trained in screening for OA using the standardised outcome measures in patients with chronic diseases such as hypertension and diabetes. Appropriate referral to physiotherapists for the assessment and management of OA and comorbidities using the developed protocol and group-based intervention should be done. Hence, better relationships between the doctors, chronic care clubs and physiotherapists in these clinics could develop to manage patients holistically.

7.8.2 Research

The studies presented in this thesis had limitations and, therefore, highlight a need for further investigation. The following research recommendations should be considered:

- The validity of the IPAQ long form, discussed in Chapter 3, should be further investigated through the comparison of an objective measure of physical activity such as accelerometers or pedometers. Further investigation is needed to determine the reliability of both the COPCORD and IPAQ long forms in similar contexts using larger samples of people and using accelerometers or pedometers as a more accurate comparator.
- The epidemiological study should be conducted in women and in men in clinics in rural areas in South Africa to determine the prevalence of OA and comorbidities.
- The mid-term and long-term effectiveness (one to five years) of the SmArt-Health intervention on health outcomes in women with OA and comorbidities are needed.
- The IPAQ should be replaced with an accelerometer to explore the effectiveness of the SmArt-Health intervention in physical activity levels in women with OA and comorbidities at CHCs in Cape Town.
- To help target hypertension in women with OA, further research with specific guidelines for monitoring of blood pressure before and after each intervention session is necessary in these clinics.
- To help reduce BMI in women with OA and comorbidities, further research using the SmArt-Health intervention with a longer duration (12 weeks or more) and a longer follow-up testing period of approximately 12 months are needed.
- It is important to determine the cost utility of the SmArt-Health combined intervention for OA compared to other treatments in terms of Quality Adjusted Life Year (QALY).

7.8.3 Social integration and community participation

In the Western Cape (WC) in South Africa, a healthy lifestyle initiative called Western Cape on Wellness (WOW) was developed by the WC government to help address the burden of non-communicable diseases and the harmful outcomes of these diseases on people living in the province. This initiative targets people with health problems such as hypertension, diabetes mellitus, obesity, unhealthy eating, and physical inactivity. Currently, there are several WOW groups that are active and engaging with a diverse group of people in the Mitchells Plain area of Cape Town.

To further help maintain the positive health outcomes in women with OA and comorbidities gained from participating in the SmArt-Health intervention at the CHC, these women should be discharged from the CHC and should be referred to a nearby WOW group in Mitchells Plain. Social integration through participating in WOW may motivate these women to implement the adopted healthy lifestyle learned through SmArt-Health daily and could result in further improvements in their health outcomes.

This thesis has shown that OA is a significant burden for women living in Mitchell's Plain. In addition, this work has demonstrated that these women are faced with the challenge of multiple morbidity and the negative impact this has on their functional activities, participation, and quality of life. This work has demonstrated the feasibility, acceptability, and effectiveness of the SmArt-Health intervention in these women and provides a foundation for implementing evidence-based management for women with OA at primary healthcare level in the Cape Town Metropole Region in South Africa.

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9 APPENDICES

Appendix A: Approval from the University of Cape Town and Western Cape Department of Health

Appendix A-1: Ethical clearance from the University of Cape Town, Human Research Ethics Committee

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 6492 • **Facsimile** [021] 406 6811
Email: Sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

10 February 2014

HREC/REF: 093/2014

Prof J Jelsma
Physiotherapy
Health & Rehabilitation Sciences
F-45
OMB

Dear Prof Jelsma

Project Title: **THE FUNCTIONAL IMPACT OF A NON-PHARMACOLOGICAL AND CONTEXTUALLY RELEVANT INTERVENTION FOR MUSCULOSKELETAL CONDITIONS IN WOMEN WITH ASSOCIATED CO-MORBIDITIES AT COMMUNITY HEALTH CENTRES IN CAPE TOWN**

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

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 28 February 2015.

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.

We acknowledge that the following student:- Candice Hendricks is also involved in this study.

Please note that the on-going ethical conduct of the study remains the responsibility of the principal investigator

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Hrec/ref:093/2014

Appendix A-2: Approval letter from the Western Cape Department of Health

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
Tel: +27 21 483 6857: fax: +27 21 483 9895
5th Floor, Norton Rose House, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: RP 030/2014
ENQUIRIES: Ms Charlene Roderick

F45 Old Main building
Groote Schuur Hospital
Department of Health and Rehabilitation Sciences
Division of Physiotherapy

For attention: **Candice Hendricks; Prof Jennifer Jelsma; Dr Romy Parker**

Re: The functional impact of a non-pharmacological and contextually relevant intervention for musculoskeletal conditions in women with associated co-morbidities at community health centres in Cape Town.

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following people to assist you with any further enquiries in accessing the following sites:

Mitchells Plain	**Ms Z Xapile**	**Contact No. 021 391 5820**
Elsies River	**Mrs R Kasker**	**Contact No. 021 931 6023**
Retreat CHC	**Mr H Lemmetjies**	**Contact No. 021 713 9741**
Dr Abdurahman	**Ms B Julius**	**Contact No. 021 638 3319**
Bishop Lavis CHC	**Sr W Allies**	**Contact No. 021 934 6050**
Delft CHC	**Mr J Van Heerden**	**Contact No. 021 954 2237**
Heideveld CHC	**Sr A Eksteen**	**Contact No. 021 637 8054/6686**
Gugulethu CHC	**Dr K Murie**	**Contact No. 021 637 1280**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.

2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. The reference number above should be quoted in all future correspondence.

We look forward to hearing from you.

Yours sincerely

DR J EVANS pp
ACTING DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 22/04/2014

CC	**MRS P OLCKERS**	**DIRECTOR: KLIPFONTEIN/MITCHELL'S PLAIN DISTRICT**
	DR L BITALO	**DIRECTOR: NORTHEN/TYGERBERG DISTRICT**
	DR K GRAMMER	**DIRECTOR: SOUTHERN/WESTERN DISTRICT**

Appendix A-3: Ethical clearance for feasibility study

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: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

11 April 2014

HREC REF: 100/2014

Ms C Hendricks
Physiotherapy
Health & Rehab
OMB

Dear Ms Hendricks

PROJECT TITLE: A PILOT STUDY TO ASSESS THE FEASIBILITY OF INVESTIGATING THE PREVALENCE AND FUNCTIONAL IMPACT OF MUSCULOSKELETAL DISORDERS AND CHRONIC DISEASES OF LIFESTYLE IN PEOPLE USING STANDARDIZED OUTCOME MEASURES

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

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 April 2015

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/research/humanethics/forms)

We acknowledge that the following students are also involved in this study:
Raeesa Ghanty, Mish-aal Hendricks, Siphesihle Mhlana & Mojapele Dhlamini

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

Please quote the HREC reference no in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human 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.

HREC 100/2014

Appendix B: Study information and informed consent forms

Appendix B-1: Information Sheet – Epidemiological Study

INFORMATION LEAFLET
EPIDEMIOLOGICAL STUDY

University of Cape Town
Division of Physiotherapy
Department of Health and Rehabilitation Sciences

Dear Participant:

I, Candice Hendricks, am currently doing my postgraduate studies in Physiotherapy (PhD) at the Department of Health and Rehabilitation Sciences at the University of Cape Town. I am very interested in finding out how joint pain (such as arthritis) and other chronic health problems (high blood pressure, sugar) make a difference to what you can do at home, work and in the community.

The topic of my study is:

"Osteoarthritis in Women living in Cape Town: characteristics and the effects of a non-pharmacological intervention"

Purpose of the survey
I am interested in knowing how many women attending the physiotherapy exercise clubs and the chronic care clubs at the day hospital have pain in their joints and have other illnesses, for example sugar; high blood and are overweight.

I am also interested in finding out how these illnesses and joint pain affect your lifestyle and how the pain in your joint and chronic illnesses prevent you from doing things in your life (e.g. climbing stairs, walking to the shop).
You have been asked to take part in the survey and some clinical tests because you are attending the exercise classes for joint pain at physiotherapy or the chronic care club and because you are between the ages of 45 – 64 years.

Description of research
You will be answering a few questions on surveys regarding your age, weight, chronic diseases, when you experience pain in your joints (if any), about activities that you struggling with at home or work because of your joint pain and your general health and about how you measure the quality of your life. It will take approximately 45 minutes to answer all the questions. I would also like to measure your sugar levels (pricking your finger and getting a reading from a portable machine), blood pressure, weight (standing on a scale) and height (standing against a wall and checking how tall you are).

You will not lose your place in the queue (line) as we will keep someone in this place for you and answering the questions will not affect your visit at the day hospital. The rest of your treatment at the day hospital will stay the same.

You are taking part in this research study as a volunteer / at your own free will and you may decide to stop taking part in the study at any time without being punished in any way. There is no danger involved in taking part in the surveys as you will only be answering questions that will be completed on paper. However, you might feel some discomfort or pain with the finger pricking test when I measure your sugar. You will not feel any pain or discomfort when I measure your blood pressure and weight.

The benefits of taking part in this study will be to know how your joint pain and chronic health problems (high blood, sugar) affect the way you walk, climb stairs, clean your house and perform at work. This study will give you the knowledge about how you measure your life (quality of life) living with joint pain and chronic medical problems. The information that we will get from this study will also help you understand if you are doing enough physical activities each day to help treat your joint pain and chronic medical problems. The other benefit will be that if you take part in this study, you could then take part in the next study which will be an exercise and education Programme if you meet all the requirements.

You will see that there is a number in the top corner of the survey and your name and telephone number will be put on a separate paper with the special number that only I will have. It will be secret to everybody else.
Nobody will be able to know which form is the information you have given - this will protect who you are (your identity). You will receive no money to take part in the survey and the clinical tests. The University of Cape Town offers a no-fault insurance that will cover you if anything happens to you during the study. You also have the right to claim payment for any injury experienced due to the negligence of the researchers.

The results of the survey might be put in a magazine for physiotherapists, doctors, nurses and other people working with health, so that they can know how many people like yourself, have problems with joint pain and other chronic illnesses in the community.

The person in charge of the day hospital and the sister in charge told me that I may do the study at the day hospital and that I may give you the form to fill in, if you want to help me. You do not have to take part and if you don't want to join the study, it will not make any difference to the treatment that you receive from the day hospital. But if you decide to take part in the study, the information will help us researchers and clinicians to better understand your medical conditions and be able to treat you better.

If you want to ask me anything before we start with the questions, or later on, please phone me, Candice Hendricks, at 0214066382 or 0847516692 or my supervisors, who are also involved in the study.

Thank you

Supervisor:

Romy Parker: 0214066431

If you have any problems or want to know more about the study or want to report anything that you feel unhappy about, please contact:

Professor Marc Blockman, the chairperson of the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town (contact number: 021 – 406 6411).

Appendix B-2: Consent to participate – Epidemiological study

CONSENT TO PARTICIPATE IN EPIDEMIOLOGICAL STUDY

University of Cape Town
Division of Physiotherapy
Department of Health and Rehabilitation Sciences

Topic of study:

"Osteoarthritis in Women living in Cape Town: characteristics and the effects of a non-pharmacological intervention"

I _____ have been approached to take part in a research study.

I have been informed regarding the study by the researcher, Candice Hendricks, from the Division of Physiotherapy of the University of the Cape Town.

I may contact Ms Hendricks at any time at 0847516692 or Prof Jelsma at 021-4066595 if I have any queries/questions regarding the study.

I may contact Prof Blockman at the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town (contact number: 021 – 406 6411 if I have any queries regarding my rights as research participant.

Taking part in the study is purely voluntary and I will not be punished or lose benefits at the Day hospital if I refuse to take part or decide to stop taking part.

If I agree to take part, I will be given a signed copy of consent to take part in the study, as well as the participant information sheet, which is a written summary of the research.

I hereby grant permission to take part in the study and for my blood pressure and blood glucose levels to be made known to the researcher. If no levels are known, I hereby consent to having measurements taken and agree to have a finger prick test done to determine blood glucose levels.

The research study, including the above information has been verbally described to me.
I understand what my involvement in the study means and I voluntarily agree to participate.

_____ _____
Signature of Participant Date

_____ _____
Signature of Translator Date

Appendix B-3: Informed Consent for contact details

University of Cape Town
Division of Physiotherapy
Department of Health and Rehabilitation Sciences

Topic of study:

""Osteoarthritis in Women living in Cape Town: characteristics and the effects of a non-pharmacological intervention"

Dear Participant:

At the end of the first study (survey), another study will take place on a later stage that will ask women, who told me that they have joint pain and other illnesses in the first survey, to join the 6 week exercise and education Programme at the day hospital to help treat the joint pain and other chronic illnesses.

Can I please ask your permission to use your cellphone/ home telephone numbers to contact you on a later stage to ask you to join this exercise Programme. If you give permission now, it does not mean that you will join the exercise Programme in the second study but it means that I can call you later about the details of second study.

I _____ have been approached to grant permission for the researcher to contact me about the second study that will take place on a later stage.

I have been informed regarding the study by the researcher, Candice Hendricks, from the Department of Physiotherapy of the University of the Cape Town.

I may contact Ms Hendricks at any time at 0847516692 or Prof Jelsma at 0214066595 if I have any queries/questions regarding the study being conducted.

I may contact the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town (contact number: 021 – 406 6411) if I have any queries/questions regarding your rights as research participant.

_____ _____
Signature of Participant Date

Appendix B-4: Information Sheet – Intervention Study

INFORMATION LEAFLET

INTERVENTION STUDY

University of Cape Town
Division of Physiotherapy
Department of Health and Rehabilitation Sciences

Dear Participant:

I, Candice Hendricks, am currently doing my postgraduate studies in Physiotherapy (PhD) at the Department of Health and Rehabilitation Sciences at the University of Cape Town. I am very interested in finding out how joint pain (such as arthritis) and other chronic medical problems (high blood pressure, sugar) make a difference to what you can do at home, work and in the community. Research is simply the process to learn the answer to a question. I would like to find out if an exercise and educational Programme will help your joint pain and improve the way you walk and move when you clean your house and do your work. Please note that you may not get better from taking part in the study. However, if the exercise Programme does help, then it will be offered to everyone who takes part in the study.

The topic of my study is:

"Osteoarthritis in Women living in Cape Town: characteristics and the effects of a non-pharmacological intervention"

Purpose of the study

You have been asked to take part in this study because you have joint pain, sugar, high blood or are overweight and is between the ages of 35 – 64 years; have participated in chronic care clubs or exercise groups at physiotherapy departments at the day hospital for more than one month; and because you are able to read and write in English, Afrikaans or isiXhosa.

I am interested in knowing how to bring about changes in your joint pain and chronic illnesses (high blood, sugar or overweight). The study will provide you with a health promotion Programme that will consist of exercises and educational talks that will be related to your joint pain and chronic illnesses. The goal of this Programme will be to educate you in how to manage your joint pain and chronic illnesses, to provide you with basic exercises and offer advice on healthy lifestyle changes.

If you decide to take part in the study then you could stand a chance in being in one of two groups. Firstly, a health promotion group, where participants will complete surveys, physical tests and take part in exercises and another group that will do the surveys and physical tests only. You will be given an envelope which will tell you in which group you are in. Both groups will get a calendar with dates for the survey and physical tests to be done. The surveys and physical tests will take place at your local day hospital on the dates and times highlighted on the calendar.

The surveys that you will need to complete for this study will be:

- Survey about your personal details (age, social, occupational, medical, pharmacological and physiotherapy history)
- Survey about your chronic pain
- Survey about how your chronic illnesses affect your physical ability in your home, work and community.
- Survey about how you measure your quality of life having chronic illnesses
- Survey to measure how physically active you are at home, work and community
- Survey to measure how you confident you are in managing your chronic illnesses

The Physical tests that you will need to complete will be:

- Tests to measure weight (using a scale) and height (standing against a wall, and measuring how tall you are)
- Tests to measure blood pressure (using a portable machine) and sugar levels (pricking your finger and getting a reading on a portable machine)
- Three tests will be done to measure your function. You will be required to walk up and down for 8 meters, climb up and down 7 steps, and standing up from sitting on a chair. All of the tests will be timed with a stopwatch by the researcher.

The surveys and physical tests will be completed at the beginning of the study, at the end of the six weeks and at the end of 12 weeks. You will be required to attend all three sessions to complete the surveys and physical tests.

We will do this to see if there is a change in your joint pain and chronic illnesses and if the exercises helped you to do things easier and better. The surveys and physical tests could take about 45 to 60 minutes to complete.

The group that will be doing the health promotion Programme will receive a little machine that will track and record your physical movement during the day. You will have to wear this small machine every day for one week before you start the exercise Programme, and for one week at the end of the 6-week Programme and again for one week after the Programme at week 12. Please note that the machine is the property of the researcher and must be given back at the end of study. You must please take care of the machine and make sure that it does not get lost or damaged.

The health promotion group will meet once a week at the day hospital for two hours. The health promotion Programme will be a six-week programme led by a physiotherapist. The Programme will include exercises for joint pain and educational talks on how to allow you to manage your chronic illnesses by yourself. You will receive a wellness booklet which will include topics about joint pain, chronic illnesses, self-management education, importance of physical activity for injury prevention, weight management, healthy nutrition and goal setting tasks. You will receive an exercise diary where you will record the exercises that you have done each week to help track your progress throughout the health promotion Programme.

The other group will be required to attend three sessions (a session before the health promotion Programme starts, a session at 6 weeks and another session at 12 weeks) as highlighted on the calendar, to do the surveys and the physical tests only. If you are in this group, you will continue with normal treatment and exercises at physiotherapy or chronic care clubs at the local day hospital. Once all the tests and information from the health promotion Programme have been analyzed and the results confirms that this health promotion Programme can help reduce joint pain; improve the ability to move better in the home or at work; and help with managing chronic illnesses as well, then this health promotion Programme will be offered to you as well to enjoy the benefits of living a healthy lifestyle.

We will not know which group you will be put into and if you agree to take part in this study, you should be happy to be in either group. If you are chosen to be in the health promotion group, a researcher will ask you certain questions to see if you are healthy enough to join the exercise Programme. During the exercise session a paramedic will also be in the room to help me if someone does not feel well or gets ill. You will be able to go home for the day and come back the next week when you feel better.

There is little chance for you to hurt yourself doing the exercises, but a little bit of pain or tightness in your muscles after the exercises is normal and should go away after a day or two. The more you exercise, the less pain and muscle tightness you will feel. I will do everything I can to make sure that you do not hurt yourself but, in the case, this does happen; the physiotherapist or physiotherapy student will refer you to the Day hospital's physiotherapy department for treatment free of charge.

'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 your 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

"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 that 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.

The benefits of taking part in this study will be that you will have an opportunity to be part of an intervention (health promotion group compared to other group) to see if exercise and education can help treat your joint pain and other chronic illnesses.

This intervention can maybe help you move or walk better in and around your house or work. It could also give you education on how to help manage your chronic illness by yourself and about the importance of doing some physical activity every day to manage your weight.

Please note that you are taking part in this study as a volunteer / at your own free will and you may decide to stop at any time of the study without being punished in any way. When completing the surveys, you will see that there is a number in the top corner of the paper that will document your readings (blood sugar, weight and blood pressure). Your name and telephone number will be put on a separate paper with the same number that only I will have.

Nobody will be able to identify who you are and will not know your readings (blood sugar, weight, and blood pressure readings) and personal information. You will receive no money to participate in this study, but I will give you money for taxi/bus fees if you are attending the three sessions to complete the surveys and physical tests or if you are attending the health promotion programme once a week for the six weeks.

The results of the study might be put in a magazine for doctors, nurses and other people working with health. The results will tell them what the effect of a health promotion programme, including exercise and education, is on people like you who suffer from joint pain and other chronic illnesses. The information gathered from this study will be used in the future to compare the effect of the health promotion programme to other health programmes conducted in other studies.

The person in charge of the Day hospital and the sister told me that I may do the study and that I may ask you to participate in this study and may give you the consent form to fill in, if you want to help me. You do not have to take part in this study if you don't want to join the study; it will not make any difference to the treatment that you receive from the day hospital. However, you will not be able to take part in the health promotion programme that is part of this study.

If you want to ask me anything before we start with the questions, or later on, you can phone me at 0214066382 or 0847516692 or contact my supervisors.

Thank you

Candice Hendricks

Supervisor:

Romy Parker: 0214066431

If you have any problems or want to know about the study or want to report anything that you feel unhappy with, please contact: Professor Marc Blockman, (contact number: 021 – 406 6411)

Appendix B-5: Consent to participate – Intervention Study

CONSENT TO PARTICIPATE IN INTERVENTION PROGRAMME

University of Cape Town
Division of Physiotherapy
Department of Health and Rehabilitation Sciences

Topic of study:

"Osteoarthritis in Women living in Cape Town: characteristics and the effects of a non-pharmacological intervention"

I _____ have been approached to take part in a research study.

I have been informed regarding the study by the researcher, Candice Hendricks, from the Department of Physiotherapy of the University of the Cape Town.

I may contact Ms Hendricks at any time at 0847516692 or Prof Jelsma at 0214066595 if I have any queries/questions regarding the study being conducted.

I may contact the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town (contact number: 021 – 406 6411) if I have any queries/questions regarding my rights as research participant.

Taking part in the study is purely voluntary and I will not be punished or lose benefits at the Day hospital if I refuse to take part or decide to stop taking part. If I agree to take part, I will be given a signed copy of the consent form to take part in the study, as well as the participant information sheet, which is a written summary of the research.

If I am chosen to be in the health promotion programme group, I hereby grant permission for my blood pressure, weight and height to be taken. I also grant permission that my blood glucose levels are measured by a finger prick test. I hereby consent to having physical tests done and answer some questions to ensure that I am healthy enough to take part in the exercises. I understand that the information gathered from this study will be possibly used in future studies to compare the effect of the health promotion programme to other health programmes and hereby consent to do this.

I understand that there is little risk for injury during the exercises, but discomfort or muscle soreness after the exercises is normal and should disappear after a day or two. The more I exercise the less the discomfort and muscle soreness will be. I also understand that great care will be taken to prevent injury but in the unfortunate case that this does happen, the physiotherapist will refer me to the physiotherapy department at the Day hospital for appropriate treatment free of charge.

'What happens if I get hurt taking part in this study?'

If I do sustain an injury because of participating in the physical tests and the health promotion programme, I understand that the researcher has insurance at UCT. I understand that I can claim for all my 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 my participation** in the intervention.

I understand that according to ABPI guidelines that the **researcher should compensate me, without having to prove that she / he was at fault** for any injury resulting from participating in the intervention or other procedures carried out according to the protocol of the study.

I understand that the researcher **will not be responsible** for any loss, injuries and/or harm that I may sustain where the loss is caused by:

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

By agreeing to participate in this study, I do not give up my right to claim compensation for injury where I can prove negligence. If I claim from UCT's insurance and I am successful in the claim, I will state that I accept this payment as full settlement of my claim. But making this statement does not mean that I give up my right to pursue a separate claim, based in negligence, against the researcher. It is my right to pursue such a claim in a South African court in terms of South African law.

If I am chosen to be in the other group (control group) I hereby grant permission for my blood pressure, weight and height to be taken. I also grant permission that my blood glucose levels are measured by a finger prick test. I hereby consent to having physical tests done to determine how much I move during my normal daily activities.

The research study, including the above information has been verbally described to me.
I understand what my involvement in the study means and I voluntarily agree to participate.

_____ _____
Signature of Participant Date

_____ _____
Signature of Translator Date

Appendix C: Permission letters to Stakeholders

Appendix C-1: Letter to Western Cape Department of Health

Western Cape Department of Health

Western Cape Health Research Committee

To whom it may concern:

RE: Requesting permission to conduct a research study

I, Candice Hendricks, am currently doing my PhD in Physiotherapy at the Department of Health and Rehabilitation Sciences at the University of Cape Town. I would like to inform you about the research study that I wish to conduct in disadvantaged women with musculoskeletal disease (MSD) and chronic diseases of lifestyle (CDL) attending Community Health Centres (CHC's) in Cape Town.

Background:
Musculoskeletal conditions (MSD) are a major health and social problem for disadvantaged middle to old-aged women. Majority of poor families in South Africa are led by middle aged and elderly women. As these women are the prime providers of care for children, they rely heavily on their physical ability and high levels of physical activity to sustain their families in an environment of low education and low income due to marginalization of apartheid system previously. Not only do these women suffer from musculoskeletal pain, joint stiffness but also experience difficulties with every day functional activities within their homes, workplaces and communities. Literature highlighted that women with MSD have been diagnosed with chronic diseases of lifestyle (CDL) such as diabetes (type II), hypertension and heart disease (Parker and Jelsma, 2010). Even though the interactions between MSD and CDL in women are not well understood in a South African context, it is currently a huge health problem for health professionals and the government, highlighting the need for further investigation.

The potential co-existence of MSD and CDL in women creates an added burden on the under-resourced primary health care facilities in the country, as it is the first point of contact for public medical care. The medical care that these women receive for the CDL at CHC's, tends to be education based and does not always include exercise. The current physiotherapy practice for MSD at these clinics involves manual therapy (massage, spinal manipulation, joint mobilizations, electrotherapy and acupuncture), rehabilitation (stretching, aerobic exercise, strength and endurance training) and education in the form or home advice. Rehabilitation or exercise groups for patients with chronic MSD (LBP, and OA) are found in some CHC's, however, there seems to be a lack of evidence in the effectiveness of these exercise groups in restoring function in patients with MSD. All the highlighted factors add significantly to the economic burden of the government, thus effective management strategies are needed to help reduce both the functional impact and socio-economic impact that MSD and CDL pose on women and the government.

A non-pharmacological management approach, comprising of exercise and education using a cognitive behavioral approach, may be a suitable method to ameliorate the impact of MSD and CDL on function and quality of life. However, there seems to be a paucity of sustainable, evidence- based, contextually relevant interventions for middle-aged women with MSD and CDL at primary health care facilities in South Africa.

Thus, the title of my study is:

""Osteoarthritis in Women living in Cape Town: characteristics and the effects of a non-pharmacological intervention"

The intention of this study is to implement a new model of rehabilitation care, advocating a patient-centred self-management approach, for women with chronic MSD and CDL at CHC's in Cape Town. This will be done by adapting, implementing and evaluating a non-pharmacological and contextually appropriate intervention for women receiving medical and rehabilitation services in urban CHC's in the Cape Town Metropole region.

The **research questions** are therefore:

- What are the characteristics, functional impact and contributing factors to MSD and CDL in women attending CHCs in Cape Town?
- What would the components of a contextually relevant intervention programme be for women with MSD and CDL?
- How effective would this intervention programme be in addressing the impairments, activity limitations and participation restrictions for these participants?

The aim for this project is firstly to establish the profile of women attending rehabilitation clubs for MSD at physiotherapy and chronic care clubs at CHC's to adapt, implement and test a non-pharmacological and contextually relevant intervention within the community health care setting.

The specific **objectives** of the study are:

- To establish the nature and functional impact of MSD, and how it affects the level of physical activity and overall health-related quality of life in South African women attending CDL clubs and MSD rehabilitation clubs at CHC's.
- To adapt an evidence- based, non-pharmacological intervention programme based on exercise, education and cognitive behaviour therapy to address all the problems highlighted by the participants in the preceding objective.
- To implement the intervention programme and to test whether it has an impact on functional ability, pain, physical activity, health-related quality of life and lifestyle behaviours.

There are two phases to the study, Phase I will consist of a descriptive cross-sectional survey to establish the profile and the contextual background of affected women and Phase II will be an experimental study to test the intervention programme. The prospective participants will have MSD and CDL receiving care at CHC's in Cape Town.

Phase I- Profile:

A sample of convenience will be used for Phase I to recruit women attending the chronic care clubs and the exercise groups at the selected CHC's. They will be required to give informed consent and understand English, Afrikaans or isiXhosa to participate in the study. Women who are unable to respond to the questionnaire due to communication or cognitive difficulties, who are too ill to participate, who present with neurological conditions (such as strokes), recent trauma, or severe intellectual impairment will be excluded. A sample size of 512 women in total from a CHC is required to achieve a 95% confidence interval in statistics (Open Epi™ Version 3, 2013).

Assessments:

Standardised outcome measures that will be used for baseline testing for Phase I are: the Brief Pain Inventory (Short Form); the EQ-5D, WHODASII, International Physical Activity Questionnaire (IPAQ), COPCORD screening tool. Clinical measures such as blood pressure, blood glucose levels, weight, height and calculated BMI will be taken by a nurse.

Phase II- Intervention:

During the first phase, a survey will be administered to establish what impact the MSD or CDL has on the participants' ability to lead full, productive lives. Based on these responses, and taking into account published evidence for both the structure and the content of exercise intervention in MSD, an intervention will be designed. Participants who indicated their willingness to participate in the intervention will be called and recruited for baseline testing, and thereafter will be randomly assigned to a control group (40 women) and experimental group (40 women). The control group will only complete the questionnaires and the physical tests and will continue with usual care at physiotherapy and chronic care clubs. The intervention group will participate in a six-week clinic-based intervention on exercise, education and self- management strategies. The participants will be encouraged to continue their new healthy lifestyle approach by joining wellness activities in the community or by starting group exercise clubs.

It is anticipated that participation will lead to improved function in daily activities, decrease in joint pain, improved quality of life and physical activity, better compliance with medication, decrease in body mass and improved ability to take part in the life of the community.

Assessments:

Standardised outcomes for the intervention (Phase I) will include: the Brief Pain Inventory (Short Form); the EQ-5D, WHODASII, IPAQ, Aggregated Locomotor Functioning Score, the Chronic disease Self-efficacy Scale, blood pressure, blood glucose measures, BMI, percentage attendance and use of pedometer.

Baseline measures will be done before, at the end of six-week clinic-based intervention programme and at the end of 12 weeks. There will be an evaluation of the outcomes of the intervention programme and of the two groups to determine effectiveness.

Ethical Considerations

The study will conform to the principles of the Declaration of Helsinki (2008). Ethical approval has been obtained from the Faculty of Health Sciences, University of Cape Town.

All information obtained from the primary health care facilities and participants will be kept confidential and their identity will be anonymous and will only be used for statistical analysis and writing of results. All stakeholders will be acknowledged with all publications and conference proceedings. The findings of the study will be disseminated to you and respective departments.

I would like to request permission to access the Community Health Centres in the Cape Town Metropole region from January 2014 up until December 2016. This is only an estimated timeframe for data collection but should the two phases of my study be completed before hand, a notification will for forwarded to your department. Annual reports on the progress of my study will be forwarded to all stakeholders involved. I also would like to request permission to obtain medical information from the folders of the participants involved in the study to confirm the self -reported information about the medical history and treatment received at the CHC. Lastly, I would like to request permission to make use of the resources (two nursing staff or health promoters involved with chronic care club, examination rooms to do baseline testing and space for the exercise intervention) available at the CHC to conduct both phases of the study. Please be advised that the intention of my study is not to affect service delivery negatively but to assist in developing a comprehensive rehabilitation model of care for women with MSD and CDL. As principle investigator, I will ensure the smooth running of services provided at the facility by managing all researchers and data collection processes. I have attached a copy of my research proposal if you require any additional information regarding my study.

I look forward to hearing from you and your assistance is greatly appreciated.

Sincerely

Ms Candice Hendricks (PhD student)
Candice.hendricks@uct.ac.za
Tel: 084-751-6692/ 0214066382

Supervisors:
Romy Parker: Romy.parker@uct.ac.za

Prof. M Blockman (Human Research Ethics Committee, Faculty of Health Sciences,)
Marc.blockman@uct.ac.za
Tel: 021-406-6626

Appendix C-2: Letter to facility managers at Mitchells Plain CHC

Facility Manager

To whom it may concern:

RE: Requesting permission to conduct a research study

I, Candice Hendricks, am currently doing my postgraduate studies in Physiotherapy (PhD) at the Department of Health and Rehabilitation Sciences at the University of Cape Town. I would like to inform you about the research study that I wish to conduct in disadvantaged women with musculoskeletal disease (MSD) and chronic diseases of lifestyle (CDL) attending Community Health Centres (CHC's) in Cape Town. More specifically, I would like to determine the profile of women attending rehabilitation clubs for MSD at physiotherapy and chronic care clubs at CHC's to develop a suitable intervention programme to help reduce the functional and socioeconomic impact of these chronic diseases on women and on state resources.

A non-pharmacological management approach, comprising of exercise and education using a cognitive behavioral approach, may be a suitable method to ameliorate the impact of MSD and CDL on function and quality of life. However, there seems to be a dearth of sustainable, evidence- based, contextually relevant interventions for middle-aged women with MSD and CDL at primary health care facilities in South Africa. Thus, the topic of my study is:

"Osteoarthritis in Women living in Cape Town: characteristics and the effects of a non-pharmacological intervention"

The intention of this study is to implement a new model of rehabilitation care, advocating a patient-centred self-management approach, for women with chronic MSD and CDL at CHC's in Cape Town. This will be done by adapting, implementing and evaluating a non-pharmacological and contextually appropriate intervention for women receiving medical and rehabilitation services in urban CHC's in the Cape Town Metropole region.

The research questions are therefore:

- What are the characteristics, functional impact and contributing factors to MSD and CDL in women attending CHCs in Cape Town?
- What would the components of a contextually relevant intervention programme be for women with MSD and CDL?
- How effective would this intervention programme be in addressing the impairments, activity limitations and participation restrictions for these participants?

The plan for this project is firstly to establish the profile of MSD and CDL in women attending CHC's in Cape Town in order to adapt, implement and test a non-pharmacological and contextually relevant intervention within the community setting.

The specific **objectives** of the study are:

- To establish the nature and functional impact of MSD, and how it affects the level of physical activity and overall health-related quality of life in South African women attending CDL clubs and MSD rehabilitation clubs at CHC's.
- To adapt an evidence- based, non-pharmacological intervention programme based on exercise, education and cognitive behaviour therapy to address all the problems highlighted by the participants in the preceding objective.
- To implement the intervention programme and to test whether it has an impact on functional ability, pain, physical activity, health-related quality of life and lifestyle behaviours.

There are two phases to the study, Phase I will consist of a descriptive cross-sectional survey to establish the profile and the contextual background of affected women and Phase II will be an experimental study to test the intervention programme. The prospective participants will have MSD and CDL receiving care at CHC's in Cape Town.

Phase I- Profile:

A sample of convenience will be used for Phase I to recruit women attending the chronic care clubs and the exercise groups at the selected CHC's. They will be required to give informed consent and understand English, Afrikaans or isiXhosa to participate in the study. Women who are unable to respond to the questionnaire due to communication or cognitive difficulties, who are too ill to participate, who present with neurological conditions (such as strokes), recent trauma, or severe intellectual impairment will be excluded. A sample size of 300 women in total from one CHC is required to achieve a 95% confidence interval in statistics (Open Epi™ Version 3, 2013).

Assessments:

Standardised outcome measures that will be used for baseline testing for Phase I are: the Brief Pain Inventory (Short Form); the EQ-5D, WHODASII, International Physical Activity Questionnaire (IPAQ), COPCORD screening tool. Clinical measures such as blood pressure, blood glucose levels, weight, height and calculated BMI will be taken by a nurse.

Phase II- Intervention:

During the first phase, a survey will be administered to establish what impact the MSD or CDL has on the participants' ability to lead full, productive lives. Based on these responses, and taking into account published evidence for both the structure and the content of exercise intervention in MSD, an intervention will be designed. Participants who indicated their willingness to participate in the intervention will be called and recruited for baseline testing, and thereafter will be randomly assigned to a control group (40 women) and experimental group (40 women). The control group will only complete the questionnaires and the physical tests and will continue with usual care at physiotherapy and chronic care clubs.

The intervention group will participate in a six-week clinic-based intervention on exercise, education and self- management strategies. The participants will be encouraged to continue their new healthy lifestyle approach by joining wellness activities in the community or by starting group exercise club.

It is anticipated that participation will lead to improved function in daily activities, decrease in joint pain, improved quality of life and physical activity, better compliance with medication, decrease in body mass and improved ability to take part in the life of the community.

Assessments:
Standardised outcomes for the intervention (Phase I) will include: the Brief Pain Inventory (Short Form); the EQ-5D, WHODASII, IPAQ, Aggregated Locomotor Functioning Score, the Chronic disease Self-efficacy Scale, blood pressure, blood glucose measures, BMI, percentage attendance and use of pedometer.

Baseline measures will be done before, at the end of six-week clinic-based intervention programme and at the end of 12 weeks. There will be an evaluation of the outcomes of the intervention programme and of the two groups to determine effectiveness.

Ethical Considerations
The study will conform to the principles of the Declaration of Helsinki (2008). Ethical approval has been obtained from the Faculty of Health Sciences, University of Cape Town. Approval has been obtained from Western Cape Department of Health to conduct the study at the selected Community Health Centres in Cape Town. All information obtained from the participants will be kept confidential and their identity will be anonymous and will only be used for statistical analysis and writing of results. All stakeholders will be acknowledged with all publications and conference proceedings. The findings of the study will be disseminated to you and respective departments.

I have attached a copy of my research proposal if you require any additional information regarding my study. I would like to request permission to access your facility to conduct my research study from January 2013 onwards. I cannot give an exact date by when the study will be completed but I would alert you on the progress of each phase of the study. I also would like to request permission to obtain medical information from the folders of the participants involved in the study. Lastly, I would like to request permission to make use of your resources (staff, examination rooms) to conduct the baseline measurements during the study period. Please be advised that I will not disrupt any services given to patients at your facility and will try my best to ensure the smooth running of services given at the facility. I look forward to hearing from you and your assistance is greatly appreciated.

Sincerely,

Ms Candice Hendricks (PhD student)
Candice.hendricks@uct.ac.za
Tel: 084-751-6692/ 0214066382
Supervisor:
Dr R Parker: Romy.parker@uct.ac.za

Prof. M Blockman (Human Research Ethics Committee, Faculty of Health Sciences,)
Marc.blockman@uct.ac.za
Tel: 021-406-6626

Appendix C-3: Letter to Physiotherapists in charge at Mitchells Plain CHC

Chief Physiotherapist

To whom it may concern:

RE: Requesting permission to conduct a research study

I, Candice Hendricks, am currently doing my PhD in Physiotherapy at the Department of Health and Rehabilitation Sciences at the University of Cape Town. I would like to inform you about the research study that I wish to conduct in disadvantaged women with musculoskeletal disease (MSD) and chronic diseases of lifestyle (CDL) attending Community Health Centres (CHC's) in Cape Town. More specifically, I would like to determine the profile of women attending rehabilitation clubs for MSD at physiotherapy and chronic care clubs at CHC's to develop a suitable intervention programme to help reduce the functional and socioeconomic impact of these chronic diseases on women and on state resources.

A non-pharmacological management approach, comprising of exercise and education using a cognitive behavioral approach, may be a suitable method to ameliorate the impact of MSD and CDL on function and quality of life. However, there seems to be a lack of sustainable, evidence- based, contextually relevant interventions for middle-aged women with MSD and CDL at primary health care facilities in South Africa. Thus, the title of my study is:

"Osteoarthritis in Women living in Cape Town: characteristics and the effects of a non-pharmacological intervention

The intention of this study is to implement a new model of rehabilitation care, advocating a patient-centred self-management approach, for women with chronic MSD and CDL at CHC's in Cape Town. This will be done by adapting, implementing and evaluating a non-pharmacological and contextually appropriate intervention for women receiving medical and rehabilitation services in urban CHC's in the Cape Town Metropole region.

The research questions are therefore:

- What are the characteristics, functional impact and contributing factors to MSD and CDL in women attending CHCs in Cape Town?
- What would the components of a contextually relevant intervention programme be for women with MSD and CDL?
- How effective would this intervention programme be in addressing the impairments, activity limitations and participation restrictions for these participants?

The plan for this project is firstly to establish the profile of MSD and CDL in women attending CHC's in Cape Town in order to adapt, implement and test a non-pharmacological and contextually relevant intervention within the community setting.

The specific **objectives** of the study are:

- To establish the nature and functional impact of MSD, and how it affects the level of physical activity and overall health-related quality of life in South African women attending CDL clubs and MSD rehabilitation clubs at CHC's.
- To adapt an evidence- based, non-pharmacological intervention programme based on exercise, education and cognitive behaviour therapy to address all the problems highlighted by the participants in the preceding objective.
- To pilot the intervention programme and to test whether it has an impact on functional ability, pain, physical activity, health-related quality of life and lifestyle behaviours.

There are two phases to the study, Phase I will consist of a descriptive cross-sectional survey to establish the profile and the contextual background of affected women and Phase II will be an experimental study to test the intervention programme. The prospective participants will have MSD and CDL receiving care at CHC's in Cape Town.

Phase I- Profile:

A sample of convenience will be used for Phase I to recruit women attending the chronic care clubs and the exercise groups at the selected CHC's. They will be required to give informed consent and understand English, Afrikaans or isiXhosa to participate in the study. Women who are unable to respond to the questionnaire due to communication or cognitive difficulties, who are too ill to participate, who present with neurological conditions (such as strokes), recent trauma, or severe intellectual impairment will be excluded. A sample size of 300 women in total from one CHC is required to achieve a 95% confidence interval in statistics (Open Epi™ Version 3, 2013).

Assessments:

Standardised outcome measures that will be used for baseline testing for Phase I are: the Brief Pain Inventory (Short Form); the EQ-5D, WHODASII, International Physical Activity Questionnaire (IPAQ), COPCORD screening tool. Clinical measures such as blood pressure, blood glucose levels, weight, height and calculated BMI will be taken by a nurse.

Phase II- Intervention:

During the first phase, a survey will be administered to establish what impact the MSD or CDL has on the participants' ability to lead full, productive lives. Based on these responses and taking into account published evidence for both the structure and the content of exercise intervention in MSD, an intervention will be designed. Participants who indicated their willingness to participate in the intervention will be called and recruited for baseline testing, and thereafter will be randomly assigned to a control group (40 women) and experimental group (40 women). The control group will only complete the questionnaires and the physical tests and will continue with usual care at physiotherapy and chronic care clubs. The intervention group will participate in a six-week clinic-based intervention on exercise, education and self- management strategies.

The participants will be encouraged to continue their new healthy lifestyle approach by joining wellness activities in the community or by starting group exercise club.

It is anticipated that participation will lead to improved function in daily activities, decrease in joint pain, improved quality of life and physical activity, better compliance with medication, decrease in body mass and improved ability to take part in the life of the community.

Assessments:
Standardised outcomes for the intervention (Phase I) will include: the Brief Pain Inventory (Short Form); the EQ-5D, WHODASII, IPAQ, Aggregated Locomotor Functioning Score, the Chronic disease Self-efficacy Scale, blood pressure, blood glucose measures, BMI, percentage attendance and use of pedometer.

Baseline measures will be done before, at the end of six-week clinic-based intervention programme and at the end of 12 weeks. There will be an evaluation of the outcomes of the intervention programme and of the two groups to determine effectiveness.

Ethical Considerations
The study will conform to the principles of the Declaration of Helsinki (2008). Ethical approval has been obtained from the Faculty of Health Sciences, University of Cape Town. Approval has been obtained from Western Cape Department of Health to conduct the study at the selected Community Health Centres in Cape Town. Permission has been obtained by the facility manager to conduct the study at the CHC. All information obtained from the participants will be kept confidential and their identity will be anonymous and will only be used for statistical analysis and writing of results. All stakeholders will be acknowledged with all publications and conference proceedings. The findings of the study will be disseminated to you and respective departments.

I would like to request permission to access the records of all participants with MSD at the physiotherapy department to confirm their medical history and treatment details. The timeframe for data collection will be from January 2014 until 2015. Please be advised that I will not interrupt any service delivery for any patients and will ensure smooth running of your department. Data collection for the first phase will end once the estimated sample size has been reached. Thereafter, the findings will be analysed and the results will assist with the development of the intervention Programme. The intervention Programme will be implemented after three to four months after the first phase. The intervention will take place over a six-week period at the CHC. The participants will be recruited from the exercise group at physiotherapy and from the chronic care club and will be monitored throughout the study period. I cannot give an exact date by when the intervention study will be completed but I would alert you on the progress of each phase of the study. I have attached a copy of my research proposal if you require any additional information regarding my study. I look forward to hearing from you and your assistance is greatly appreciated.
Sincerely

Ms Candice Hendricks (PhD student) Candice.hendricks@uct.ac.za
Tel: 084-751-6692/ 0214066382

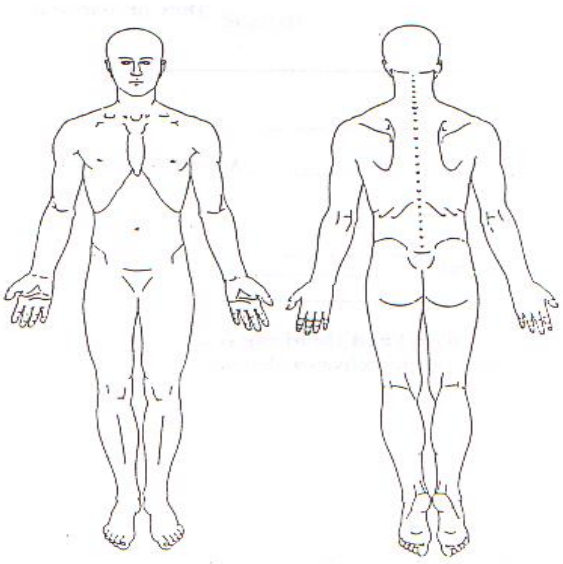
Supervisor:
Romy Parker: Romy.parker@uct.ac.za
Prof. M Blockman (Human Research Ethics Committee, Faculty of Health Sciences,)
Marc.blockman@uct.ac.za Tel: 021-406-6626

APPENDIX D: Outcome measure instruments used in the study

Appendix D-1: 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** on 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	

This is the end of the questionnaire, thank you for participating.

Appendix D-2: WHODAS 2.0-12 item questionnaire

This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.

Think back over the past 30 days and answer these questions, thinking about how much difficulty you had doing the following activities. For each question, please circle only one response.

In the past 30 days, how much difficulty did you have in:

S1	Standing for long periods such as 30minutes?	None	Mild	Moderate	Severe	Extreme or cannot do
S2	Taking care of your household responsibilities?	None	Mild	Moderate	Severe	Extreme or cannot do
S3	Learning a new task, for example, learning how to get to a new place?	None	Mild	Moderate	Severe	Extreme or cannot do
S4	How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	None	Mild	Moderate	Severe	Extreme or cannot do
S5	How much have you been emotionally affected by your health problems?	None	Mild	Moderate	Severe	Extreme or cannot do

S6	Concentrating on doing something for ten minutes?	None	Mild	Moderate	Severe	Extreme or cannot do
S7	Walking a long distance such as a kilometre [or equivalent]?	None	Mild	Moderate	Severe	Extreme or cannot do
S8	Washing your whole body?	None	Mild	Moderate	Severe	Extreme or cannot do
S9	Getting dressed?	None	Mild	Moderate	Severe	Extreme or cannot do
S10	Dealing with people you do not know?	None	Mild	Moderate	Severe	Extreme or cannot do
S11	Maintaining a friendship?	None	Mild	Moderate	Severe	Extreme or cannot do
S12	Your day-to-day work?	None	Mild	Moderate	Severe	Extreme or cannot do

H1	Overall, in the past 30 days, how many days were these difficulties present?	*Record number of days* ____
H2	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	*Record number of days* ____
H3	In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	*Record number of days* ____

Appendix D-3: EQ-5D-3L

EQ - 5D

Health Questionnaire

South African English version

By placing a tick in one box in each group below, please indicate which statements best describe your own state of health TODAY.

Mobility

I have no problems in walking about	❑
I have some problems in walking about	❑
I am confined to bed	❑

Self-Care

I have no problems with self-care	❑
I have some 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 with performing my usual activities	❑
I have some problems with performing my usual activities	❑
I am unable to perform my usual activities	❑

Pain/Discomfort

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

Anxiety/Depression

I am not anxious or depressed	❑
I am moderately anxious or depressed	❑
I am extremely anxious or depressed	❑

Compared with my general

level of health over the past 12 months,

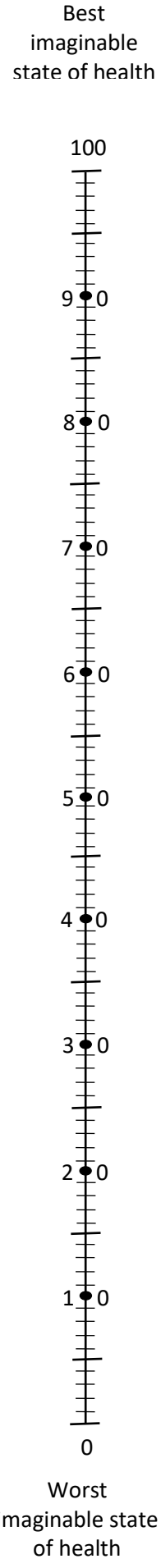
my state of health today is:

Better	❑	PLEASE TICK
Much the same	❑	ONE
Worse	❑	BOX

To help people say how good or bad their state of health is, we have drawn a scale on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale, in your opinion, how good or bad your own health is today. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

Your own state of health today



state of health

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

1. Have you experienced serious illness?

	Yes	No
yourself	❑	❑
in your family	❑	❑
while caring for others	❑	❑

PLEASE TICK APPROPRIATE BOXES

2. What is your age in years ? ☐

3. Are you male or female?

Male	Female
❑	❑

PLEASE TICK APPROPRIATE BOX

4.

I smoke	❑
I used to smoke	❑
I have never smoked	❑

PLEASE TICK APPROPRIATE BOX

5. Do you now, or did you ever, work in health services or social welfare?

Yes	No
❑	❑

If so, in what capacity?.....

PLEASE TICK APPROPRIATE BOX

6. Which of the following best describes your main activity?

self employed	❑
in formal employment	❑
retired	❑
homemaker/domestic worker	❑
student	❑
seeking work	❑
other (please specify)	❑ .....

7. What was the highest grade that you attained at school?

	Yes	No	PLEASE TICK APPROPRIATE BOX
8. Do you have a diploma or equivalent?	❑	❑	

9. If you know the area/suburb in which you stay, please write it here.....

Appendix D-4: Aggregated Locomotor Function score and baseline sheet

Date: _ _ _ _ _ __ _ __ _ _ _ _ __ _ __ _ _ _ _ __ _ _
ID code _ _ _ _ _ __ _

Activity	Description	Baseline reading	6 weeks	12 weeks
Walk 8 meters	Patients were asked to walk, at their own naturally preferred 'comfortable' pace, across the floor of a gymnasium. A 10 m stretch of floor was used. An 8 m distance was marked on the gymnasium floor. Timing of the central 8 m allowed one or two steps at either end of the walk for untimed acceleration and deceleration. The time (s) taken to complete the distance was measured using a hand-held stopwatch. Patients were permitted to use walking aids if they required them. Three repetitions of the walk were undertaken and the times recorded. The mean of times was calculated and used for subsequent analysis.			
Climbing 7 steps	Patients were asked to ascend and then descend seven steps (four of 15 cm and three of 20 cm). Patients were instructed to undertake this task at their naturally preferred comfortable pace. The method that the patient employed to negotiate the stairs was recorded, i.e. whether they used alternate legs, used the banisters or always led with one leg. Patients were permitted to use the two banisters if they felt it necessary, as the use of banisters has been shown to not affect times. Patients were timed (in seconds) using a hand-held stopwatch and repeated the test four times. The mean of the four repetitions was calculated and used for subsequent analysis. Four repetitions were used as the stairs used had steps of different heights; thus, by going over the steps in one direction and then the other the patients ascended and descended the different height steps twice.			
Transfer from sit to stand	Patients were asked to walk, at their own natural pace, a distance of 2 m to a chair and sit down, then immediately stand up and walk back to the start. Patients were timed (in seconds) using a hand-held stopwatch as they approached and retreated from the chair. The chair had no arms and a seat height of 0.46 m, typical of a toilet seat height. Patients undertook three timed repetitions, the mean of which was calculated and used for subsequent analysis.			

Appendix D-5: BMI, Blood pressure and Blood glucose sheets

Date: _
ID code _ _ _ _ _ _ _ _

Description	Baseline reading	After 6 weeks	After 3 months
Height (cm) – to nearest 0.1 cm			
Weight (kg) – accurate to 0.05 kg			
Body Mass Index (weight in kg ÷ height in cm ^{2})			
Blood pressure (mmHg)			
Blood glucose (mmol/L)			

Appendix D-6: Self-efficacy for managing chronic disease 6-item scale

STANFORD
PATIENT EDUCATION
RESEARCH CENTER

Self-Efficacy for Managing Chronic Disease 6-Item Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?

6. How confident are you that you can do things other than just taking medication to reduce how much you illness affects your everyday life?

not at all confident | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | totally confident

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the six items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

Appendix D-7: Telephonic questions and screening for exercise using the ACSM screening guidelines

1. How old are you?
2. Can you understand, read and write either English or Afrikaans or isiXhosa?
3. Do you have osteoarthritis in your legs? Which joint/s is affected?
4. Have you had any accidents/ previous surgery for problems in your legs before?
5. Do you have any other joint problems?
6. Do you have any condition which affects your ability to understand concepts?

As part of this study you will be asked to do exercises. I need to ask you some questions now to make sure that it will be safe for you to do these exercises. Can I ask you these questions now?

a. 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

b. 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

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?

YES to 2 or more of these 4 following questions not eligible, end interview, thank you for your time

Appendix D-8: Validated COPCORD

English version of COPCORD

This questionnaire is for anyone attending Community Health Centres.

This questionnaire is about chronic joint pain, obesity, hypertension and diabetes mellitus type II.

This questionnaire is completely voluntary. You may choose not to participate or not to answer any specific question.

This questionnaire is completely anonymous.

The data will be used to develop a health promotion Programme.

INSTRUCTIONS

Select only one response, unless instructed otherwise.

Please tick the appropriate answer e.g. □√ or circle one correct answer where indicated

Thank you very much for your co-operation

ID code _ _ _ _ _ __ _ _
Date: _ _ _ _ _ __ _ __ _ _ _ _ __ _ __ _ _ _ _ __ _ _
Community Health Centre: _ _ _ _ _ __ _ __ _ _ _ _ __ _ __ _ _ _ _ __ _

PHASE I:

(Q1 – Q7 are used for screening of MSD and CDL)

Q1. Age: _ _ __ _ _ _ years old OR Date of birth: _ _ _ _ _ _ _ __ _ _ _ _ _ _ _

Q2 a. Do you have a diagnosed musculoskeletal problem in the joints or spine?
□ No □ Yes

Q2 b. If yes, do you attend the rehabilitation/ exercise classes at physiotherapy?
□ No □ Yes

Q3 a. Do you suffer from chronic diseases of lifestyle?
□ No □ Yes

Q3 b. If yes, please tick the chronic diseases that you suffer from.

□ Cancer □ Sugar (Diabetes Mellitus Type I)
□ Cardio-vascular diseases (Coronary heart disease)
□ Depression □ Chronic respiratory disease
□ High blood pressure (Hypertension)
□ Other

Q4. Do you attend the chronic care club at the day hospital?
□ No □ Yes

Q5. Literacy in home language:
□ Read only □ Read and write
□ None

Q6. Do you suffer from any of the following acute illnesses/ injuries today?
□ cold/ flu □ gastroenteritis,
□ diarrhoea □ acute musculoskeletal injuries (muscle pain, sprain)
□ infection

Q7. Do you have any of the following conditions/ impairments?
□ neurological conditions (stroke, spinal cord injury)
□ intellectual/ cognitive impairments
□ fractures

THE FOLLOWING QUESTIONS ASK ABOUT YOUR PERSONAL DATA AND MEDICAL HISTORY

DEMOGRAPHIC INFORMATION:

Q8. Gender

□ Male □ Female

Q9. Home language:

□ Afrikaans □ English
□ isiXhosa □ Other

Q10. Marital status:

□ Single □ Married
□ Separated / divorced □ Widowed
□ Live with partner

Q11. Children:

□ None □ 1 child
□ 2 children □ 3 children
□ More than 3 children

*Q12. Highest level of education:

□ No schooling □ Grades 10 to 12
□ Grades R to 3 □ College, university or technicon
□ Grades 4 to 6
□ Grades 7 to 9

Q13. Current job:

□ Housewife □ Teacher
□ Desk job □ Work at shop or business
□ Factory worker □ Domestic worker
□ Military □ Police
□ Retired □ Unemployed
□ Other

Q14. If you are working, describe the nature of your work:

□ Light
□ Moderate
□ Heavy
□ Other

Q15 a. If you are not working, did you stop working due to any illness/ injury?

□ No □Yes

Q15 b. If Yes, please specify:

□ Musculoskeletal condition (stiff joints/ spine) □ Chronic diseases
□ Accident/ traumatic Injury □ Physical disability
□ Other Illness

Q16a. Have you changed work due to any illness/ injury?

□ No □Yes

Q16b. If Yes, please specify:

□ Musculoskeletal condition (stiff joints/ spine) □ Chronic diseases
□ Accident/traumatic Injury □ Physical disability
□ Other Illness

Q17. Do you receive a government pension or grant?

□ Yes □ No

Q18. Monthly income:

_____

Q19. Are you the only provider for the family (breadwinner)?

□ Yes □ No

Q20. History of smoking:

□ Never smoked □ Stopped smoking
□ Currently smoke
□ If smoking, how many cigarettes per day? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
□ If smoking, at what age did you start? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Q21. History of alcohol use:

□ Never used alcohol □ Currently drinking alcohol
□ Stopped drinking alcohol
□ If drinking alcohol, how many times per week do you drink? _ _ _ _ _ _ _ _ _ _
□ If drinking alcohol, at what age did you start? _

THE FOLLOWING QUESTIONS ASK ABOUT YOUR HEALTH:

Q22. Have you been diagnosed with any of these chronic diseases?

□ High blood (Hypertension) □ Sugar (Diabetes Mellitus Type II)
□ Obesity (overweight) □ Cholesterol (hyperlipidemia)

Q23. How long (months/years) have you been diagnosed with these conditions?

High blood _____ Sugar _____
Obesity _____ Cholesterol _____

Q24. Did you use medication for these chronic diseases in the last 3 months?

□ Yes □ No

Q25. If yes, what medication did you use?

□ Over the counter pain killers
□ Prescribed medication for high blood pressure
□ Prescribed medication for diabetes
□ Prescribed medication for high cholesterol
□ Natural remedies, herbs, supplements
□ Other

Q26 a. Do you use the prescribed medication on a regular basis as advised?
□ Yes □ No

Q26 b. If no, what is the reason for not taking the medication on time?

□ I don't like taking too many pills
□ I forget
□ Some tablets make me feel sick, drowsy or sleepy
□ Other reason

Q27 a. Were you involved in a traumatic accident before?
□ Yes □ No

Q27 b. IF YES, how did the accident occur?
□ Vehicle □ Agriculture / Field
□ Industrial □ Violence
□ Fall □ Other

Q28 a. Nature of traumatic injury
□ Fracture □ Sprain
□ Paralysis □ Other

Q28 b. Result of traumatic injury
□ Cured □ Disabled
□ Chronic pain □ Joint stiffness
□ Deformity □ Other

Q29 a. Has your doctor/ nurse ever told you to follow an exercise Programmed?

□ Yes □ No
□ Not sure

Q29 b. If yes, have you followed an exercise Programmed yet?

□ Yes □ No

Q30 a. During the last 3 months have you experienced pain, aching, swelling, stiffness (tightness) in or around your joints or back which is not related to an injury / accident?

□ Yes □ No
□ Not sure

Q30 b. During the last 7 days have you experienced pain, aching, swelling, stiffness (tightness) in or around your joints or back which is not related to an injury / accident?

□ Yes □ No
□ Not sure

ID code _ _ _ _ _ __ _ _

Date: _ _ _ _ _ __ _ __ _ _ _ _ __ __ _ _ _ _ __ _ _

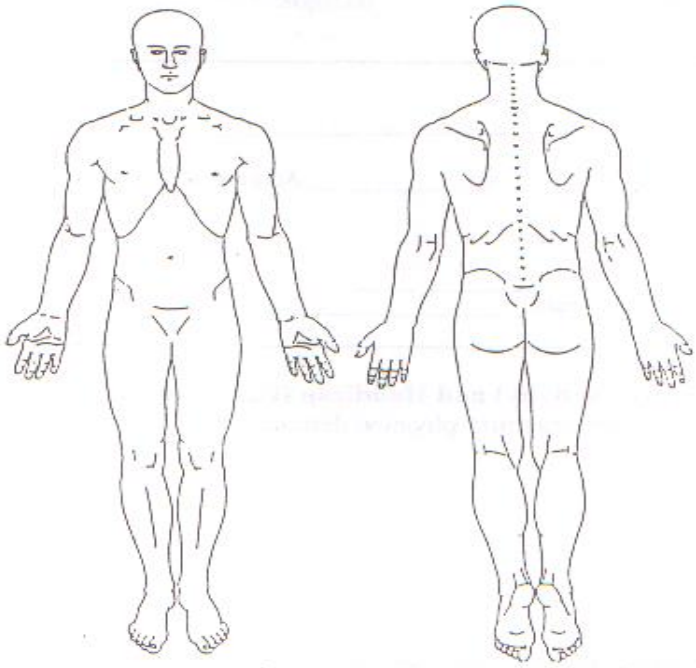
Community Health Centre: _ _ _ _ _ __ _ __ _ _ _ _ __ __ _ _ _ _ __ _

PHASE II:

THE FOLLOWING QUESTIONS ASK ABOUT YOUR JOINT OR MUSCLE PAIN, STIFFNESS / TIGHTNESS OR SWELLING AROUND YOUR JOINTS, OR LESS MOVEMENT IN ANY JOINTS

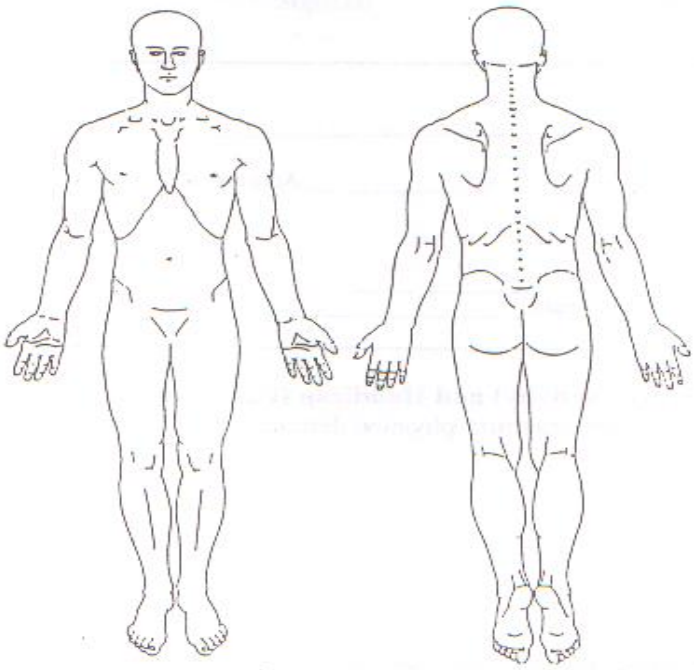
Q1a. Please indicate on the figure below, with an ✓ all the sites where you have experienced **pain** in the last 3 months and with a X all the sites where you have experienced **swelling**.

Front Back



Q1b. Please indicate on the figure below, with an ✓ all the sites where you have experienced pain in the last 7 days and with a X all the sites where you have experienced swelling.

Front Back



Q2. When did your pain start?

□ Less than 7 days ago
□ In the last 3 months
□ 3 months to 1 year ago
□ More than 1 year ago

Q4. How long does the episode of pain last?

□ Few days
□ 4 to 6 weeks
□ 6 to 12 weeks
□ More than 3 months

Q6. When is the pain most intense?

□ In the morning
□ After an activity (doing something)
□ While resting at night
□ Other

Q7 a. During the last year have you experienced stiffness in your joints in the morning after getting out of bed or after a long rest without movement?

□ Yes
□ No
□ Not sure

Q7 b. If yes, indicate the site/s of stiffness in the following joints

□ Neck
□ Shoulder
□ Elbow
□ Wrist
□ Fingers
□ Upper Back
□ Lower Back
□ Hip
□ Knee
□ Ankle
□ Toes

Q8. Did the stiffness go away after exercise or movement of the joint?

□ Yes
□ No
□ Not sure

Q9. Have you been diagnosed with arthritis or other joint diseases like rheumatism?

□ Yes
□ No

Q10. Have you been taking any medication for joint or back pain, not related to an injury, in the last 3 months?

□ Yes
□ No

Q11. If yes, what medication was used?

□ Over the counter pain killers
□ Natural remedies, herbs, supplements
□ Over the counter anti-inflammatory drugs (NSAIDS's)
□ Prescribed anti-inflammatory drugs (NSAID's)
□ Injection
□ Other

Q12. Did the medication reduce your joint pain or back pain?

□ Yes
□ No

Q13. Have you received any type of treatment, other than medication, for pain?

□ Yes
□ No

Q14. If yes, please specify the type of treatment that you received at the day hospital.

□ Exercise
□ Massage
□ Acupuncture
□ Joint mobilizations
□ Other
□ Education
□ Herbal/ natural
□ Electrotherapy machines
□ Strapping/ bracing

Q15. Did the above treatment reduce your joint pain or stiffness?
□ Yes
□ No

Q16. What treatment worked best in reducing your pain and stiffness?

□ Exercise
□ Massage
□ Acupuncture
□ Joint mobilizations
□ Medication
□ Education
□ Herbal/ natural
□ Electrotherapy machines
□ Strapping/ bracing
□ Injection

Q17. Are you easily depressed or get anxious because of the pain/ joint stiffness?

□ Yes □ No

Q18. Do you experience abnormal sleeping patterns because of the pain /joint stiffness?

□ Yes □ No

Q19. Do you feel physically tired due to the pain / joint stiffness (not able to manage everyday tasks)?

□ Yes □ No

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE.

Appendix D-9: English version of IPAQ

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active **in the last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous and moderate** activities that you did **in the past 7 days**. **Vigorous** physical activities refer to the activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities inside refer to activities that take moderate physical effort and make you breath somewhat harder than normal.

PART* 1: *PHYSICAL ACTIVITY RELATED TO THE JOB

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do you do any unpaid work outside your home?

□ Yes

□ No Skip ***to Part 2: Transportation***

The next questions are about all the physical activity you did **in the last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. **During the last 7 days**, on how many days did you do vigorous physical **activities** like heavy lifting, digging, heavy construction, or **climbing up stairs as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

__ days per week

□ No vigorous job-related physical activity ⟶ ***Skip to question 4***

3. How much time did you usually spend on one of those days doing vigorous physical activities as part of your work?

__ **hours per day**

__ **minutes per day**

4. Again, think about only those physical activities that you did for at least for 10 minutes at a time. **During the last 7 days**, on how many days did you do moderate physical activities like carrying light loads as part of your work? Please do not include walking.

__ **days per week**

□ No moderate job-related physical activity ⟶ ***Skip to question 6***

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

__ **hours per week**

__ **minutes per week**

6. **During the last 7 days**, on how many days did you walk for at least 10 minutes at a time as part of your work? Please do not count any walking you did to travel to or from work.

__ **days per week**

□ No job-related walking ⟶ Skip to question ***2: TRANSPORTATION***

7. How much time did you usually spend on one of those days walking as part of your work?

__ **hours per week**

__ **minutes per week**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you travelled from place to place, including to places like work, shops, movies, and so on.

8. **During the last 7 days**, on how many days did you travel in a motor vehicle like a train, bus, car or tram?

__ days per week

□ No traveling in a motor vehicle ⟶ ***Skip to question 10***

9. How much time did you usually spend on one of those days traveling in a train, bus, car, tram, or other kind of motor vehicle?

__ hours per week

__ minutes per week

Now only think of the **bicycling and walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. **During the last 7 days**, on how many days did you bicycle for at least 10 minutes at a time to go from place to place?

__ days per week

□ No bicycling from place to place ⟶ ***Skip to question 12***

11. How much time did you usually spend on one of those days to bicycle from place to place?

__ hours per week

__ minutes per week

12. **During the last 7 days**, on how many days did you walk for at least 10 minutes at a time to go from place to place?

__ days per week

□ No walking from place to place ⟶ ***Skip to Part 3: HOUSEWORK, HOUSE MAINTAINANCE, CARING FOR FAMILY***

13. How much time did you usually spend on one of those days **walking** from place to place?

__ hours per week

__ minutes per week

PART 3: HOUSEWORK, HOUSE MAINTAINANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the last 7 days in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes a time. **During the last 7 days**, on how many days did you do vigorous activities like heavy lifting, chopping wood, shovelling snow, or digging **in the garden or the yard?**

__ **days per week**

□ No vigorous activity in garden or yard ⟶ ***Skip to question 16***

15. How much time did you usually spend on one of those days doing vigorous physical activities **in the garden or the yard**?

__ **hours per week**

__ **minutes per week**

16. Again, think about only those physical activities that you did for at least 10 minutes a time. **During the last 7 days**, on how many days did you do moderate physical activities like carrying light loads, sweeping, washing windows and raking **in the garden or the yard**?

__ **days per week**

□ No moderate activity in garden or yard ⟶ ***Skip to question 18***

17. How much time did you usually on one of those days doing **moderate** physical activities in the garden or yard?

__ **hours per week**

__ **minutes per week**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. **During the last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, washing windows, scrubbing floors, and sweeping inside your home?

__ **days per week**

□ No moderate activity at home ⟶ ***Skip to Part 4: RECREATION, SPORTS AND LEISURE-TIME PHYSICAL ACTIVITY***

19. How much time did you usually spend on one of those days doing moderate physical activities inside your home?

__ **hours per week**

__ **minutes per week**

PART 4: RECREATION, SPORTS AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the last 7 days solely for recreation, sports, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the last 7 days, on how many days you walk for at least 10 minutes at a time in your leisure time?

__ **days per week**

□ No walking in leisure time ⟶ ***Skip to question 22***

21. How much time did you usually spend on one of those days walking in your leisure time?

__ **hours per week**

__ **minutes per week**

22. Think about only those physical activities that you did for at least 10 minutes at a time. **During the last 7 days**, on how many days did you do vigorous physical activities like aerobics, running, fast bicycling, or fast swimming in **your leisure time**?

__ **days per week**

□ No vigorous activity in leisure time ⟶ ***Skip to question 24***

23. How much time did you usually spend on one of those days doing vigorous physical activities in your leisure time?

__ **hours per week**

__ **minutes per week**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. **During the last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular speed, swimming at a regular speed, and doubles tennis in your **leisure time**?

__ **days per week**

□ No moderate activities in leisure time ***Skip to Part 5: TIME SPENT SITTING DOWN***

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?

__ **hours per week**

__ **minutes per week**

Part 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work or during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time sitting in a motor vehicle that you have already told me about.

26. **During the last 7 days**, how much time did you usually spend **sitting on a weekday**?

__ **hours per week**

__ **minutes per week**

27. **During the last 7 days**, how much time do you usually spend **sitting on a weekend day**?

__ **hours per week**

__ **minutes per week**

This is the end of the questionnaire, thank you for participating.

Appendix E: SmArt-Health Intervention

Appendix E-1: SmArt-Health Workbook

SmArt

"Self- management for Arthritis and High blood pressure with education, activity and lifestyle modification therapy"

Patient Workbook

Welcome to the "**SmArt-Health**" course

Self- management for Arthritis and High blood pressure with education, activity and lifestyle modification therapy

---

This is a workbook designed to be used over 6 weeks. We hope that by using the workbook people will learn more about osteoarthritis and high blood pressure and develop self-management skills for living with these chronic conditions. Using this workbook is not about sitting and reading or listening. In order to get the most out of this course you will be asked to share your experiences, you will need to set goals and share those goals with others and you will need to take part in activities. This workbook is NOT a substitute for any other medical care that has been recommended for the treatment of your conditions but an addition to see if it helps you in any way.

You will benefit most from this workbook if you commit yourself to completing all the sessions within a 6 week period of time. Scientific research tells us that these courses are of great benefit to people living with chronic diseases such as diabetes, osteoarthritis, high blood pressure and HIV/AIDS. But to benefit from the course, using the workbook regularly over 6 weeks and participating in activities is essential. The workbook is divided into six sections:

- **Week 1: Osteoarthritis, High blood pressure Self-management and Exercise**
- **Week 2: Managing common symptoms**
- **Week 3: Stress Management**
- **Week 4: Eating Well**
- **Week 5: Medication and disease-related problem solving**
- **Week 6: Continuing as a successful self-manager**

Your course leader is _____. She is a qualified physiotherapist a
the information you will be going through in the discussions. She is als
to exercise and in relaxation techniques.

Week 1: Osteoarthritis, Self-management and Exercise

What is Osteoarthritis?

What is osteoarthritis? It is a degenerative joint disease which we often call OA. In simple terms, it is the breakdown of previously healthy joint surfaces, causing the two bones that make up the joint to rub against each other. This wears away the bone's surface (the cushioning of the joint) and can become painful.

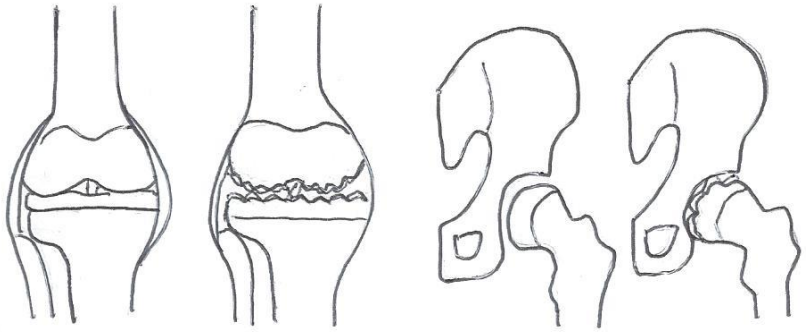


Figure 40 Normal knee. OA of the knee. Normal hip. OA of the hip

OA is different in every person and the way it progresses differs for each person too. Usually, as a person ages the condition progresses until in some people there is a lot of joint damage with deformities. OA is most common in the hips, knees and hand joints. The cause of OA is very seldom due to one factor alone, but rather a combination of things acting together usually brings about this condition. Known causes/risk factors for OA include but are not limited to:

- age
- inherited or genetic predisposition to developing OA, especially in the hands
- gender – females are seen to have OA more commonly than males
- obesity and being overweight
- faulty alignments or having poor posture
- certain occupations/ sports/ repeated stresses on the joints
- previous trauma

Diagnosis:

It is fairly simple for a doctor to make a diagnosis of OA. The doctor makes the diagnosis by examining you and by taking a history of the main symptoms. X-rays can help in correctly diagnosing OA, but these are not always necessary. Changes which we look for on the X-rays

include narrowing of the space between the two bones, evidence of wear and tear of joint surfaces and extra bone forming at some areas.

People who have OA mainly complain of:

- pain in the affected joint or limb
- stiffness, particularly in the morning for less than two hours
- muscle weakness
- difficulties in performing daily tasks like walking or climbing the stairs

Management options:

Scientific research shows that educating people about their condition in order that they may understand it better and manage it better, is the best way to treat it and that this works well. People are advised to become more active by exercising and balancing this with rest.

Physiotherapy, which focusses on education and exercise, can also help. There are medicines that your doctor will can prescribe for you to treat your pain or inflammation. Different surgical methods can also be used to treat this condition, the most effective being a joint replacement. Joint replacements are big operations though, so they are only done when the OA is very bad.

Now that you know a bit more about what osteoarthritis is, let us look at some information about high blood pressure.

What is high blood pressure?

It is a condition in which the blood vessels in the body have constant high pressure. Blood is pumped from the heart to all parts of the body through blood vessels. Each time the heart beats, it pumps blood into the vessels. Blood pressure is created by the force of blood pushing against the inner walls of blood vessels as it is pumped by the heart. If the pressure is high, the heart has to work much harder to pump the blood to the body.

High blood pressure is one of the leading factors for cardiovascular diseases (group of disorders of the heart and blood vessels) and deaths around the world. If left uncontrolled, high blood pressure can lead to a heart attack, an enlargement of the heart and eventually heart failure. The pressure in the blood vessels can also cause blood to leak out into the brain. This can cause a stroke. High blood pressure can also lead to kidney failure, blindness, rupture of blood vessels and learning difficulties.

Heart attacks and strokes are usually caused by a blockage of fat on the inner walls that prevents blood from flowing to the heart or brain. The cause of heart attacks and strokes are usually from a combination of factors such as:

- tobacco use,
- alcohol use
- unhealthy diet and obesity,
- lack of physical activity,
- high blood pressure,
- diabetes and
- high levels of fat in the blood.

To prevent heart attacks and strokes, it is important to have early screening of high blood pressure, high sugar levels in the blood, high fat levels in the blood and to screen for obesity. It is also important to make changes to your life to adopt healthier ways of living by changing your diet and improving your physical activity levels.

Diagnosis:

The doctor or nurse can diagnose you with high blood pressure by testing your blood pressure with different machines. There are different machines that are used to measure blood pressure. Research recommends the use of affordable and reliable electronic machines that can be used on the upper arm. Blood pressure measurements need to be recorded for several days before a diagnosis of high blood pressure can be made.

Blood pressure is measured in millimetres of mercury (mm Hg) and is recorded as two numbers usually written one above the other. The upper number is the systolic blood pressure -the highest pressure in blood vessels and happens when the heart contracts, or beats. The lower number is the diastolic blood pressure - the lowest pressure in blood vessels in between heartbeats when the heart muscle relaxes.

Normal adult blood pressure is defined as a systolic blood pressure of 120 mm Hg and a diastolic blood pressure of 80 mm Hg.

High blood pressure is defined as a systolic blood pressure equal to or above **140 mm Hg** and/or diastolic blood pressure equal to or above **90 mm Hg.**

Normal levels of both systolic and diastolic blood pressure are important for the efficient function of vital organs such as the heart, brain and kidneys and for overall health and wellbeing.

What can physiotherapy do for high blood pressure?

As you have read, people with high blood pressure should adopt a healthy lifestyle to avoid heart disease and strokes by exercising, eating healthy foods, maintaining a healthy weight, avoiding harmful substances and managing stress levels with relaxation techniques. Physiotherapy, which focuses on education about adopting a healthy lifestyle, exercise and relaxation, can definitely help people with high blood pressure. There are medicines that your doctor will prescribe for you to help control your high blood pressure. Physiotherapy cannot prescribe any medication for high blood pressure, so remember to continue with your medication, but it can assist you with adopting a healthier lifestyle which is needed to help control your chronic illness as well.

Now that you know a bit more about your chronic illnesses, we will go through what we mean by self-management.

What is meant by "self-management"?

Self-management does not mean that you are expected to look after your health on your own with no help. No, someone who is a successful self-manager takes responsibility for their health. This means that they choose to work with the health team, with their medication and with themselves to live a healthy life (just like a manager in a business – they don't do everything themselves, they work with a team).

There are lots of things you can learn to do which will help you to be a successful self-manager. First of all it is important to understand your chronic illnesses such as osteoarthritis and high blood pressure. This is what we have just covered. You need to understand what the condition is, why it happens, how it changes and how it impacts on your life. You also need to know about the ways to treat it and medications which may be used.

The next step in being a self-manager is being able to think about this information in terms of how it affects you. The final step in being a self-manager is to think about what it is that you want to be able to do, decide how you are going to do it and then to learn and practice the skills you need to be able to do it. Some of the things you will learn about and practice every day when you do this course include exercising, relaxation techniques and healthy eating.

By using this workbook you will learn about exercise and its benefits, in the second section you will learn a bit about the common symptoms of osteoarthritis and how to manage these. The third section will focus on stress management, the final sections focus on eating well and medications. Some people using this workbook may already know a lot about these topics, others may not know very much. It is important to share information and make sure that everyone has the knowledge they need to become a self-manager, even if you think you know a lot about these topics it is still worth your going through the workbook to make sure you have not missed out on any information. Scientific research tells us that people who are well informed about their health manage better and have a better quality of life.

Using this workbook, you will also learn about and discuss the steps that are needed to become a good self-manager. Let's look at these steps here.

Self-management steps

Step 1:

To be good at self-management you need to learn and practice several skills which you will practice through using this workbook. The first step is to **decide what it is you want to be able to do.** This can be the hardest step to think about. For example you might be feeling very sad and depressed. First you need to think about why you are feeling that way. Perhaps one of the reasons you are feeling that way is that you have lost touch with your friends. Your first step might be to decide that you need to reconnect with your friends or to meet people and make friends. This will help you to feel less sad and depressed.

Write down here three things that you **want to be able to do**:

1)_____

2)_____

3)_____

Step 2:

But deciding that you are going to meet people and make friends doesn't mean it will happen. You have to make it happen. The second step in being a self-manager is to decide ***how*** **you are going to do it**. Sometimes the thought of doing something new can seem too much and we don't even try. If you want to meet people to make friends you need to think about all the different options you have to do this. For example you could invite your neighbours for tea, or you could decide you would meet people by going to church, by joining a support group or an exercise group. **Never assume that what you want to be able to do is impossible**. Always look for every option and look at it from every angle.

Write down here three different ways that you **could try to achieve what you want to do**:

1)_____

2)_____

3)_____

Now that you have decided on *how* you can try to achieve what you *want*, **you need to make an action plan**. It is important that this plan is realistic otherwise it is likely you will not succeed. How do you do this?

- First decide what you are going to do *this week*
- Now make a *specific plan*

Action plans, goal setting

Saying that this week I'm going to try to meet some people is NOT a specific plan. To be specific, the plan must have different parts. It is useful to ask yourself some questions to help develop a specific plan. Questions like:

- *What?*
  Exactly what are you going to do? For example you could decide that to meet people you are going to invite your neighbour for tea.
- *How much?*
  Then you must decide how much you are going to do. For example are you going to invite one neighbour for tea or are you going to invite lots of neighbours over. Lots of people are much more tiring than one person. Or do you want to invite your neighbour for lunch? But lunch means a lot more preparation and time and will make you more tired. So you have to decide how much you can do.
- *When will you do it?*
  Then you must decide on exactly which day you are going to do the activity and at what time of the day. Maybe it is better to invite your neighbour for tea in the morning because you get tired in the afternoon. Or if you feel sick in the morning from your medicines maybe it is better to invite your neighbour for afternoon tea. Or maybe your neighbour works and you need to invite them for tea at the weekend.

- *How often?*

This is always the hardest part. We all would like to be able to do more things every day. But we are human and this is not always possible. When people want to start exercising, we often say we are going to do it every day. But this is often just not possible and if we then miss a day we feel that we have failed and we give up. How often will you invite your neighbour for tea? Not every day but maybe once a week. You know that you won't become friends immediately and that it will take time.

- *Is it a good plan?*
  To test whether you have come up with a good plan you need to ask yourself this question:
  "*If I give myself a score from 0 -10 for how confident I am that I will achieve my plan this week, where 0 is not at all confident, and 10 is totally confident. What score will I give to show how confident I am that I can complete this plan?*"
  If your answer is 7 or more out of 10 then this is probably a very good plan. If your score is less than 7 you need to think about why you are not confident. What are the problems or barriers? Can you change the plan or solve the problems to make yourself feel more confident?

Step 3:

Now, you need to **write your plan down and put it somewhere you will see it every day**. There is an action plan form at the end of this section and more in this book. Use them every week while you are using this workbook. You can always draw more of them to keep working on your plans in the future.

A good action plan is:

- Something I want to do
- Something I can expect to do this week
- Is specific
- Answers the questions: What? How much? When? How often?
- I am confident that I can achieve with a score of at least 7 out of 10.

Now you need to carry out your action plan. If it is a good plan then doing it is usually fairly easy. It helps to tell family or friends what your plan is and to report back to them on how you are

doing. On this course you are going to make a plan every week and record how you get on. It helps to report back on things because you can then have an idea on how well you are doing. If you haven't been able to keep to the plan you can discuss the problems you might have had and make plans to cope with them.

Step 4:

Always check your results and give yourself a reward for having achieved your plan. Also think about how achieving your plan is making you feel. In the example we talked about, you could congratulate yourself for having invited your neighbour for tea, you would also think about how you now feel. Is the plan helping you to achieve what you want?

What happens if something doesn't go according to plan?

What if your plan doesn't work? Are you going to give up and decide you had a bad plan? There are seven steps to solving problems. These are:

1. Deciding what the problem is (you might need friends and family to help here)
2. List ideas to solve the problem
3. Select one idea to try
4. How did it go?
5. If it didn't work, try another idea
6. If your ideas don't work, ask friends, family, counsellors, professionals for ideas
7. Finally you might have to accept that you can't solve the problem now.

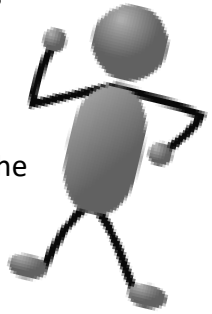
At the end of each section and at the back of the workbook there are "Action Plan Forms". Use these forms to plan what you want to do and how you are going to do it. We are now going to discuss exercise and we are going to use the "Action Plan Form" at the end of this section to plan what exercise you are going to do this week.

A successful self-manager is someone who:

- Sets goals
- Makes a list of ways to achieve those goals
- Makes action plans to achieve the goals
- Carries out the action plans
- Checks on their progress every week
- Can change the action plan if there are problems
- Gives themselves a reward for achieving their goals

Exercise dos and don’ts

Exercise is a very important way to keep healthy. Scientific research tells us that **exercise has a lot of good effects on our bodies** like helping our digestive system absorb and process food; it trains our hearts so that they are strong and healthy and keeps our lungs working well. Exercise makes our muscles and bones strong and our joints flexible so that we can keep moving. Exercise also helps to make us feel happy, improves concentration and memory, improves sleep and exercise helps to decrease the chances of developing serious health problems such as strokes or heart attacks in people with high blood pressure and cancers.



In the past, when people became ill with a chronic illness like high blood pressure or diabetes or arthritis, medical care focused on helping them when their symptoms became worse. Treatment focused on using medicine and people were often advised to rest or decrease their activity. Today we know that if we teach people who develop chronic illnesses about their disease and encourage them to do the right exercise **we can prevent a lot of the problems** which used to be treated with medicines. We also know that exercise can help to treat a lot of the symptoms which people with chronic diseases develop. Symptoms which may be caused by the disease or by the drugs used to treat the disease.

Exercise is good for:

- Improving mood
- Strength
- Improving sleep
- Concentration and memory
- Heart and lung health
- Decreasing body fat
- Digestion

You may be wondering if it is safe for you to exercise when you have osteoarthritis and high blood pressure. Research tells us that **exercise has been shown to be beneficial** in people with osteoarthritis, as well as in those who need a joint replacement and other chronic illnesses like high blood pressure and even diabetes (sugar disease). Exercise can help slow down the degenerative processes that happen with arthritis when you aren't exercising. Exercise can also help you to lose weight which helps with osteoarthritis of the legs as there are less forces through the knee joint. We know that people who are physically fit get fewer colds and take fewer days off work because of illness. One of the biggest benefits of exercise is that exercising regularly makes you feel more in control of your life.

Although exercise is good for you and safe for you to do, **sometimes your body will give you clues that you need to cancel your exercise** for the day. If you have a fever, feel dizzy, have vomiting or diarrhoea, if your joints have suddenly become swollen, or if you have a pain which is new and you are not sure what is causing it, it is better to miss an exercise session until you can speak to a doctor or physiotherapist.

Do not exercise if:

- You have a fever
- You are dizzy
- You have been vomiting
- You have diarrhoea
- Your joints have suddenly become swollen
- You have a new pain which you don't know the cause of

Miss one exercise session if you have one of these problems until you can speak to a nurse or doctor. This does not mean you should never exercise but you need to make sure you are not becoming ill.

Types of exercise

You do not have to join a gym or a club to get exercise. There are lots of ways of exercising from formal sports like running, playing football or netball, swimming or playing tennis. But, walking is also a very good way to exercise. Any activity which makes your heart beat faster and makes you breathe a little harder is exercise. Dancing is exercise, walking up the stairs is exercise, gardening is exercise. There are lots of ways that we can exercise every day without having to go to a class or join a club. You could walk a little further before catching the bus or the taxi or you could play with your children or grandchildren!

There are three general kinds of exercise you can do.

1. **Endurance exercise:** like walking, running, dancing or swimming. Endurance exercise is sometimes called aerobic exercise which means that you will be breathing faster and your heart will be beating faster too. We know that this kind of exercise is very important to keep healthy and we need to do 30 minutes of this kind of exercise three times a week to keep healthy. People that suffer from high blood pressure should try to do this kind of exercise for 30 minutes every day or at least for five days of the week.

2. **Strengthening exercise**: this kind of exercise focuses on making us stronger. To make muscles stronger we have to do exercises which make the muscles work hard against a resistance, like weight training but you can also do strength training by working with heavy bags of shopping!

3. **Stretching exercise**: this focuses on keeping us mobile and flexible.

Types of exercise:

- **Endurance exercise** which makes you breathe harder (sometimes called aerobic)
- **Strengthening exercise** which makes you stronger
- **Stretching or flexibility exercise** which makes you more mobile and supple

We gain and aga we stick to it. We all make lots of excuses why we can't exercise. Let's look at the most common excuses.

"I don't have time"

It doesn't take a lot of time to start exercising. Five minutes a day is a good start. We make time to take medicine because we know without it we would become ill. Exercise is as important as medicine to help us remain healthy (remember it can never replace your drugs). If we know that it is that important we can make time for it.

"I'm too tired"

When people become ill they often become less active. As you become less active, your body loses fitness and you become weaker, you may feel stiffer and you tire more easily. This means that exercising might feel harder and so you exercise less. This often results in a downward spiral of activity and people often get to the point where even walking down the street to visit the neighbour can feel like too much. Being active or doing exercise when you are feeling tired will give you more energy and make you feel less tired.

"I'm too sick"

You may be too sick to undertake very vigorous exercise but you can still aim to be more active. You can even break your exercise into one minute sessions which you repeat several times through your day. The fitter you get, the better you will be able to cope with your illness

"I get enough exercise already"

You may be getting a lot of exercise already in your job or simply walking around doing your daily chores. But for most people if we add this time up, it still isn't enough exercise to keep them fully fit. This kind of exercise also doesn't include one of the most important components that make exercise good for us – fun!

"Exercise is boring"

You don't have to do the exercises that everyone else does if they are boring. Choose something that is fun, exercise with a friend or with your favourite music or listen to the radio. You can also keep your exercises fun by changing them regularly.

"Exercise is painful"

Exercise may be uncomfortable but it shouldn't be painful. If you have pain before you start to exercise, it should not get worse while you are exercising. If you do not have pain before you start to exercise and you start to feel pain while you exercise you need to stop exercising and evaluate your pain using the guidelines in Week 2. If you have muscle or joint pain for more than two hours after you exercise then you have probably done too much. Next time do a little less, either exercise for less time or less vigorously.

"It's too dangerous, it's too hot, it's too cold"

There are always reasons like this not to exercise. Remember that exercise can be done anywhere and anytime. You can put on music in your home and dance, if it's too hot you could walk around shops which have air-conditioning. Finding a group of people to exercise with will not only make it safer but also more fun!

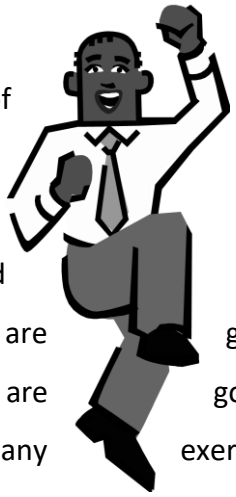
"I know I won't stick to it so there is no point in starting"

First review the steps we discussed on how to be a successful self-manager. If you set your exercise goals using these steps you have more chance of sticking to your exercises. Remember too, the important step of rewarding yourself for achieving your goals; this makes it easier to move on to your next goal. We are now going to have a look at the important steps to take to be successful at putting your exercise plan into action.

Steps to success with exercise:

- Set a clear goal using the steps outlined in "How to be a successful self-manager"
- Choose exercise or activity that you want to do and that is fun
- Set a specific time and place to do your exercise
- Decide how long you are going to stick to the plan before you think about changing it (6 to 8 weeks is a good time to work on things)
- Keep an exercise diary to keep track of how you are doing (there is one at the back of this booklet for you to use)
- Keep track of your progress using the exercise diaries in this workbook.
- Start – don't wait, start now. Begin gradually and proceed slowly
- Revise your programme. At the end of the 6 – 8 weeks make a new plan for the next 6 weeks
- Reward yourself. It is a reward to feel better and healthier but also give

Your exercise Programme:



An exercise Programme should include the three different types of exercise; remember they were endurance, flexibility and strength exercise. Following the steps in the box “Steps to success with exercise”, you need to decide on what you want to be able to do and what exercise you would like to do. Now that you know what exercise you are going to do, you need to decide how much to do. The amount of exercise you are going to begin with will depend on a lot of different things. If you have not done any exercise for a long time or have been feeling unwell, have had difficulty breathing or been short of breath, if you have had stiffness or pain or weakness that interferes with your daily activities then you need to start your exercise slowly. You can begin slowly by starting with some flexibility and strengthening exercises. Do these exercises every other day for 5 minutes. Once you can do that comfortably and without feeling stiff or sore the next day, increase it to 10 minutes.

Once you can do 10 minutes comfortably, you can start doing the exercises every day (when we say exercise every day, we usually mean exercise for 5 days of the week; it can be very hard to keep a routine to exercise on weekends when activities are different). Once you can do at least 10 minutes every day then you are ready to begin endurance exercises. Choose your exercises from the ones set out in the sections below. Follow the instructions in the box to make sure you get the most out of the exercises and do them safely.

Getting the most out of your flexibility and strength exercises:

- Move slowly and gently. *Do not* use jerking or bouncing movements as these will make your muscles shorter and tighter.
- Stretch to the point of *tension* in a muscle and hold for 20 seconds before you relax
- Don't push until it hurts, *stretch to tension not pain*
- Start off with 5 repetitions of each exercise. After one week increase it to 7, after another week increase to 10.
- Always do the *same number* of exercises on the left side and the right side of your body
- *Keep breathing*; do not hold your breath when you exercise. Think about breathing out as you move to make sure you do not hold your breath.
- Use the *two hour rule*. If you have increased symptoms (like pain) for more than two hours after you exercise you have probably done too much. Don't stop doing the exercises but decrease how much you do next time.
- If you find an exercise difficult this does not mean you should not do it at all. You should adapt it, do it as completely as you can.

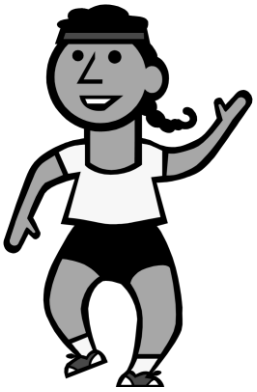
Flexibility Exercises:

Remember, these exercises are aimed at improving your ability to move. There is a long list of exercises that could be included here and you might not be able to do them all every time you exercise. Try to ensure that you do flexibility exercises at least once a week.

Strengthening Exercises:

You do not need to go to a gym to do strength exercises, the exercises described here can be done at home. To make muscles stronger you must make the muscles work against a resistance or a force – they have to push or pull. You should not do strength exercises every day, rather they should be done every second day. Your muscles need a day of rest to adapt and get stronger. To make a muscle stronger you need to repeat each exercise 5 times to start with. Once you can do an exercise 10 times you will not get stronger by doing more exercises. Now you will need to add more resistance to the exercise to get stronger.

Endurance Exercises:



The most difficult thing for most people is deciding how much exercise to start with. The easiest starting point is to ask yourself the question: "how much do I think I can do without suffering for it tomorrow?" If you feel you can do 5 minutes, then do 5 minutes. Remember that any exercise is better than none. You don't have to do 30 minutes from the first day. It is important to start slowly and increase very gradually. It is better to start off by doing less than you think you can and increase it from there.

There are three things you need to think about when you do endurance exercise. These three things are *frequency* (how often am I going to do this exercise); *duration* (how long am I going to exercise for when I do exercise) and *intensity* (how hard am I going to work when I exercise).

Frequency:

Try to do endurance exercise 3 or 4 times a week. By doing this you can rest every second day and allow your body to recover. All athletes have at least one day a week when they rest. Rest does not mean that they lie in bed all day though, it means that they do not do their exercises.

Duration:

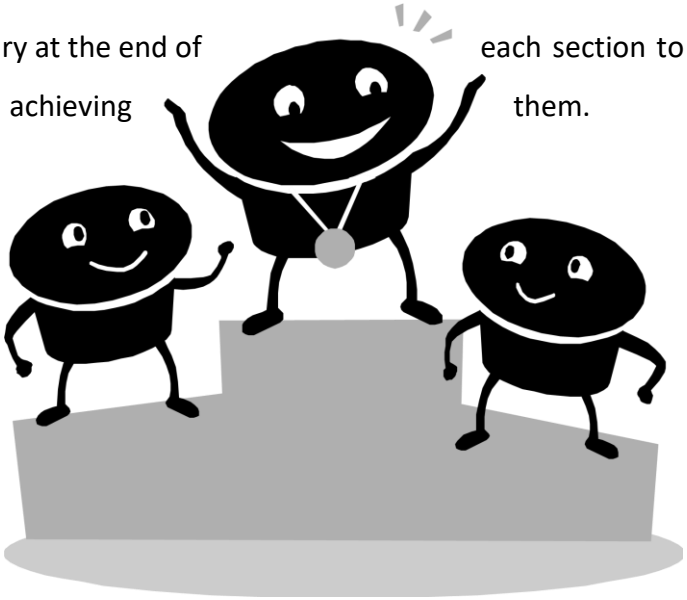
How much can I do without suffering for it tomorrow? That is your starting point. If you are starting with just a few minutes you can gradually increase it over time until you can do 30 minutes at a time. The easiest way to increase the time is to use intervals of exercise. For example to walk hard for 3 minutes, then walk slowly for 2 minutes, then walk hard again for another 3 minutes. Slowly over time cut down the slow walking and increase the hard walking. You could also break your exercise into separate sessions. You could walk for 10 or 15 minutes in the morning and do it again in the evening. This would still count as 30 minutes of exercise.

Intensity:

How will you know that you are exercising hard enough to be doing some good? How will you know if you are exercising too hard? When doing endurance exercise the easiest way to check the intensity is to use the **"Talk Test".** When you are doing moderate intensity exercise you should be able to talk comfortably, but if you tried to sing it would be a little difficult and you would have to stop singing to take bigger breaths. Moderate intensity means you should feel that you are breathing a little faster and a little harder but you can still talk. It may take you a while to find the right intensity for you for the whole of your exercise session. This is normal; take your time to get to know how your body will respond.

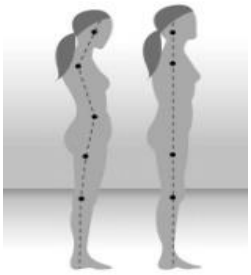
How will you know you are improving in your exercises? For the flexibility and strength exercises it is easy to feel the improvements as you will feel that moving is easier and you are stronger and can lift heavier items. For some people it is harder to know if you are improving with the endurance exercises. One way to see if you are improving is to do a test. One of the easiest tests to do is a timed test. Decide on a route that you can walk near your home. Walk this route at a moderate intensity and time how long it takes. After several weeks of exercise walk the route again and time it again. You may see that you can walk the same route faster within 4 weeks, but it may take 8 to 12 weeks before you see that you can do the route in a faster time. The goal is to complete the same route faster or in the same time but at a lower intensity (breathing much easier).

Use the exercise diary at the end of each section to record your goals and your progress in achieving them.



- **An exercise routine**

This is a 20 – 30-minute exercise routine which is safe for people living with osteoarthritis. This routine includes exercises which make you stronger (strength exercises), more flexible (stretching exercises) and fitter (endurance exercises).



1. Start by standing up straight and tall, feel your weight across your feet, relax your shoulders and open your chest, hold your head straight. Take a deep breath in and breathe out.

2. March on the spot for 2 minutes. March at a steady pace – that is a pace which you can maintain for 2 minutes. Do not start fast and get slower or start slowly and get faster. Pace yourself, start and finish at the same speed. You should be marching so that you can feel you are breathing a little bit harder than normal, you should be able to talk but not be able to sing.

3. Now stretch your neck – keep your shoulders relaxed and turn to look over your right shoulder – hold it for 20 seconds. Bring your head back to the middle, then turn to look over your left shoulder – hold it for 20 seconds and then bring your head back to the middle. Now put your left ear on your left shoulder - hold it for 20 seconds and then bring your head back to the middle. Repeat to the right. Now put your chin on your chest - hold it for 20 seconds and then bring your head back to the middle.

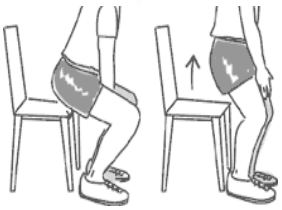
4. Roll shoulders forwards 5 times, then roll your shoulders backwards 5 times. Then stretch your arms by stretching your right arm across your body to the left and holding for 20 seconds and then repeat with the other arm.

5. March on the spot for another 2 minutes – 30 steps normal, 30 steps lift your knees up as high as you can. Keep changing every 30 steps.
6. Stretch your quadriceps muscles by bending your right leg backwards and holding your foot if possible below your buttock. You will feel the stretch down the front of your thigh. Hold it for 20 seconds and then do the same on the left.

7. Stretch your hamstring muscle by putting your right heel on the ground and pulling your toes upwards, put your hands above your knee and lean forward to feel the stretch behind your knee. Repeat on the left for 20 seconds too.

8. Sit on a chair – make both your knees straight and then bend again. Do this 30 times. This works your front thigh muscles.

   Then with your arms folded on your chest, stand up from the chair and sit down again. Keep sitting down and standing up for 2 minutes. Do this at a steady pace – that is a pace which you can maintain for 2 minutes.



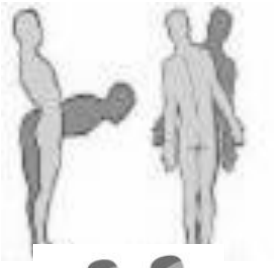
9. March on the spot for 2 minutes – 30 steps normal, 30 steps lift your feet up as high as you can (try to kick your buttocks). Keep changing every 30 steps.

10. Stand on one leg at a time for 30 seconds each: use support by putting your hand on a wall or chair if necessary but try balance without holding on. Do this twice on each leg

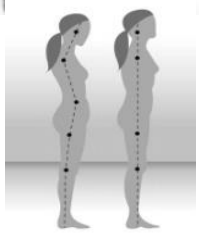
11. Step ups: Step onto and off of a low step for 2 minutes. Start with the right leg and then step up with the left leg and alternate. This works both your front and back legs muscles as well as your hip muscles.

12. March on the spot for 2 minutes – 30 steps normal, 30 steps lift your knees up as high as you can. Keep changing every 30 steps.

13. End off the session by stretching your trunk: Slide your hands down the front of your thighs to see if you can touch your toes. Bend sideways by sliding your hand down the side of your leg. Hold this for 30 seconds and then do it to the other side.



Finish by standing up straight and tall, feel your weight across your feet, relax your shoulders and open your chest, hold your head straight. Take a deep breath in and breathe out.



Action Plan Form - Exercise

Use this form to develop an action plan on exercise. What exercise would you like to do?

Be sure your action plan includes:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____*(what)*

_____*(how much)*

_____*(when)*

_____*(how many?)*

How confident are you that you can complete this action plan?

_____

Not at all | | | | | | | | | | Totally

confident 1 2 3 4 5 6 7 8 9 10 confident

Keep a record of how you did:

	I Plan to…..	I did…..
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		

Week 2: Managing common symptoms

Osteoarthritis is known to greatly affect a person's quality of life, with **pain** being the most common reason for seeing a doctor or physiotherapist. Most people with high blood pressure have no symptoms at all, but some people can also experience pain such as constant headaches and will go to the doctor for treatment.

Other symptoms which are often present are:

- **joint stiffness** (especially following a period of rest or early morning stiffness for less than two hours),
- **swelling** and problems moving the joint through the whole range of motion
- **difficulty** in performing daily tasks
- **Fatigue**
- **Frustration, isolation, depression**

Less common symptoms of high blood pressure are:

- **shortness of breath**,
- dizziness,
- chest pain,
- palpitations of the heart and nose bleeds

We will look at what each of these are and how you can manage them at home if you experience any of the above.

- **What is pain?**

It is important for you to understand what pain is and what type of pain you may experience with OA in some cases with high blood pressure in order to manage these symptoms.

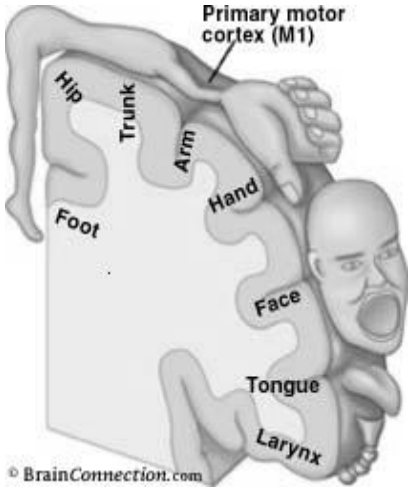
Acute pain is a normal sensation triggered in the nervous system when nerves in the body are stimulated and send messages up to the brain to say that there may be damage to your body. Acute pain comes on suddenly (e.g. after banging your finger in a door), and lasts for a few days or even weeks (usually less than six weeks) while the body heals itself.

This pain is useful as it protects the part while the body heals. Once the body is healed, there is no more pain.

OA initially presents as acute pain, which means that pain starts suddenly and lasts for a short time. This usually happens when the joint is moved or used and then the pain subsides. OA doesn't always remain as acute pain but sometimes changes to what we call chronic pain. This can cause pain when you aren't moving or even at night or during movements/activities that don't usually cause pain. Chronic pain is described as pain that is experienced on most days for at least three months. The reason behind why the pain in OA starts out as acute and then becomes chronic is not yet known but research is being done to explain this better. Chronic pain is not helpful as acute pain is. It occurs after the body has healed itself and this means that there shouldn't be a reason why we need to protect that area anymore. But often we listen to the pain and don't use that joint or do certain things in case we cause damage. In OA the "damage" in the joint is not something new that we can injure more by using it or moving it but it is caused by the wear and tear as talked about before.

The reason why chronic pain is different from acute pain is because there are changes that take place in your nervous system when you have had chronic pain for some time. These changes can explain a lot of why you may experience pain more than someone else. When acute pain happens, the normal messages that are sent via your nerves to and from the brain are often changed in people who experience chronic pain. The pathways often make the messages bigger than they usually are and this can cause a person to be more sensitive to normal feelings and feel pain more easily than someone whose messages are not sensitive.

There is also a “map” in the brain which locates each area of the body and in people with chronic pain, the areas which represent the painful area gets bigger and smudged so the brain focuses on this and can confuse some normal areas with the painful areas. This explains why the pain can feel like it is spreading from just one area as the map in your brain is not as clear as it was before.



Here is the take-home message about pain:

- **Hurt does not always mean harm**. There can be pain without injury or something being wrong due to the changes that take place in the nervous system.
- There are physiological reasons why there is pain without injury.
- Your pain is **NOT** imaginary or in your head or psychological.
- Chronic pain is **NOT** the same as acute pain.
- Chronic pain is **NOT** a sign of ongoing damage
- Chronic pain cannot be “switched off.”
- Non-pain messengers (e.g. stretching or pressure) may send pain signals rather than Stretching or pressure messages to the brain.
- An increase in your pain (with or without exercise) does not mean a new injury.

Flare ups of pain

It is possible to have both pains (acute pain and chronic pain) at the same time; this can confuse the picture. Although a person with OA may have chronic pain, pain is not necessarily present at all times and you can experience periods of less or worse pain. When pain becomes worse this is called a flare up. This means you will have acute pain at this time and there are ways to deal with this. It is important to note what causes such a flare up so you know what and how those activities can be modified in an attempt to reduce the flare up of pain again.

Common signs of a flare up are:

- a sudden increase in pain
- redness
- a warm or hot joint
- swelling

What can I do about pain in a flare up?

A flare up can be managed by taking a short time to rest from whatever has caused the flare up to allow it to settle. We don't want to rest TOO much either as then your joints can get stiff. It is helpful to take painkillers as prescribed by your doctor if your pain gets worse but we will talk about medication later on too. Putting ice onto the joint can also help to settle the flare up. Use ice for no more than 10 - 20 minutes at a time on the painful area. You can use a small bag of ice wrapped in a towel, a gel-filled ice pack or wrap a towel around a bag of frozen vegetables. Don't put ice directly onto bare skin.

- **What is stiffness?**

Stiffness is when your joints feel like they aren't able to move easily or they feel stuck. This is common in the morning just after waking up as your joints have not been moving much while you sleep. The joints get used to being in the one position and then when you try to get up and start moving it feels difficult to move (stiff).

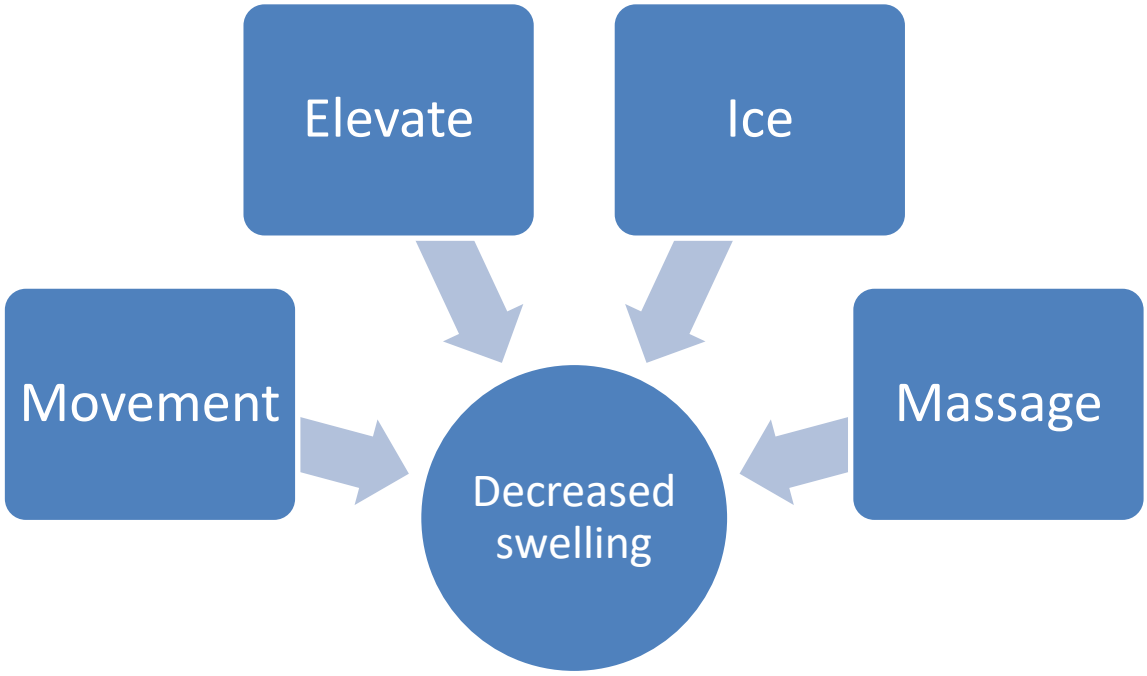
What can I do about stiffness?

After such a period of rest/sleep or limited movement the joints need to slowly get moving in order to get used to moving again. So before getting out of bed in the morning move your ankles up and down 20 times. Then bend each knee up and down 20 times and open and close your legs 20 times to get the joints warmed up. Warmth also helps the muscles around the joint to relax so a warm water bottle before rising or a warm shower in the morning will help get you moving. Make sure you can feel the warmth but it should not be directly on your skin or too hot that it will burn you. It's like the parts in a machine that need oil to work well; we need to "oil" our joints first before they work without being so stiff.

- **What is swelling?**

Swelling is a common symptom of a flare up or may be a regular symptom experienced during OA. Swelling is caused by a build-up of fluid in the tissues in and around the joint. This causes the area to feel bigger than usual, hard, painful and it's difficult to move the swollen area.

- **What can I do about swelling?**



Movement is the best option to deal with swelling as it causes blood (rich in oxygen) to flow to the area and flush out the build-up of fluid and waste in the area of swelling. Staying in one position is probably the worst thing for swelling so we want you to start moving. You can also move your feet up and down and bend your hips and knees while sitting/lying down and go for a walk to get your body active.

- It can help to **elevate the area** when sitting or lying so that gravity can help move the fluid back to the body instead of collecting in the leg. You can put your leg up on a small chair or two pillows when in a chair or the bed.
- **Rubbing/ massaging the area** from the furthest point towards the body can assist the fluid moving back to the body too. Normal body cream or baby oil will make it smooth to rub with your hands around the area. Never push the swelling downwards.
- **Putting ice on the affected area** for no more than 10 - 20 minutes at a time also helps with swelling, as explained above.

Difficulties doing certain activities:

Sometimes you may feel that you are unable to do a specific task at home or outside of the house. You may feel too stiff, weak or sore to do a certain activity. You may just need to "warm up" in the morning before trying something or you may be having a flare up and then you should follow the management tips as given above. It is alright to ask for help from a family member if you are struggling with something in the home but be careful not to be asking for your family to do everything for you.

What can I do when I am struggling with doing an activity?

First try and think about WHY you are struggling with a certain activity and then how you might be able to deal with this. There are some ways to help yourself when you feel like there are certain activities you are struggling with:

Joint protection, assistive devices

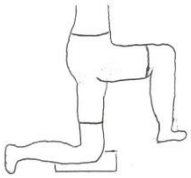
To reduce the weight and stresses through the joint, an assistive device such as a walking stick, crutch or walker can be very helpful to protect extra strain on your joints. This allows your arms to bear some of the weight of your body when stepping on the affected leg. Using one stick or crutch gives you a little support and allows one of your arms to take the full weight of your body off your leg but also allows your other arm to be free to use during activities such as preparing food or carrying items. Two crutches or a walking frame uses both arms to push through and gives more support but often take up more space while walking and both hands are being used on the device instead of being able to use them for daily activities. Try and start with the least supportive if you do feel like you need something like this.

If you have pain and stiffness in your wrist, fingers and hands due to OA, and you cannot do your normal activities like your house chores, splints or braces can often be used during activities to help protect and provide external support to weak and unstable joints.

Activity modifications:

There are certain things that can be changed in the way you do activities in order to protect the joint.

- Avoiding certain activities that put a lot of strain on the joint, like kneeling or climbing steps can be done.
- Use a padded pillow under your knee if you insist on kneeling for certain reasons
- Sit on a chair instead of kneeling
- If you struggle to stand up after sitting for some time then try sitting on a harder chair so you are not deep in the chair.
- Using a chair with armrests makes it easier to stand from.
- Avoid sitting on a low chair as it is more difficult to stand up from a lower chair than from a higher one.
- Walking up a ramp or using the elevator is better than struggling to climb steps if this is available.
- Wheelchairs are useful to use if you are going to be doing a lot of walking at one time. Like going to the shops or taking a day's outing somewhere. This may just be too much



walking at one time for your joints. Most big shopping malls have wheelchairs that you can borrow for the time you are there. Or another option is hiring a wheelchair or buying one from a pharmacy if you have the money. It is important to not rely on the wheelchair for everyday activities in the home if it's not necessary but just to use it for pacing or long distances if needed. Remember we want to keep you as able as possible.

Wheelchair hiring contact details:

Orthocare Medical Hire and sales (Bellville) 021 946 1717

Solutions Medical (Goodwood) 021 592 3370

M-Kem pharmacy (Bellville) 021 948 5706

St Giles 021 689 8328

Medical Hire 021 425 2012

If you have OA in the shoulder, elbow, wrist or hand then the following guidelines to changing your activities may be useful:

- Use larger stronger joints for activities to spread load of activity over unaffected and stronger joints. If your shoulders and hands are affected and you need to lift objects from a table, move close to the object, try bending the knees first, hug the object with both arms, bend elbows so that object is squeezed tightly to your chest and straighten the knees. Keep holding the object by keeping your elbows bent.
- If objects are too heavy to lift- then try to push object in a shopping trolley or use a bag with wheels.
- To pick up objects from the floor, move close to the object, bend down slowly with knees and hips bent and use both arms to grip the object and stand up or sit in a chair first then bend over to pick up the object.
- Avoid gripping objects tightly. Rather use a relaxed grip on pot handles, cutlery and equipment.
- Make use of both hands when doing your activities and take regular breaks during activities.
- Avoid holding hands in the same position for long periods of time.

Pacing and activity/ resting cycles:

During exercise and daily life, you need to learn to pace yourself. When you finish an activity/exercise you need energy at the end of it for your body to recover easily to enable you to carry on for the rest of the day. Exercise should not cripple you for 2 days after you do the exercise. When you start an activity you need to pace yourself at a speed at which you can maintain throughout the activity without getting faster or slower. At the end you should still have energy left over to be able to do more.

How to pace?

- Pace your activities during the day so that they are spread out with adequate rest periods in between so you don't tire yourself out in one session of too many activities.
- Find a balance between completing a task and resting. You should not do an activity for too long that you feel exhausted afterwards and you should also not rest too long so that you feel too stiff to get moving again.

For instance if you have washing and cleaning and ironing to do in a week, instead of doing all three on one day, spread them out over three days or if needed, with a day in between. Or while exercising or if you have a long day of shopping ahead of you, start exercising or walking with the trolley at a pace that you know you can keep the same until the end, without stopping or slowing down. If you find you are too tired then you must start slower or do less at one time and find the balance.

What is fatigue?

If too many activities are attempted at one time or in a short time without break periods of rest, your body will feel extremely tired and you will experience fatigue. It is important to slowly start small activities and short times of exercise to allow your body to adjust accordingly. If you do experience fatigue then it is wise to stop the activity and rest for a short while (1-2 days) until you have recovered from this tiredness.

This does not mean you need to lie in bed for this time; you can continue with your day but take a break from the exercise and then once you begin again, listen to your body and look for signs of doing too much in one go. This could be getting short of breath or your muscles feeling weak or shaky, your legs feeling like they want to give way etc and slow down.

- **What is frustration/ isolation / depression?**

It is common for people living with osteoarthritis to become frustrated and to have feelings of isolation/depression. This could be due to not being able to do everything as they could before, being reliant on others for normal tasks, not being able to participate in activities amongst friends that leads to feelings of being alone and often useless/ a burden on others.

Frustration:

As we said above, try to understand why you struggle with a certain activity and use the tips to try and help yourself in these situations before feeling frustrated or useless and giving up. It's important to look at your situation positively and see how you can solve a problem instead of feeling frustrated about it.

Isolation:

Don't stop seeing your family or friends in social gatherings because of your condition. As we mentioned, there are ways to still be social (like using a walking device or a wheelchair when necessary) and having OA should not cause you to be alone or lose your friends.

Depression:

People with chronic pain can also be depressed due to the large effect such a condition can have on daily life. This is often not picked up by the nurses and doctors at the clinic. It is important for you to tell your nurse or doctor if you think you have depression. Depression is an illness; it is not simply being sad, scared, lonely and stressed feelings. Depression develops over a few weeks and is a general feeling of depressed mood which happens with physical symptoms. This is caused by an imbalance of chemicals in the brain. See the depression checklist below – if you think you have depression and you have many of these symptoms then you probably have some degree of depression.

This can be treated with medicine and psychological support. It is not something to be ashamed of. Go to the clinic and tell the nurse or doctor how you are feeling so that they cans start you on treatment.

Depression Check List:

- Do you feel down most of the time?
- Do you lack enjoyment with fun things like music, soccer or chocolate?
- Do you try to find peace by overeating?
- Or do you lack appetite and lose weight?
- Do you sleep badly at night?
- Do you struggle to get up in the mornings?
- Do you feel angry and agitated very quickly?
- Do you feel very passive?
- Do you lack energy every day?
- Do you struggle to concentrate?
- Is it difficult to make decisions about simple matters?
- Do you feel guilty?
- Do you feel worthless sometimes?
- Do you think of death a lot?
- Do you think of killing yourself?

If you answer yes to <u>many</u> of these questions, then you may have some degree of depression. Speak to the doctor or nurse at the clinic about how you are feeling.

Home treatment for Depression:

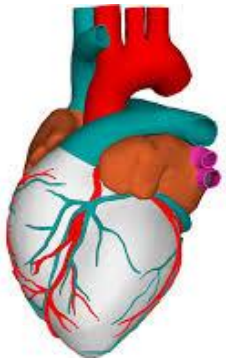
There are many things you can do to help manage depression. Make sure that you get help straight away if you feel like hurting yourself or someone else. Often talking to a person who understand or to a health professional will help you through this mood. Cut back on alcohol, although it might make you feel better in the short term. In the long term it affects the way your brain works and you will not be able to escape the depression. Keep active, make you sure you get up every day, get dressed and get out of the house. Even if you don't feel like doing things, it's important to keep active, visit friends, and join a group. If you start to lose contact with people and withdraw your mood will only get worse. Make plans for the future, for tomorrow, for next week, for next month. Make sure you do 20 to 30 minutes of exercise every day. As we said in Week 1, exercise is very important to keep us healthy and help our moods. Depression feeds on depression, when you believe that things will get better, they will start to change. Use the suggestions in the section on Week 3: Stress Management to help you manage your symptoms.

What are common symptoms of high blood pressure?

High blood pressure is known to be a big risk factor for cardiovascular disease which could lead to heart attacks, stroke and even death. High blood pressure can in turn affect a person's quality of life, as people suffering from this chronic illness may experience other chronic illnesses such as an enlarged heart, heart failure, diabetes mellitus type 2, high cholesterol, kidney disease, asthma and arthritis. Multiple chronic illnesses can have a negative impact on a person's quality of life and functioning.

It is a fact that people with high blood pressure does not complain of any symptoms. However, in the unusual case, some people may complain of the following symptoms:

- headache,
- shortness of breath, dizziness,
- chest pain,
- palpitations of the heart and
- nose bleeds



It can be dangerous to ignore such symptoms. High blood pressure is a serious warning sign that significant lifestyle changes are required. The condition can be a silent killer and it is important for everybody to know their blood pressure reading.

In the event of having any of the symptoms listed above, it is important that you take note of these symptoms and see a doctor immediately. If you should experience any of the above symptoms and delay to see a doctor, you might be at risk of getting a heart attack or a stroke.

What is the cause of headaches related to high blood pressure?

Headaches related to high blood pressure usually happens in the mornings than other times during the day. The headache is usually felt at the back of the head or pressure is felt just behind the eye. Sometimes the headache can come with dizziness as well.

Research says that these headaches can become worse in women older than 50 years, who are overweight and who are pregnant. Stress can also cause headaches related to high blood pressure. Should you experience such a headache, please remember to take the headache as a signal sent from your body to inform you that your blood pressure is not okay.

Consult your doctor about these headaches so that the problem for the headaches can be found and treated.

What can I do if I get a headache?

When you feel a headache that is related to your high blood pressure, do the following:

- Don't always run to drink your medication- once the problem for the headaches is identified, it can be treated correctly and your headache will soon disappear. Medication can be used effectively to treat headaches especially when it is combined with healthier lifestyle changes.
- Change your diet- high salt intake is a big factor for high blood pressure, reduce salt intake to less than 5g of salt per day.
- Reduce eating red meat- the high animal fat found in red meat can increase your blood pressure by causing blockages in your blood vessels. Dietary changes will be covered more in detail in week 4.
- Increase your metabolism- eating healthy foods and exercise can help you to lose weight which will increase your metabolism to help breakdown foods faster to be absorbed in your body. A slow metabolism can cause poor circulation which can cause high blood pressure.
- Reduce stress levels - refer to stress management in week 3.

Why do I feel shortness of breath at times?

Difficulty in breathing can be caused by medical problems in the body or can be caused by too much exertion. If shortness of breath (SOB) is present for a long time and occurs on a regular basis, it may be necessary for you to consult your doctor for a check-up.

If you have shortness of breath (SOB) and the other symptoms below, please see your doctor immediately:

- Shortness of breath at rest or when lying down
- Chest pain
- Pain in one or both arms, travelling to jaw or in neck
- Swelling in ankles
- Unusual tiredness
- Sweating
- Fever
- Blue discolouration of lips or fingertips
- Fainting, dizzy spells or light-headedness

What is cause of shortness of breath?

- Shortness of breath can be caused by different problems from different organs in the body
- Lung problems such as bronchitis or pneumonia or TB can cause SOB
- Asthma caused by narrowed airways which causes wheezing can cause SOB
- Lung cancer and other tumors can cause SOB
- Clots in the lungs can cause breathlessness- it is usually sudden and people breath quickly and can have chest pain as well
- Heart problems:
    - Heart failure- SOB is caused by decreased ability of the heart to fill and empty blood. People feel SOB when lying down, waking up at night with SOB, swelling of the ankles, unusual tiredness and SOB with activity.
    - Heart failure is caused by damage to the heart muscle which is caused by a heart attack or by narrowed heart valves, infections or other factors such as alcohol and drug abuse.
- Anemia- low red blood cell count causing low levels of oxygen in blood.
- Anxiety disorders can be linked to fast breathing and SOB usually stops once anxiety ends

What can I do when I feel shortness of breath?

The type of treatment depends on the medical problem causing the SOB. If you have heart failure, certain medications will be given to you such as fluid pills (diuretics). If asthma or lung infection is the cause, treatment with medications to help reduce the inflammation of the airways can be used**.**

Do the following to help reduce shortness of breath:

- If smoking- quit immediately. This will relieve some of the symptoms and reduce chance of cancer
- If asthmatic, avoid places that are dusty or that will cause your allergies to get worse
- If overweight, change lifestyle by eating healthy foods and exercising regularly
- If you have heart failure- take your prescribed medications regularly and on time

Simple resting positions below to improve your breathing:

- *Sitting a): Rest your feet flat on the floor, lean chest slightly forward. Rest elbows on your knees. Relax your neck and shoulder muscles.*

- *Sitting b): Rest your feet flat on the floor, lean chest slightly forward. Rest your arms on a table. Rest your head on your forearms or on some pillows*

- *Standing a): Stand with feet shoulder width apart, lean your hips against the wall, rest your hands on your thighs, relax your shoulders leaning forward slightly and hang your arms in front of you.*

- *Standing b): Lean forward and rest your elbows or hands on a table or any furniture that is stable, relax your neck and rest your head on your forearms.*

- *Sleeping a): Lie on your side with a pillow between your legs and your head lifted with pillows. Keep your back straight.*

- *Sleeping b): Lie on your back with your head lifted on pillows, your knees bent with a pillow under the knees.*

Why do I get chest pain?

Angina is chest pain caused by lack of blood going to the heart muscle. The pain can feel like something is pressing or squeezing your chest. Angina is not a disease but rather a symptom that is

caused by a heart problem such as coronary heart disease or narrowing of coronary arteries due to blockage of fats.

If you have the following factors below, you at higher risk of getting chest pain:

- High cholesterol levels
- High blood pressure
- Smoking
- Diabetes
- Overweight or obese
- Lack of physical activity
- Unhealthy diet
- Older age (>55 years)
- Family history of heart disease

What can I do if I have chest pain?

If you have some of these factors, please consult your doctor immediately to identify if you have angina so that you can get treatment for it. The doctor might send you for further tests (stress test, blood tests) to confirm if you have angina.

- Once diagnosed, medications will be given to you to treat the medical problem. Use it regularly.
- Lifestyle changes – healthy diet (avoid animal fats) and exercise is important to encourage good heart health and assist to lose weight.
- Quit smoking- by stopping smoking for one year, you can reduce the risk of coronary heart disease by 50%.

If you suffer from any of these symptoms because of high blood pressure and experience chronic pain from OA, you will most likely have problems and difficulty in performing your usual activities at home or work. **Refer back to section on difficulties doing certain activities** *for advice on how to manage your activities.*

You will probably also experience fatigue or tiredness from having shortness of breath and pain. If you experience this, you could feel frustrated about your health condition and overall quality of life. *Feelings of frustration, isolation and depression could also affect you. Reflect back to section about* **fatigue, frustration and depression on advice on how to deal with these problems.**

Recap: What happens when you have pain and other symptoms?

What to do to manage with this?

Action Plan Form – Managing common symptoms

Use this form to develop an action plan on exercise. What exercise would you like to do?

Be sure your action plan includes:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will use an assistive device (*what*) like 1 crutch (*how much*) when walking outside (*when*) at least three times (*how many*).

This week I will:

_____*(what)*

_____*(how much)*

_____*(when)*

_____*(how many?)*

How confident are you that you can complete this action plan?

Not at all | | | | | | | | | | Totally

confident 1 2 3 4 5 6 7 8 9 10 confident

Keep a record o

	I Plan to…..	I did…..
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Week 3: Stress Management

- **What is stress?**

In our society, we talk about stress a lot. We might say that it is stressful to live in South Africa. That it is stressful to worry about our children or our families, it is stressful to worry about money or it is stressful worrying about getting a job or coping with my job. We use the word stress a lot, but what does it mean? Stress is a feeling; it is a combination of feeling tense and worried. When we feel stressed we may be irritable, and find it difficult to concentrate or remember things, stress can affect our sleep, our appetite and our relationships.

The most common reason why we feel stressed is a lack of control. We tend to feel that things are stressful if we don't have any control over them. We feel stressed if we are going to be late for work because the trains are late – this is out of our control. We feel stressed about where we live if we don't feel safe there – those who commit crimes against us are also out of our control. In the same way, we may feel stressed when we have a chronic illness like arthritis or diabetes or high blood pressure. If you feel that your illness is out of your control and there is nothing you can do to affect it, this makes you feel stressed.

Stress is not always bad. We know that stress can be useful too. For many people if we feel some stress, we might feel under pressure to perform better. You might feel stressed because your family is coming to visit, but this stress makes you tidy up your home – a good effect of the stress. Students who are studying will only complete their studies if there are exams and deadlines for assignments, without the stress of the deadline, the students would not complete the work.

Sometimes we wish for a “stress-free” life. But, we know that if there was no stress in our lives, if we did not have to do anything all day long, this would not be good for us either. If I lay in bed all day and did not do anything, my muscles would get weak, my joints would get stiff and I would become ill. We need some stress in our lives to keep us healthy. The important thing is to keep the amount of stress at a level that we feel we can manage. This is why we talk about stress management, not stress elimination!

- **Managing stress**

There are many different things we can do in our lives to manage stress. The first step is to understand why we are feeling stressed. There are usually three things which affect how stressed we feel.

1. The stressful situation:

Usually the less you expect the situation and the less familiar you are with a situation, the more stressful it will be. If you needed to take the train to work but you knew the day before that the trains would be late, this would be less stressful than finding out after you have got onto the train that it is going to be late. If you think about having pain, if you know the cause of the pain is it more or less stressful? If you don’t know what is causing your pain and you are worrying that there is something seriously wrong, is this more or less stressful?

2. How you see the situation and how you cope with it:

If the situation you are in is not important to you, you are likely to feel less stressed about it. If you are on a train which is going to be late, but you are going shopping on your own, then you are likely not to get so stressed about it. If you are on a train which is going to be late and you are going to work this might be more stressful, but if you have a cell phone with you and you have airtime on the cell phone and you telephone your boss to explain why you will be late, then this might be less stressful. Your ability to cope with the situation, affects the amount of stress you feel. While it is stressful to live with a chronic disease like arthritis, diabetes or high blood pressure, if you thought you could cope with it and it would not interfere with your job and your life, would it be more or less stressful? Having knowledge

about your condition allows you to think about it in a different way and will change the way that you cope.

3. Support from family and friends:

Friends and family who understand and support you will affect your levels of stress. Feeling alone and like you have no support will probably make you feel more stressed. If you think about living with osteoarthritis, would it be more or less stressful if there were no one to support you? But, we do need to be careful about support from family and friends. If they take over doing everything for us (because they care about us and are trying to help), we might feel useless and like we don't have a purpose. Supporting me does not mean doing everything for me.

Stress is not just the things that happen to us. The amount of stress that we feel depends on a lot of different things which can change every day. There are many different things we can do to manage stress every day.

Dealing with the cause of the stress

The first step in dealing with stress is to identify why you are feeling this way. Use the self-management steps to help you identify the problem. Once you know why you are feeling this way then you need to decide what you can do about it. Sometimes dealing with the things that stress us is easy, if you are friends with your neighbours and the noise from their television is irritating you, it might be easy to ask them to turn down the volume. If you are not friends with your neighbours, or you are very shy, it might be quite difficult to ask them to turn down the volume. Sometimes we can identify the things that stress us and do something about it. But, often we either cannot deal with it or it is out of our control. If you cannot deal with it or it is out of your control, the next step is to change the way you are looking at the problem.

Look at the problem in a different way

Think about how you are feeling. Are your thoughts and feelings about the problem inaccurate? Maybe you are very worried about your health, this is stressing you. Are you worried that you will be very ill and unable to work soon? Are these thoughts and feelings accurate? On what information are you basing these thoughts and feelings? Have you spoken to experts about your health or are you basing your thoughts and feelings and stress on poor information?

Plan your life

Do you get stressed by the same things over and over again? Or do you find yourself getting stressed because there are times when your life is very busy? If you are doing the same things over and over and getting stressed, you might want to look at how you are dealing with it and see if you can try a different plan. What about a busy life? This is also about planning, being very busy and having no time for ourselves, can be very stressful. Plan things over time carefully, make sure you have time to at least do some relaxation or exercise even when you are very busy. Do not leave things for the last minute.

Get help from family, friends and support groups

These are a great way to decrease stress. If we want support from people though, we have to tell them clearly what the problem is and what we would like from them. Often we do not communicate clearly and this might make the stress worse! If you find your family or friends are not very helpful or supportive, it might be worth sitting down with them when you are not feeling stressed to talk about these things. It might be that they see things differently to you, this does not mean they are right and you are wrong, or that you are right and they are wrong. It just means that you see things differently and you can discuss how to handle things better. If having a discussion like this is difficult, it might be useful to ask a counsellor to help with the conversation. You can ask for assistance at a clinic or you can go to an organisation like FAMSA who specialise in family and relationship counselling.

Exercise

Exercise is a very effective way of managing stress. People who exercise regularly doing at least 20 to 30 minutes of exercise, 3 times a week have less risk of suffering from stress related illnesses. Go back to the section on exercise for more on how to exercise safely and effectively.

Exercise:

- ***Decreases stress***
- ***Helps us sleep better***
- ***Decreases pain***
- Makes us healthy and decreases our chances of developing other illnesses

Relaxation skills

When we feel relaxed, we feel calm. Sometimes if we are relaxed and we are tired, we might feel sleepy. At other times we might feel relaxed and alert and be able to concentrate calmly on tasks. Relaxation can help us to concentrate and it can help us to unwind and go to sleep. Relaxation is a very useful way to manage stress and some of the symptoms of chronic diseases such as pain.

If we are stressed, this can make our muscles tense, our hearts beat faster and we breathe faster, if we are also feeling unwell and have pain we will feel worse. Relaxation can decrease the tension in muscles and slow down our hearts and breathing and help to make us feel better. If we are stressed we often become irritable and moody, relaxation helps to calm you and make you feel more in control of your life. When we are stressed sometimes it is difficult to fall asleep as we are worrying about things out of our control, if you are also unwell, not sleeping will make you feel worse. Relaxation will help you get to sleep, this will help manage your stress and improve your health.

Just like learning to play a new sport or doing exercise, relaxation takes practice. The specific way that you relax doesn't matter; we are all different and might relax in different ways. The important thing is to practice it regularly. There are two different ways of relaxing described at the end of this section. You can do these at home in a quiet and comfortable safe place to begin with. But, once you get good at relaxation, you can relax in a crowded waiting room, on a train or a taxi. You can do relaxation anywhere!

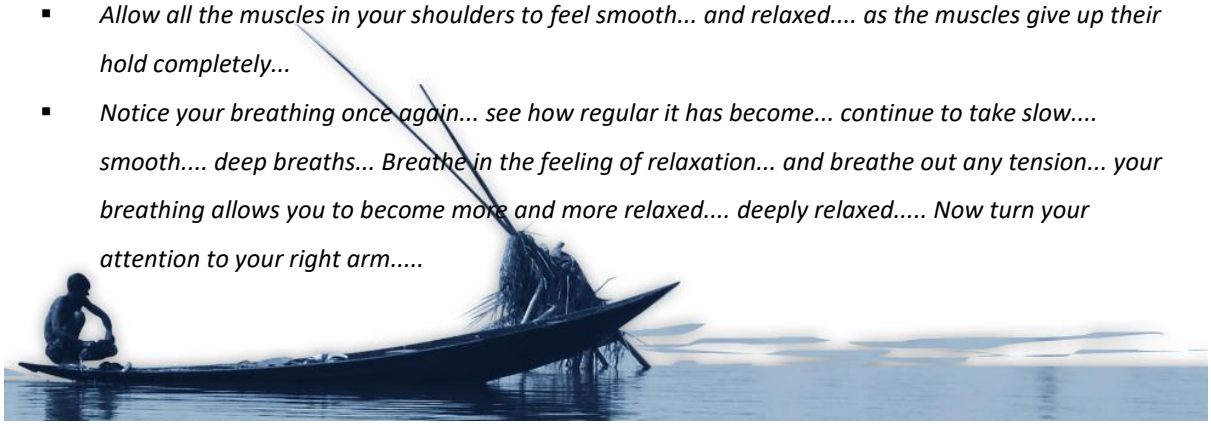
Good times to practice relaxing are when:

- ***You feel you are getting tense or irritable or you are worried***
- ***You feel you are in pain***
- ***You want to go to sleep***

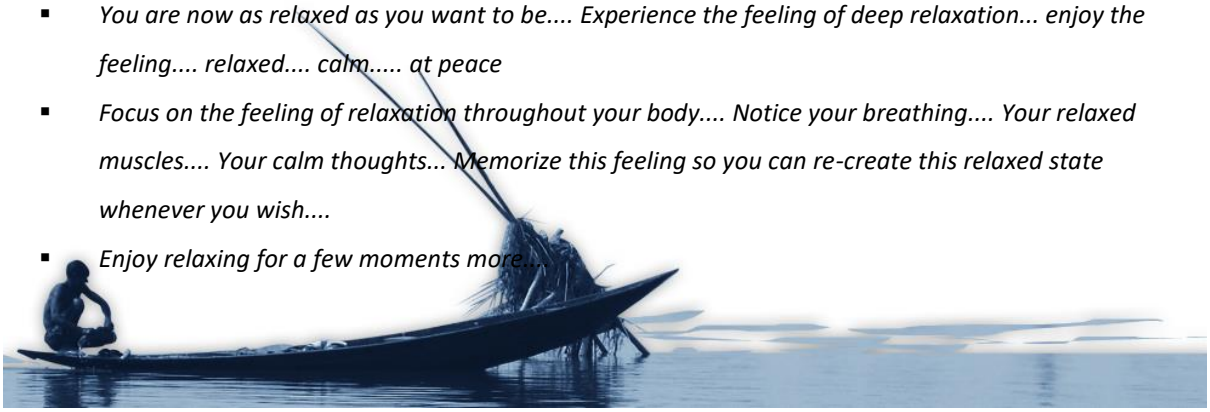
Relaxation techniques:

Long relaxation:

- *Find a comfortable position. Lie on your back or sit in a chair with your back supported.*
- *Place your hands at your sides, palms up. Close your eyes if you wish.*
- *Now begin to become aware of your breathing..... Focus on slowing down the rhythm of your breathing..... Your chest and tummy will expand outward with each breath, like a balloon gently filling with air....*
- *Imagine your ribcage moving out to the sides when you breathe in.... and gently inward as you breathe out....*
- *Slowly take a deep breath in.... Pause for a moment.... and then slowly breathe out. Let the tension melt away as you relax more deeply with each breath...*
- *Continue breathing slowly and gently....*
- *Now think about the top of your head. Feel the skin on the top of your head beginning to relax, and spreading slowly downwards....*
- *Even your ears are becoming relaxed and heavy.... Feel your eyebrows resting....*
- *Your forehead is becoming relaxed and smooth....all the lines on your face are becoming smooth..*
- *Let your jaw relax by allowing your mouth to be slightly open.... Allow your tongue to relax...*
- *Feel your throat relaxing.... relax your cheeks, nose, and eyes.... Feel your eyelids becoming very heavy.... and very relaxed.... more and more relaxed....*
- *Enjoy the feeling of relaxation you are experiencing.*
- *Now think about your neck.... allow a feeling of relaxation to begin at the top of your neck, and flow downward...*
- *Feel the relaxation as your shoulders become relaxed and loose.... Let your shoulders gently sink downward.... as they become relaxed.... and heavy.... very heavy.... and very relaxed.... deeper and deeper.... relaxed....*
- *Feel your collar bones becoming relaxed as your shoulders move gently back, and your chest widens slightly....*
- *Allow all the muscles in your shoulders to feel smooth... and relaxed.... as the muscles give up their hold completely...*
- *Notice your breathing once again... see how regular it has become... continue to take slow.... smooth.... deep breaths... Breathe in the feeling of relaxation... and breathe out any tension... your breathing allows you to become more and more relaxed.... deeply relaxed..... Now turn your attention to your right arm.....*



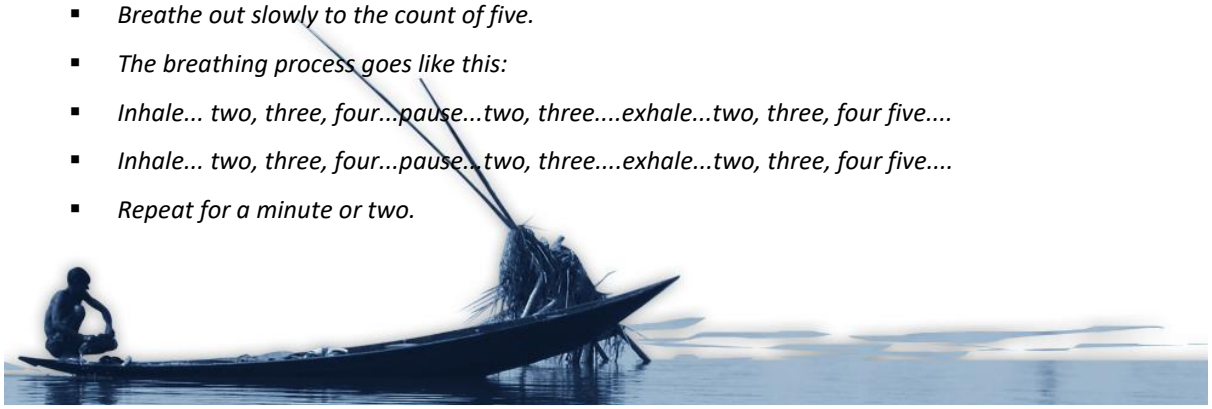
- *Feel the relaxation flowing down from your right shoulder.... allow your upper arm to relax... your elbow.... lower arm... and wrist become loose and relaxed....*
- *Enjoy the feeling of relaxation as the muscles of your right arm give up their hold.... Feel the relaxation flowing into your hand... Let all the tension drain out of each finger tip and flow away.... the relaxation spreads to your thumb... index finger.... middle finger... ring finger... and little finger....*
- *Feel the relaxation flowing down your left arm... Let the muscles of the left upper arm relax.... Relax your elbow.... lower arm.... and wrist....*
- *Enjoy the feeling of relaxation you are experiencing.*
- *Let the tension melt away.... imagine the tension flowing right out of your finger tips... Allow your left hand to relax completely.... relax your thumb... index finger.... middle finger... ring finger... and little finger....*
- *Both of your arms are now totally relaxed... allow them to be free and limp... pleasantly relaxed...*
- *Enjoy the feeling of relaxation you are experiencing...*
- *Allow the feeling of relaxation to continue to your chest and stomach....feel the relaxation there... becoming deeper with each breath....*
- *Now turn your attention to your upper back... Feel the relaxation flow down your spine... Let all the muscles give up their hold.... relax your upper back... middle and lower back.... allow your back to relax completely..... Feel the relaxation in your whole upper body ....*
- *Relax more deeply with each breath.... more and more relaxed.... deeply relaxed and calm....*
- *Let your hip muscles relax.... Relax all the way from your buttocks (bottom), down the back of your thighs... relax the muscles on the front of your thighs...Feel the relaxation in your upper legs moving down to your knees... your calves and shins.... your ankles.... and your feet.... allow all the muscles to relax and go limp....*
- *Allow any last bits of tension to flow right out of the soles of your feet....Feel the relaxation flowing through your body... From the top of your head... down to the bottoms of your feet.... become more relaxed with each breath.... enjoy the feeling of total relaxation.....*
- *You are now as relaxed as you want to be.... Experience the feeling of deep relaxation... enjoy the feeling.... relaxed.... calm..... at peace*
- *Focus on the feeling of relaxation throughout your body.... Notice your breathing.... Your relaxed muscles.... Your calm thoughts... Memorize this feeling so you can re-create this relaxed state whenever you wish....*
- *Enjoy relaxing for a few moments more...*



- *When you are ready to return to your day, reawaken your body slowly... gently move your muscles... roll your shoulders slowly forward....then slowly backward.... lean your head gently to the left... return to centre.... lean your head gently to the right... turn your head...*
- *Wriggle your fingers and toes....Gently open your eyes.... Feeling alert... calm.... and full of energy.*

Short relaxation:

- *Deep breathing not only helps to cure anxiety and stress, it also triggers relaxation. Here's how to breathe deeply.*
- *Breathe in slowly to the count of four (count slowly; to the pace of one-one-thousand, two-one-thousand....). Pause to the count of three.*
- *Breathe out slowly to the count of five.*
- *The breathing process goes like this:*
- *Inhale... two, three, four...pause...two, three....exhale...two, three, four five....*
- *Inhale... two, three, four...pause...two, three....exhale...two, three, four five....*
- *Repeat for a minute or two.*



Sleep management

People with chronic illnesses often struggle to sleep because they are stressed and worried about their condition, they worry about what this means for them, for their family, for their future. People also often struggle to sleep because of the illness itself, perhaps you have pain, you feel sick or you may even be so tired you can't sleep. Some people find it difficult to get to sleep and only fall asleep very late at night, others find that they fall asleep but then wake up during the night and can't get back to sleep. Some people find it difficult to sleep at all at night and sleep during the day.

Sleep is very important to keep healthy. We all need different amounts of sleep. Some people need 8 hours of sleep a night, some may need 10 hours and some people only need 5 hours of sleep. We are all different. We have been learning how to fall asleep and sleep well since we were babies. If you do not sleep well, following these steps will help you to learn how to fall asleep and sleep well. Remember that like learning anything new, this will take time. It might take up to 3 months to learn to sleep well if you have been struggling with sleep for a while.

Suggestions for Improving Sleep

1. Have a bedtime routine: try to go to bed at around the same time every night and always do the same things before getting into bed. A bedtime routine could be to lock the house, get undressed, wash your face, clean your teeth, get into bed and do a relaxation session.
2. You can't sleep because of worrying: write down your problems or the things that are worrying you, then write down the next step that you think could help sort out the problem. If you wake up during the night worrying about the problem, remind yourself that you've gone over it and you have a plan. If you wake up with a new worry, write down that problem to deal with in the morning. Practice your relaxation to take your mind off the worry. If you still can't sleep, it may be better to get up and do something relaxing like reading, watching TV, listening to relaxing music or doing relaxation.

3. Your bed and bedroom are for sleeping: try not to use your bedroom during the day. Do not watch TV in bed. If you are not asleep within 30 minutes of going to bed, get up and do something else. Do not lie in bed and worry that you have not fallen asleep. This will only make you feel stressed and lessen the chance of falling asleep.
4. Have a morning routine: get up at the same time every day, even if you don't feel like it. Our bodies like to work on regular patterns to fall asleep and get up at the same time every day.
5. Avoid drinks containing caffeine for at least 4 hours before going to sleep (drinks like coke, tea or coffee).
6. Never use alcohol to help you sleep. It might make you feel relaxed at first, but once this wears off it is likely to make you feel jumpy and you are likely to wake up during the night.

Good sleep habits:

- ***Go to sleep at the same time every day***
- ***Have a bedtime routine***
- ***Do relaxation before going to sleep***
- ***Use your bed only for sleeping or relaxing***
- ***Get up at the same time every day***
- ***Have a morning routine***

Communication with your health carer

Anyone living with a long-term health problem, whether it is arthritis or high blood pressure or diabetes will have to visit their clinic regularly. Visiting the clinic regularly can be stressful because it takes time, you have to plan ahead, you might not be sure how long you are going to have to wait, you might be worrying about what the health carers are going to tell you. One of the most important ways of managing the stress associated with visiting clinics and seeing health carers is to think about and plan how to communicate with them.

When visiting the clinic to see a health care practitioner it is important that you feel comfortable asking questions (any questions, even if you feel they are "silly" or "stupid" questions) and comfortable expressing how you feel. It is also important that you feel you can negotiate your treatment with your health care provider so that both you and the carer

feel that you are receiving the best care for you. It is important that you not feel that your health care provider is ignoring you, “puts you down” or treats you like a child. We know that doctors and nurses have a lot of patients to see and they have little time to spend with each person. One helpful way to make sure that you get the most out of your appointments with the doctor or nurse is for you to take PART – Prepare, Ask, Repeat, Take action.

Take PART:

Prepare:

Before your appointment at a clinic it is important to prepare. Think about the reason for your appointment and whether there are any issues in particular that are worrying you. Write down your questions or the things that are worrying you. You need to be realistic about the list you write down, there will probably only be time to answer one or two of the things on your list. Make sure the most important problems are at the top of the list. Take your list with you to your clinic appointment, then when the doctor or nurse asks if there is anything you want to ask, you can use your list.

If there are particular symptoms or health issues you want to discuss, prepare for your appointment by writing down specific information the doctor or nurse will want to know. Things that are helpful are: when did it start, how long do the symptoms last, where are they in your body, what makes you feel better or worse, have you had a problem like this before and how was it treated; have you changed anything such as your diet, exercise, medicines. If you have already received treatment for a problem, be ready to report back on how well it has worked, or on whether it has not worked at all.

Be open about how you are feeling and about the things that are worrying you. The more open you are, the more the health care provider can help you. Finally, give feedback. If you don’t like the way you have been treated you can tell the doctor or nurse.

If you do not want to tell them directly then you can speak to someone else in the clinic or to someone in a support group. Remember too that doctors and nurses and other health care providers also appreciate being complimented. If you feel that you have been treated well and are happy with your treatment, it is acceptable to compliment the health carer.

Ask:

Another important step in having good communication and decreasing stress is to ask questions. Having good information is essential to you being successful in self-managing your health. Ask questions about your diagnosis such as what is wrong, what has caused it, is it contagious and what is going to happen now? Then ask questions if you have had tests, what is the test for; what if I don't have the test and what will the test involve? Remember to ask questions about your treatment options, what are the benefits of treatment and what are the risks and side effects? Finally ask questions about follow-up, when should you return to the clinic, what should you watch out for and what should you do next?

If you find you have difficulty remembering information it is a good idea to write things down during your visit. Or you could ask someone you trust to come to the appointment with you to help with remembering.

Repeat:

One of the important things to do to help with remembering things is to repeat it. So if the nurse or doctor explains something to you, repeat back to them in your own words what you have understood. This is very useful to make sure there are no misunderstandings.

Take Action:

At the end of your appointment, it is important that you know exactly what you will need to do next. It might be that you need to make another appointment, or that you need to go home and change something or get new medicine from the pharmacy. Make sure that you are clear about what you need to do next, and then do it!

Action Plan Form – Stress management

Use this form to develop an action plan on exercise. What exercise would you like to do? Be sure your action plan includes:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will relax (*what*) using long relaxation (*how much*) at bedtime (*when*) at least three times (*how many*).

This week I will:

_____*(what)*

_____*(how much)*

_____*(when)*

_____*(how many?)*

How confident are you that you can complete this action plan?

_____

Not at all | | | | | | | | | |

Totally

confident 1 2 3 4 5 6 7 8 9 10 confident

Keep a record of how you did:

	I Plan to…..	I did…..
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Week 4: Eating well

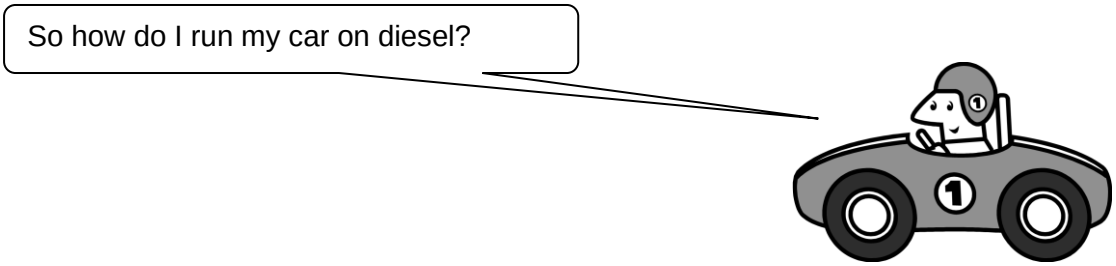
You are probably wondering why we talk about nutrition at this course. What has food got to do with osteoarthritis or the pain you are having? Well there are many good reasons for that, but if you think about it; if managing your pain is all about lifestyle changes and making decisions that are good for your health and body, surely wise food choices fit in to that as well. This section is not about weight loss – there are many people out there who are not overweight, but still suffer from terrible chronic diseases such as diabetes, high cholesterol and hypertension, on the other hand there are also overweight people, who exercise and eat a well balanced diet, but don't suffer from chronic illnesses. So it is really about how we are built and how our bodies burn what we decide to feed it. What is common for all, is the fact that when we eat a well-balanced diet that is good for us, we feel better, we have more energy and we are happier. We will try and explore why that is now.

The Diesel Diet

Think of the Human Body as a Diesel car. The Human body needs to work and chug along at a constant pace throughout the day; it can't be like a Formula One car that goes very fast for a short amount of time and then stops!

Therefore we must re-fuel our bodies constantly so we are able chug along for the whole day without running out of energy. But we also have to be careful about what kind of fuel we put into our bodies. It has to be diesel that will last us for a long time. If we give ourselves high octane petrol fuel it will give us a quick burst of energy but will run out quickly.

So, to make it easy for everyone, the "diesel" we need to feed our bodies is food that will keep us full for long and keep the body's blood sugar levels steady. It is the high octane fuel we need to keep clear of. These are for example sugary and highly processed foods, such as cakes, pies, chocolates and any "quick fixes"; the kinds of foods which most parents know that if they gave it to small children would give them lots of energy to run around a lot before they collapsed exhausted!



Two Schools of Thought

At the moment there is a lot of scientific research about what kind of foods we can categorise as healthy. There are generally two schools of thought. **One favours a low fat and high carbohydrate diet** and the **other favours high protein and low carbohydrate diet**. In this booklet there will be a choice of the two. With your doctor or a dietician, you can decide which one would suit you better. It is very important to emphasise that whichever suits you, neither one should contain high simple carbohydrates, that is foods containing a lot of sugar and starch. So in order to understand the options, we need to look at the food groups, from which we make our food choices. Let us have a look at what these food groups are:

Carbohydrates

Carbohydrates are often called starches or carbs. There are two kinds of carbohydrates – simple and complex. They both provide the body with energy. But the simple carbs give you a quick fix (lots of energy very quickly and a subsequent high rise in blood sugar, followed by a rapid drop and you feel tired and hungry again quickly). The complex carbs raise your blood sugar more slowly and so you feel more energised for longer. It is safe to say, we need more of the complex carbs than the simple ones. Let's look at the difference.

Examples of complex carbs

Examples of simple carbs

Why do we need Complex Carbohydrates?

Carbohydrates are your most important source of energy.

Where do the Complex Carbohydrates (diesel fuel) come from?

- Grains
- Brown Rice
- Oats
- Whole Wheat
- Lentils
- Vegetables – mainly green and leafy (broccoli, cabbage, lettuce)
- Whole wheat Pasta
- Whole Wheat/Brown Bread/rye bread
- Potatoes

What are the Simple Carbohydrates (high octane fuel)?

- Sweets
- Cake
- Sugar
- Biscuits
- Syrup
- Sweetened Cereals (e.g. Fruit Loops, Coco Pops)
- **White Rice**
- **Wheat based pasta**
- **White Bread**
- Chips/Crisps
- Pies & Pastries
- Fizzy drinks like Coca Cola

NB! **Even on a high carbohydrate diet, you need to keep clear of the simple carbohydrates! Simple carbs are very addictive – the more you eat the more your body wants. They are easily accessible, take no time to prepare and unfortunately are often cheap choices.**

Protein

Why do we need Protein?

Proteins are important for building and repairing muscle, blood cells, bone, hair, organs, other bodily cells and making hormones. They are also an important source of energy.

Where does the Protein come from?

- Animal Products
    - Meat (Red meat, Fish, F
    - Eggs
    - Milk
    - Cheese
    - All other Dairy Product
- Beans
- Seeds & Nuts
- Grains
- Soy Products

Fibre

Why do we need Fibre?

- Fibre is important for the smooth running of our stomachs.
- It helps prevent constipation.
- It helps prevent Stomach Cancer
- **It is especially important if you are taking lots of pain killers and anti- inflammatory drugs, which slow the stomach down.**

Where does the Fibre come from?

- Vegetables
- Fruit

- Whole-Grain Bread, Pasta & cereals
- Oats, Oat bran
- Brown Rice, beans, lentils
- Potato Skins

Fat

Why do we need Fat?

- A source of fuel for muscles and brain
- Primary source of energy when exercising hard.
- Helps with constipation

Where does the Fat come from?

Good (unsaturated) Fat

- Vegetables
- Fish Oil
- Olive oil
- Nuts& Seeds
- Avocados

Bad (Saturated) Fat

- Animal Foods
- Dairy Food
  - Butter
  - Milk
  - Cream
- Margarine
- "Snack" Foods
  - Chips/Crisps
  - Samoosas
  - Pastries

- Fried Foods
- Trans Fats

l

Some helpful Guidelines:

- Bad (saturated) fat and increased fat consumption can increase your chance of having a Heart Attack, Stroke and Diabetes.
- Avoid hard fats such as butter, margarine and animal fats. Focus on olive oils, grape seed oil and oil from avocados, nuts and seeds.
- Don’t fry or roast food, rather, steam or microwave the food or eat it raw.
- Rather Grill meat than fry it or roast it.
- Use Olive oil rather than butter, Canola Oil or Lard.
- **Read the food labels and eat low fat food! The total fat should be less than 10g per 100g**.
- Use non-stick pans instead of oil.

So now that we know all about the food groups, how do we put it all together? Let us have a look at the two different kinds of diets described earlier:

LOW FAT – HIGH CARBOHYDRATE DIET

If you burn carbohydrates well, or feel like you need to lose some weight or at least want to benefit from better nutrition, a balanced diet of very little saturated fats, complex carbohydrates and some protein might do the trick.

On this kind of diet, it is important to keep the diesel going throughout the day and in doing so eating 5-6 smaller meals is the best way. There are more carbohydrates in this diet, which will not keep you full for as long as the protein rich diet, so you will need to eat more often. It is therefore suggested that your daily meals consist of:

1. Breakfast
2. Mid Morning Snack
3. Lunch
4. Afternoon snack
5. Supper
6. Late night snack (if you go to bed late).

The following foods are recommended for this kind of diet:

- Whole Grain foods

  (Oats, brown/whole wheat bread, Low GI bread, Oat cereals, Whole wheat cereals)

  - Protein – lean fish and chicken, only red meat occasionally
- Fruit
- Vegetables
- Fats – no saturated fats. Stick to olive oils, nuts, avocado, seeds

This kind of diet should contain a balanced variety of the following food groups:

- Carbohydrates (complex!)
- Proteins
- Fibre
- Fat
- Vitamins and minerals

How much carbohydrate?

- 25-50% of all food intake
- At one meal the carbohydrates should amount to the size of your first.
- Keep clear of simple (high octane) carbs

Some helpful Guidelines!

- Cut Back on High Octane Foods; avoid fizzy drinks

  (A single can of fizzy drink has up to 3 tablespoons of sugar in it!)
- Try eating as much whole grain and whole wheat as possible
- Eat your carbs with help of **The Tables 1, 2, 3 below**

How do I choose the right carbs?

The tables below will help you choose the right kind of carbs. **Table 1** we call ***"The Good Carbs"***. You should choose most of your carbs from this table. The carbs from Table 1 will help you sustain your energy levels – this is food that is good for your brain and muscles. These foods help prevent tiredness and give you a nice even flow of energy throughout the day. They are also ideal in maintaining your weight in the sense that they don't make you crave more foods like the bad carbs often do. In other words they are not quick fixes. **Table 2** ***"The Not so Good Carbs"*** are carbs that you should be aware of not eating too many of and finally **Table 3** ***"The Bad Carbs"*** should be avoided as much as possible. Here is a recap:

Table 1: Good Carbs - Eat most of your carbs from this group

Table 2: Not so Good Carbs - Eat in moderation from this group

Table 3: Bad Carbs - Avoid eating from this group

TABLE 1	***GOOD CARBS***
Food Group	***Examples of foods***
Dairy	Low fat/fat free: Milk, Yoghurt, heart foundation margarine spreads, cottage cheese.
Starches	All dried and canned beans, Peas, Lentils\Dahl, Baked beans, Boiled barley wheat, Pasta made from whole wheat or durum wheat-semolina, Sweet potato, Mealies/corn, cold samp, brown rice.
Bread	Provita, Seed loaf bread no added sugar, Pimpernickel bread, rye bread, any other bread with lots of whole kernels, crushed wheat, and oat bran inside.
Cereals	Bokomo Pronutro Wholewheat, Hi Fibre Bran, Cold Mealie meal, Oat Bran, All-bran flakes, Fine Form muesli no added sugar, shredded all bran.
Vegetables	All vegetables not mentioned in table 2 and 3. Stick to leafy and green ones.
Fruit	All deciduous fruit e.g. apricots, cherries, peaches, plums, pears, apples. All citrus fruit e.g. oranges, naartjies, grapefruit and lemons. Kiwi and grapes – watch portions there is a lot of sugar in fruit – if in doubt stick to berries. Avoid: See fruits in Table 2 and 3
Snacks	Sugar –free jams and sweets, low fat popcorn.
Drinks	WATER! Sugar free cool drinks, no more than 2 glasses of fruit juice per day.

TABLE 2	***NOT SO GOOD CARBS***
Food Group	***Examples of foods***
Dairy	
Starches	Sweetcorn, potatoes with skin, coarse mealie meal porridge, white rice, couscous.
Bread	Ryvita, brown bread
Cereals	Kellogg's fruitful bran, Bokomo pronutro flakes, Tastee wheat Kellogg's corn pops, Kellogg's frosties, Kellogg's choc's, Mealie meal –reheated or with added corn
Vegetables	Beetroot
Fruit	Tropical fruit e.g. banana, mango, sultanas, paw-paw, pineapple and litchis, grapes, melons. Dried fruit: sultana, dates and raisins.
Snacks	Bakers Home-wheat digestive biscuits, Low fat biscuits containing oat bran, Low fat bran/fruit muffins/pancakes, Low fat oat bran crumpets, Raw honey, Jam Sugar, Fine form canned peaches, Fine Form apricot jam
Drinks	Juice of fruits in this table – 1 glass only, Regular cold drink- cordials and soft drinks

TABLE 3	***BAD CARBS***
Food Group	***Examples of foods***
Dairy	
Starches	Potatoes: boiled, mashed, baked and fried, Minute noodles, Rice especially sticky rice, Samp, Mealie rice.
Breads	All white bread, all bread rolls and anything made with cake flour, bread flour and nutty wheat flour, Rice Cakes, Snackbreads
Cereals	Mealie meal – refined and sugar added, Puffed wheat, Maltabella, Instant Oats, Kellogg's strawberry pops and frosties (any sugary cereal).
Vegetables	Carrots and carrot juice, Pumpkin, Hubbard Squash, Butternut, Parsnips
Fruit	Watermelon, Dried fruit rolls
Snacks	Sweets –boiled and jelly type, Bakers Marie biscuits, Commercial honey, Glucose, Maltose
Drinks	Game, Energade, Powerade, Lucozade

Protein

How much do I need?

- 50-65g per day.

Some helpful Guidelines!

- Lean meat, poultry or fish (the size of a deck of cards) contain 25 to 35 grams of protein. Remember this is a low fat diet and all animal produce contain saturated fats, therefore you need to avoid fatty meats and processed meats.
- One cup of cooked beans or lentils contains about 18 grams of protein.
- One cup of low fat cottage cheese contains 28 grams of protein.
- 60 grams of solid cheese contains about 16 grams.
- One cup of low fat milk contains 8 grams.
- Two tablespoons of peanut butter contain 8 grams.
- One serving of grain foods (barley, pasta, cereals, whole wheat bread, for example) generally contains 3 to 6 grams of protein.
- One serving of vegetables ranges from 1 to 3 grams

FIBRE

How much do I need?

- You need 25-35g of fibre per day

Some helpful Guidelines!

- Choose whole-grain breads and pasta. (Flour from whole wheat contains three times as much fibre as refined white flour.)
- Choose brown rice instead of white. (Brown rice has three times as much fibre).
- Eat the whole fruit instead of juice. (One orange contains about six times as much fibre as a glass of juice).
- Stir a few tablespoons of wheat germ into yogurt or hot cereal; add a couple of tablespoons of bran to pancake or waffle batter.
- Start your morning with cold or hot cereals that contain at least 4 grams of fibre in a serving. Read package labels and compare fibre content. Add fruit to your breakfast cereal.

- Pack cold cereal, fruit or cut-up vegetables in your briefcase or handbag for nibbles.
- Buy cut-up raw veggies at a salad bar or vegetable stand if time is short.

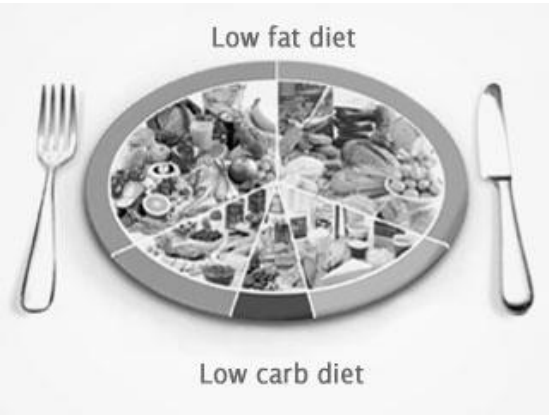
FAT

Remember there are saturated and unsaturated fats. On this diet you need to focus on the unsaturated fats which come from non-animal sources such as olive oils and low-fat spreads or your avocado, nut and seed oils, as well as fish oils.

How much do I need?

- For one meal the total fat should amount to the same size as the tip of your thumb or one to two teaspoons.

HIGH PROTEIN – LOW CARBOHYDRATE DIET



There is good scientific research showing that if you suffer from a sluggish metabolism, that is your body doesn't burn food very efficiently, you may benefit from a high protein – low carbohydrate diet. People who suffer from this have a hard time losing weight, you gain weight easily, get easily bloated when eating bread, rice, pasta and cereal. The researchers think this is because some people's bodies do not metabolise carbohydrates that well – even some of the carbohydrates that are more complex, such as pasta and rice.

On the high protein diet the main focus is on eating good and wholesome protein, such as lean meat, chicken, ostrich and fish. The kind of protein that you should keep clear of are processed meats like

salami, poloni and spreads. They often contain a lot of saturated fats, sugar, flour and additives that are not good for us. With this kind of diet you are allowed to eat dairy foods too, for example cheese, eggs, full cream milks and yoghurts. Like any other diet it is encouraged that you choose nuts and seeds and good oils for fats and use less saturated fats such as cream and butter.

In terms of complex carbohydrates, these are very important but in this diet you get these from leafy vegetables. These leafy vegetables include broccoli, cabbage, lettuce, sprouts – basically most vegetable are acceptable BUT you need to avoid starchy vegetables such as potatoes, pumpkin, sweet potatoes and parsnips. These vegetables have a lot of natural sugars in them and if your body doesn't need them, they are converted into fat and your blood sugar levels rise.

You can eat some grains – but stick to brown rice, barley wheat, bulgur and quinoa for example. Like any diet it is important that you get fibre to maintain your stomach health. Most of your fibres you will get from the vegetables. Although it is not recommended to have lots of fruit, some is ok, especially berries as they are high in fibre and low in sugar content. Don't drink fruit juice as it will overload you with sugar (many pieces of fruit go into one glass of juice).

Eating Guidelines

PROTEIN	Amount	Avoid	CARBS	Amount	Avoid
Lean meats: Beef, pork, chicken, fish, ostrich, ham, tofu	About 150-250g/daily	Processed meat like Salami,pollony, sausages	Green vegetables	A good fist size portionwith every meal	Starchy vegetable like potatoes, sweet pot. Parsnip,
Diary eggs, cheese or full cream yoghurt or milk	About 50-100g/daily	Avoid too much cream	Other vegetables i.e. tomatoes, cucumber, peppers, carrots	In moderation	Pumpkin, butternut
Nuts and seeds	50g/daily		Grains brown rice, barley wheat, bulgur, quinoa	Small portions	Bread in general, but especially wheat based, white pasta and rice
Legumes and lentils	50g/daily	Too many – they also high in carbs	Fruit stick to berries	1-2 pcs per day (large)or handful of berries	Sugary fruits like grapes and bananas

FATS	Amount	Avoid
Omega 6 oils: Olive oil, grape seed oil, rape seed oil, avo oil	In moderation with all meals	Margarine spreads. Sunflower oils
butter	Only small amounts (thumb sized)	Mayonnaise (made from sunflower oil)
Avocado, nuts and seeds	½ avo per day, 50g of nuts and seeds per day	

What foods should I avoid eating for my high blood pressure?

As you have read in the previous sections, changes to your diet is very important to help control your blood pressure and to prevent heart attacks and strokes.

Research has found that people who have high blood pressure should reduce or eliminate salt from their diets to help manage their chronic diseases.

It is recommended that adults should use **less than 5 grams of salt (one level teaspoon)**, and at least **3,510 mg of potassium per day.** Even a small reduction in the sodium in your diet can reduce blood pressure by 2 to 8 mm Hg.

To decrease sodium in your diet, consider these tips:

- Read food labels. Choose low sodium foods and drinks
- Sodium or salt is found naturally in a variety of foods, including milk and cream and eggs- do not add salt to these foods
- Salt is also found, in much higher amounts, in processed foods, such as bread, processed meats like polony and viennas, snack foods such as pretzels, chips, cheese puffs and popcorn.
- Salt is found in sauces such as soy sauce, tomato sauce, stock cubes and instant soups.
- Fast foods such as fish and chips, gatsbys, chip rolls, pies have high amounts of salt in it as well.
- Do not add extra table salt to your cooked foods; rather use fresh herbs for additional flavour.
- Avoid drinking alcohol as it can increase your blood pressure
- Drink less coffee as it increases your blood pressure- drink fresh water instead or herbal teas.

Potassium can lessen the effects of sodium on blood pressure. The best source of potassium is food, such as fruits and vegetables, rather than supplements.

Potassium-rich foods that you should include in your diet:

- Beans and peas, nuts, vegetables such as spinach, cabbage and parsley
- Fruits such as bananas, papayas and dates.
- Processing reduces the amount of potassium in many food products.

What about drinking habits?

On all healthy diets we need fluids. Often when we feel hungry, it is the body telling us we are in fact thirsty. So we need to drink enough fluids and our main source of good fluid is of course water. We have some of the cleanest tap water in the world here in South Africa – and it is free! SO go ahead and have a free treat! But in all seriousness, why is it important to drink water and avoid some of the other choices of drinks out there? Let us explore:

Water

Why do we need water?

- Water makes up 50-55% of your body weight.
- Water and Oxygen are the most needed elements for life.
- Carries nutrients to, and waste away from cells
- Cools the body
- Necessary for proper body and organ function.

Where does the water come from?

- The fluid you drink
- The water in the food you eat
- Chemical reactions inside your body

How much do I need?

- We usually recommend that adults drink 6 to 8 glasses of water a day but this water includes the water in the food we eat so you don't have to be drinking a whole 8 glasses.
- If it is **very hot** or you are doing **lots of exercise** you need to drink **more** than 8 glasses.

Some helpful Guidelines!

- Drink when you are thirsty.
- Drink at least one glass of water/juice every morning with breakfast.
- Drink 2 glasses one hour before exercising and another after exercising.
- Caffeine (Coffee, tea & Coke) and Alcohol make you lose water. These are poor sources of water.
- Often when you take a lot of medication you lose your appetite and you might resort to coffee and tea with lots of sugar. Try to avoid this and stick to 1-2 cups per day. Also try and substitute normal tea with rooibos teas.
- Alcohol really doesn't go well with medication. But if you really enjoy it, women shouldn't drink more than 1.5 glasses per occasion and men 2 glasses. You should also know that alcohol has been shown to worsen the symptoms of osteoarthritis.
- In general, juices from supermarkets are highly processed and contain a lot of sugar even when labels say 100% fruit juice. If you have juice, one glass a day is plenty – and when possible, rather a piece of fruit and then a glass of water.

Losing Weight

Now that we know about healthy diet options, the question remains: *Why do I actually need to lose weight?* There are several answers to this, but first and foremost, not all of us need to lose weight. It is only when you are heavily overweight or what doctors call obese, that your weight becomes a big problem. Remember when you first came to the hospital to do questionnaires and tests? We also measured your BMI (Body Mass Index), which is a measurement of your weight according to your height. If you have a BMI of more than 25, you should be concerned. If you don't know whether your weight is a problem, here is a way to calculate your BMI: Your weight in kg divided by your height in meters times your height in meters. To give you an example: If a person weighs 88kg and she is 1.70m tall, her BMI = 88/1.70x1.70 = 30. This person would be classified as obese 1 according to the table below.

BMI Class	Range
Underweight	<18
Normal	18-25
Overweight	25-30
Obese 1	31-35
Obese 2	35-40
Obese 3	>40

What we know from research is that osteoarthritis is closely linked to obesity and being heavily overweight. What this means, is that when you weigh a lot more than you should, there are added stresses and strains on your body's joints. In particular the big joints like the hips and knees. This means that when doing daily activities or exercise your symptoms of pain increase and the natural reaction is to stop being active. Therefore, if you are heavy, losing weight will improve your condition by decreasing the loading on your joints and it will feel a lot easier for you to move around, do exercise and daily activities. It is never too late to change your mind set and lose weight – and no matter how old, young, tall or short – it will make you feel good about yourself.

Therefore, should you choose to lose weight, you can follow the guidelines for diets, which we have already gone through. Remember losing weight is not about starving yourself, but making

sure that the food we eat, fills us up, gives us energy throughout the day and makes us shed the unwanted kilos.

What about those who's BMI is normal? Well, as we have already talked about – you can be thin or normal and still benefit from a healthy diet. It will still give you the improved energy and make you feel less fatigued and most importantly help with your medicine uptake (we will talk more about this in a later chapter).

"I find it hard to eat well!"

Now that you know what you should be eating let's talk about why people living with OA may be struggling to eat enough. The reasons for not eating enough could be that they do not want to eat because they just don't feel hungry or because they are too tired to eat or they are too worried to eat or they feel like they will vomit if they eat, or food just doesn't taste good any more. The next section gives ideas on ways to manage these problems.

t

"I'm not hungry"

On the days when you do feel like eating, make sure you eat well to make up for days when you might not be eating so well. On the days when you do not feel like eating try to eat small meals more often, maybe 6 times a day. Eat in a relaxing place, maybe with a friend. Keep small snacks (healthy) with you in your bag or next to your bed so that if you wake up or suddenly feel hungry you can eat straight away. Make sure these snacks have lots of energy in them (are complex carbs). Make sure you have your favourite foods to eat, even if it's just a little bit, it helps.

"I get full too quickly"

You might be trying to get all your food at one meal. Try to spread it out more by eating five or six times a day. When you do eat, make sure it is food with lots of energy and protein. Don't eat foods without energy first and then feel too full for the important foods.

"Food doesn't taste so good"

Medicines can change the way food tastes. Sometimes you may have a bitter taste or a taste of metal in your mouth. Try cleaning your teeth and your tongue before you eat. If you have a taste of metal in your mouth, try to drink orange juice or another tart drink.

"My mouth is dry"

A dry mouth might be a side effect of medications. You can help this by avoiding smoking and drinking alcohol as well as sugary drinks as these irritate your mouth and throat and make you even more thirsty. Eat softer food, if you mash your food or make soup as this will be easier to swallow. Try not to eat food with a lot of spices or drink fizzy drinks. Keep a bottle of water next to your bed so that you can drink during the night.

Action Plan Form – Nutrition

Think about your eating habits. Use this form to come up with a plan to improve ***one*** thing about your nutrition.

Be sure your action plan includes:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will eat less simple carbs (*what*) by cutting out one (*how much*) during dinner (*when*) everyday (*how many*).

This week I will:

_____*(what)*

_____*(how much)*

_____*(when)*

_____*(how many?)*

How confident are you that you can complete this action plan?

_____

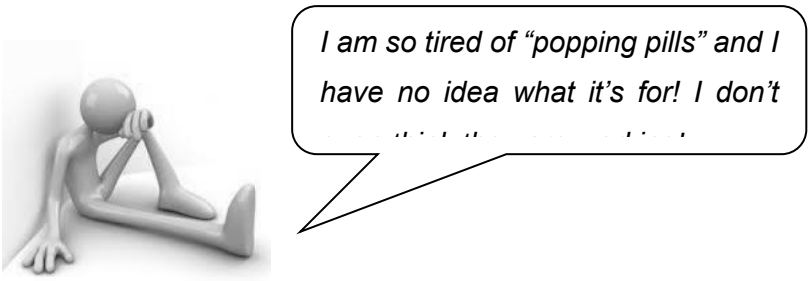
Not at all | | | | | | | | | | Totally confident

1 2 3 4 5 6 7 8 9 10

Keep a record o

	I Plan to…..	**I did…..**
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Week 5: Medication and disease related problem solving



Surely you can recognise the above? At this stage, "popping pills" is not an unusual occurrence to you. Unfortunately with a chronic condition like osteoarthritis and high blood pressure, taking medication is a huge part of trying to keep the symptoms at bay. Unfortunately it often comes with a lot of physical negatives and unanswered questions. One of the most common experiences for OA patients is that after taking the medications for many years – they seem to lose their effect. Why is that? Also, many OA patients take many different kinds of medication, without always understanding how they work and what they are for – what is each medication meant to do? In this section we will look at the different kinds of groups of medications and try to understand it all a little better. There are a few things that research has found out as well, and that is if a patient understands the medication and its purpose, the medication becomes more effective.

Many kinds of drugs are used for osteoarthritis and its symptom management. The majority of them fall into one of 4 categories.

- Analgesic Drugs
- Anti-Inflammatory Drugs
- Anti-spasmodic Drugs
- Antidepressants and Antiepileptic Drugs.

Analgesic Drugs

The name is derived from the Greek word analgia: **an-**, "without", and **-algia**, "pain". In other words analgesic drugs are what we commonly refer to as “painkillers.” The analgesic drugs act in various ways on the nerves. These are the nerves in our brains (the central nervous system) and our bodies (the peripheral nervous system) peripheral and central nervous system. There are 3 main types of analgesic drugs, let us have a look at them:

Mild Pain Killers

These painkillers don’t treat the cause of the pain but they work on the nerves in the peripheral nervous system which are telling you that you are in pain. They basically tell the nerve to stop sending messages. ***I.e. they tell the nerve to shut up!*** This is exactly what is needed for people with osteoarthritis and associated chronic pain, because the painkillers decrease the number of signals in the peripheral nervous system – remember when pain has been ongoing for a long time, it often intensifies and “gets louder” even though your tissue is not getting more damaged. In other words the nervous system is malfunctioning and sending mixed up messages. The mild pain killers have very few side effects, which makes them attractive compared to some of the stronger medications. These medications are available over the counter. Examples of such drugs are: **Panado, Paracetemol, Grandpa, Disprin, Asprin, Panadol, Calpol, Panaleve**

Strong Pain Killers - Opioid Analgesic Drugs (MORPHINE BASED)

These drugs are a lot stronger than the normal pain killers. They are similar to a hormone that the body produces, called Opiates…which is why we call them Opioid Analgesics. These drugs work straight on the nerves by blocking the messages in the brain and spinal cord. These medications need to be used carefully as there is a small chance that they can produce dependence, addiction and tolerance. Other side effects include drowsiness, decreased alertness (take care when driving a car), sedation, elation (sudden joy) or dysphoria (unhappiness). Respiratory side effects can include feeling short of breath and not coughing as much as you should.

People with asthma or chronic obstructive lung disease should be careful when using these drugs. Other side effects from these drugs can be nausea, dry mouth and vomiting, constipation and difficulty in passing urine and itching. If you take opioids for a long time, the effects often fade. Many oral opioids are used in the treatment of chronic pain. Combining opioids with other painkillers such as paracetamol and NSAIDs involves attacking the pain in the different areas of the nervous system. This often decreases your opioid requirements, which then leads to improved pain relief and a reduced risk of side effects. These medications require a prescription from your doctor. Examples of these drugs are**: Morphine, Fentanyl, Methadone, Pethidine, Tramaset, Tramadol, Codeine**

Medium Strong Painkillers + Codeine

These drugs are a combination between the Mild Pain Killers and the Opioid Analgesics. The dosage of codeine is much lower than the strong pain killers. They are stronger than the Mild Pain killers but weaker than the Opioid Analgesics. Anything with a “co” or a “codeine” added to the name will fall into this category. For Example: Panado Co, Myprodol, Empacod and Tramadol. These medications are sometimes available over the counter and you need to be careful if you are taking these and one of the other mild or strong painkillers as you might be taking too much of one drug without realising it.

Anti-inflammatory Drugs

These drugs reduce inflammation. Inflammation is the body’s response to injury. For example when you twist your ankle, it will go hot and red and become swollen and painful. These are all signs of inflammation. Like pain, inflammation can be acute or chronic. Acute inflammation last only for a few days, whereas chronic inflammation lasts longer. Anti-inflammatory drugs treat both acute and chronic inflammation. Unlike analgesics they treat the cause; Anti-inflammatory drugs help to decrease the heat, redness and swelling. There are 2 types of Anti-inflammatory drugs.

Non-Steroidal Anti-inflammatory drugs (NSAIDs)

This group of drugs is effective against mild to moderate pain and inflammation. They are widely used for arthritis and pain conditions. “Non-steroidal” means that they are not steroids (i.e. they do not belong to the “cortisone” family). Steroids are very effective against inflammation, and the term NSAID is used to tell the difference between this group of drugs from the steroid family of drugs.

“Anti-inflammatory” means that they are effective against inflammation. Some are better against pain and some better against inflammation. It is also important to know that different people react differently, so that one product might work well for one person, but may not be as effective in another person. It is important you talk to your doctor about these issues.

Some of these drugs also have negative effects on the stomach and digestive system. They can cause constipation, ulceration in the stomach and even bleeding in the stomach. It is therefore important to take NSAIDs with or after food. If you have a sensitive stomach with these drugs your doctor will prescribe one of the new NSAID drugs which do not have the same effect on the stomach. With chronic pain it is important that you take these drugs regularly for them to be effective. Examples of NSAIDS are: **Ibuprofen, Brufen, Voltarin, Asprin/Disprin, Paracetamol, Pyroxicam, Betacin, Naproxen, Ketoprofen** Sometimes doctors will combine anti-inflammatory drugs with Mild Pain Killers because they work better together than each on its own. Some pills come with them already together in one pill. E.g. (Mypradol).

Steroidal Anti-inflammatory Drugs

These drugs are made to mimic natural steroids that your body produces. They are very strong anti-inflammatories and are often used for arthritic conditions. However there are negative effects of short term and long term use. In the long term it can cause high blood pressure, high blood sugar levels, eye problems, fragile skin, osteoporosis and muscle wasting. Steroidal injections have fewer side effects than orally taken steroidal anti-inflammatory drugs and are used more often for arthritic conditions. Examples are: **Cortisone, Cortisol**

Anti-spasmodic Drugs

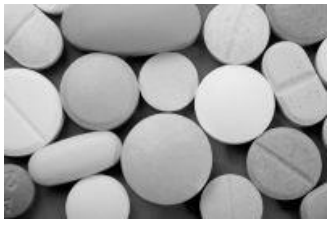
When a person is in pain, their muscles become very tense and can often spasm. These drugs are used to relieve the spasm. However they do come with severe side effects if taken for longer than recommend – especially if taken together with other chronic medication. It is therefore important to understand these when your doctor prescribes them. Commonly used antispasmodic medication used for chronic pain is: **Diazepam, Baclofen**

Anti-depressant & Anti-Epileptic Drugs

The brain is very sensitive to chemicals therefore, there is something called a Blood-Brain Barrier, which filters all the blood going to the brain to make sure there are no chemicals in the blood that would harm the brain. Because of this, drugs like mild painkillers cannot reach the brain. Antidepressants and Antiepileptic drugs are able to pass through the barrier and act on the brain. For this reason they are given to patients with chronic pain. You remember all the changes to the nerves that happen in the brain in a person with chronic pain. These drugs can help to normalise the pain signals in the brain. They are given to chronic pain patients in much smaller doses than they would be given to a clinically depressed person or a person who has epilepsy.

It is important that these drugs are taken regularly and for at least 2 weeks before they begin to be effective. Side effects can include: Scratchy eyes, drowsiness, dry mouth, constipation and blurred vision. But these side effects usually decrease with time.

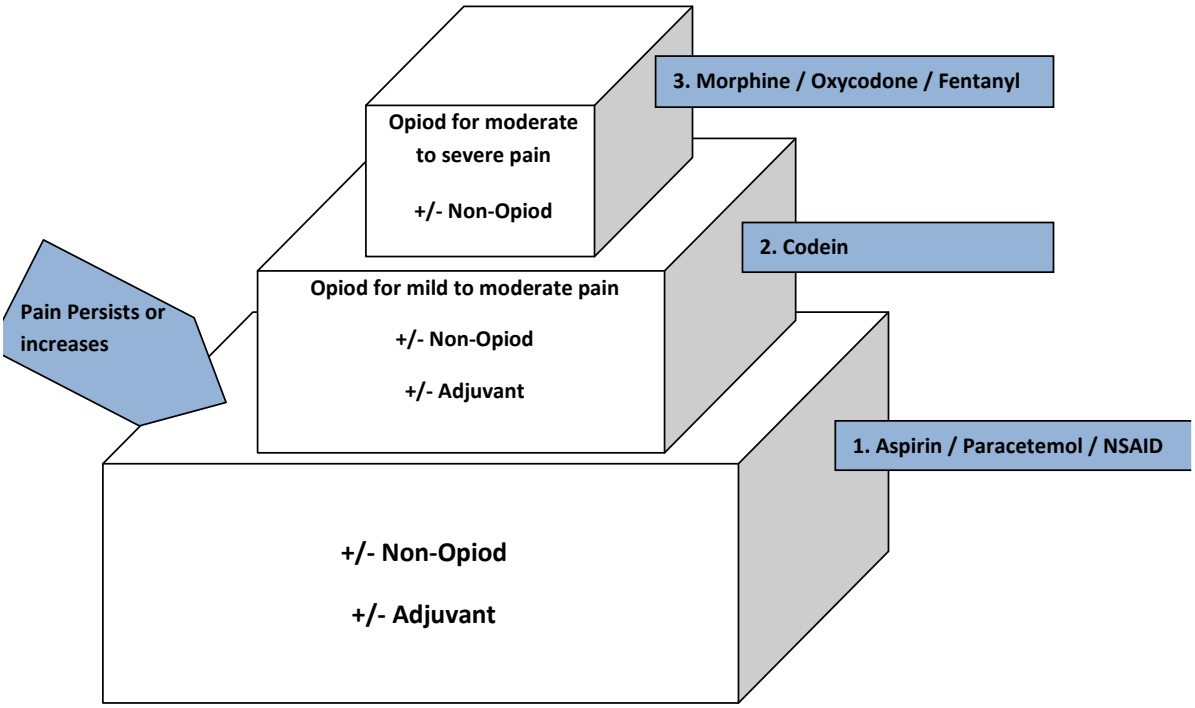
Examples of **ANTIDEPRESSANTS** are: **Amitriptyline, Doxepin, Desipramine, Imipramine**. Examples of **ANTIEPILEPTICS** are: **Gabapentin, Topiramate, Vigabatin, Phenytoin, Oxcarbazepine, Sodium Valporate, Carbamazepine, Lamotrigine**



The Analgesic Ladder

The analgesic ladder was designed by the World Health Organisation (WHO) to assist the doctors when prescribing analgesic drugs by suggesting a logical way for managing pain in chronic conditions.

The ladder takes into consideration the analgesics we have already described earlier. At every step of the analgesic ladder non-opioid analgesics form the basis of the pain management. Paracetamol and NSAID should therefore always be prescribed with opioid analgesia (weak or strong). This is known as multi-modal analgesia and is the concept that pain is best managed, not by a single drug or therapy, but by combinations, with maximum effect whilst keeping side-effects low. Scientific research has demonstrated that when this happens pain relief is better, smaller amounts of pain killers are needed and fewer side effects occur.



Medication for High blood pressure

Many kinds of drugs are used for **high blood pressure and its symptom management**.

The major types of medications are:

- Thiazide-type diuretics
- Angiotensin-converting enzyme (ACE) inhibitors
- Calcium channel blockers
- Beta blockers

Thiazide diuretics

Thiazide diuretics (water pills) are medications that *help the body get rid of excess sodium (salt) and water and help control blood pressure*. They work by reducing the ability of the kidneys to reabsorb salt and water from the urine and into the body thereby increasing the production and output of urine.

Thiazide diuretics are used to treat high blood pressure and congestive heart failure as well as the accumulation of fluid and swelling of the body caused by conditions such as heart failure, cirrhosis, chronic kidney failure and corticosteroid medications.

What are some examples of thiazide diuretics?

- chlorthalidone (Thalitone)
- hydrochlorothiazide (Ridaq)
- methyclothiazide
- furosemide (Lasix)

What are the side effects of thiazide diuretics?

- dizziness and light-headedness,
- blurred vision,
- loss of appetite,
- itching,
- stomach upset,
- headache, and
- weakness.

Other side effects and adverse reactions are:

- An increased sensitivity to sunlight (prolonged sun exposure should be avoided)
- Owing to their ability to increase the production of urine, these drugs may lower levels in the body of potassium and magnesium which also are present in urine.
- Thiazide diuretics may increase uric acid levels in blood.
- Like other antihypertensive medications, thiazides cause sexual dysfunction.

With which drugs do thiazide diuretics interact?

- Thiazide diuretics can lower potassium and magnesium blood levels since they are both eliminated in urine. Low levels of potassium and magnesium in the blood can result in abnormal heart rhythms.
- Drugs such as nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen can reduce the effectiveness of thiazide diuretics in lowering blood pressure because they may reduce the ability of the kidneys to make urine, particularly in patients who have reduced kidney function.
- People who have diabetes may have increased blood sugar levels when taking thiazide diuretics.
- It is not recommended to use thiazide diuretics drugs used for treating abnormal heart rhythms.

Angiotensin-converting enzyme (ACE) inhibitors

Angiotensin II is a very potent chemical produced by the body that primarily circulates in the blood. It causes the muscles surrounding blood vessels to contract, thereby narrowing vessels. ACE inhibitors are medications that slow (inhibit) the activity of the ACE enzyme, which decreases the production of angiotensin II, a substance in your body that affects your

cardiovascular system by narrowing your blood vessels and releasing hormones that can raise your blood pressure.

As a result, blood vessels enlarge or dilate, and blood pressure is reduced. This lower blood pressure makes it easier for the heart to pump blood and can improve the function of a failing heart.

Examples of ACE inhibitors

Many ACE inhibitors are available. Which one is best for you depends on your health and the condition being treated.

Examples of ACE inhibitors include:

- Benazepril (Lotensin)
- Captopril
- Enalapril (Pharmapress)
- Fosinopril
- Lisinopril (Zestril)
- Moexipril (Univasc)
- Perindopril (Aceon)
- Quinapril (Accupril)
- Ramipril (Altace)
- Trandolapril (Mavik)

What are the side effects of ACE inhibitors?

ACE inhibitors are well-tolerated by most individuals. Nevertheless, they are not free of side effects, and some patients should not use ACE inhibitors.

ACE inhibitors usually are not prescribed for pregnant women because they may cause birth defects.

Individuals with bilateral renal artery stenosis (narrowing) may experience worsening of kidney function, and people who have had a severe reaction to ACE inhibitors probably should avoid them.

The most common side effects are:

- Cough
- Elevated blood potassium levels
- Low blood pressure, dizziness
- Headache
- Drowsiness
- Weakness
- Abnormal taste (metallic or salty taste)
- Rash

For what conditions are ACE inhibitors used?

- ACE inhibitors are used for controlling high blood pressure, treating heart failure, preventing strokes, and preventing kidney damage in people with hypertension or diabetes.
- ACE inhibitors also improve survival after heart attacks. In studies, individuals with hypertension, heart failure, or prior heart attacks who were treated with an ACE inhibitor lived longer than patients who did not take an ACE inhibitor.
- ACE inhibitors are an important group of drugs because they prevent early death resulting from hypertension, heart failure or heart attacks.
- Some individuals with hypertension do not respond sufficiently to ACE inhibitors alone. In these cases, other drugs often are used in combination with ACE inhibitors.

With which drugs do ACE inhibitors interact?

ACE inhibitors have few interactions with other drugs. Since ACE inhibitors may increase blood levels of potassium, the use of potassium supplements, salt substitutes (which often contain potassium), or other drugs that increase the body's potassium may result in excessive blood potassium levels.

There have been reports that aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDS) such as ibuprofen may reduce the blood pressure lowering effects of ACE inhibitors.

Patients receiving diuretics may experience excessive reduction in blood pressure when ACE inhibitors are started. Stopping the diuretic or increasing salt intake prior to taking the ACE inhibitor may prevent excessive blood pressure reduction.

Calcium channel blockers (CCBs)

In order to pump blood, the heart needs oxygen. The harder the heart works, the more oxygen it requires. Angina (heart pain) occurs when the supply of oxygen to the heart is inadequate. By dilating the arteries, CCBs reduce the pressure in the arteries. This makes it easier for the heart to pump blood, and, as a result, the heart needs less oxygen. By reducing the heart's need for oxygen, CCBs relieve or prevent angina. CCBs also are used for treating high blood pressure because of their blood pressure-lowering effects.

For what conditions are calcium channel blockers used?

CCBs are used for treating high blood pressure, angina, and abnormal heart rhythms (for example, atrial fibrillation, paroxysmal supraventricular tachycardia).

They also may be used after a heart attack, particularly among patients who cannot tolerate beta-blocking drugs, have atrial fibrillation, or require treatment for their angina. CCBs are as effective as ACE inhibitors in reducing blood pressure, but they may not be as effective as ACE inhibitors in preventing the kidney failure caused by high blood pressure or diabetes.

CCBs are also used in the prevention of migraine headaches.

What are the side effects of calcium channel blockers?

- The most common side effects of CCBs are constipation, nausea, headache, rash, edema (swelling of the legs and feet with fluid), low blood pressure, drowsiness, and dizziness.
- Liver dysfunction and over growth of gums may also occur.
- Like other blood pressure medications, CCBs are associated with sexual dysfunction.

What calcium channel blockers are available?

- amlodipine (Norvasc)
- amlodipine and atorvastatin (Caduet)
- amlodipine and benazepril (Lotrel)
- amlodipine and valsartan (Exforge)
- clevidipine (Cleviprex)

- diltiazem (Cardizem)
- felodipine (Plendil)
- isradipine (Dynacirc)
- nifedipine (Adalat, Procardia)
- nicardipine (Cardene)
- nimodipine (Nimotop)
- nisoldipine (Sular)
- verapamil (Calan, Isoptin

Beta blockers

Beta blockers, also known as beta-adrenergic blocking agents, are drugs that block norepinephrine and epinephrine (adrenaline) from binding to beta receptors on nerves. Norephinephrine and epninephrine are produced by nerves throughout the body as well as by the adrenal gland. They serve as neurotransmitters (chemicals that nerves use to communicate with one another), and also are released into the blood. There are three types of beta receptors and they control several different functions based on their location in the body.

- beta-1 (β1) receptors are located in the heart, eye, and kidneys;
- beta (β2) receptors are found in the lungs, gastrointestinal tract, liver, uterus, blood vessels, and skeletal muscle; and
- beta (β3) receptors are located in fat cells.

Beta blockers primarily block β1 and β2 receptors and thereby the effects of norepinephrine and epinephrine. By blocking the effects of norepinephrine and epinephrine, beta blockers reduce heart rate; reduce blood pressure by dilating blood vessels; and may constrict air passages by stimulating the muscles that surround the air passages to contract considered an adverse side effect.

What are some examples of beta blockers?

- acebutolol (Sectral)
- atenolol (Tenormin)
- betaxolol (Kerlone)
- betaxolol (Betoptic S)
- bisoprolol fumarate (Zebeta)
- carteolol (Cartrol, discontinued)
- carvedilol (Coreg)
- esmolol (Brevibloc)

What are the side effects of beta blockers?

Beta blockers may cause:

- Diarrhea
- Stomach cramps
- Nausea
- Vomiting

Other important side effects include:

- rash,
- blurred vision,
- muscle cramps, and
- fatigue

As an extension of their beneficial effect, they slow heart rate, reduce blood pressure, but may cause heart failure or heart block in patients with heart problems.

Beta blockers should not be withdrawn suddenly because sudden withdrawal may worsen angina (chest pain) and cause heart attacks or sudden death.

- Beta blockers that block β2 receptors may cause shortness of breath in asthmatics.
- As with other drugs used for treating high blood pressure, sexual dysfunction may occur.
- Beta blockers may cause low or high blood glucose and mask the symptoms of low blood glucose (hypoglycemia) in patients with diabetes patients.

For what conditions are beta blockers used?

Beta blockers are used for treating:

- Abnormal heart rhythm
- High blood pressure
- Heart failure
- Angina (heart pain)
- Tremor
- Prevention of migraines

They also have been found to prevent further heart attacks and death after a heart attack.

With which drugs do beta blockers interact?

Aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) (for example, ibuprofen) may counteract the blood pressure reducing effects of beta blockers by reducing the effects of prostaglandins. Prostaglandins play a role in control of blood pressure.

Making informed treatment decisions

By understanding the medication you are being prescribed, it will help you to understand its action as well as why it is to be taken together with other drugs or at specific times. For example it makes sense to take NSAIDS with healthy food, as we have learned that they can be rather rough on the stomach. If you were to take the NSAIDS with coffee and or very acidic foods, you have a high chance of getting an irritated stomach and or heart burn. In relation to the stronger pain killers, which might make you drowsy, they can be taken at a time where you don't have to be so alert or have to drive.

By understanding the medication you are on, research has shown us that the medication actually works better. Knowing more about your medicines also helps you understand, why you might at times have new and strange symptoms, these being related to some of the side effects we have discussed earlier. In this way your conversations with your doctor can improve, as you will be in a better position to tell him or her what does or does not seem to work for you.

By understanding the medicinal options for osteoarthritis, it becomes easier for you to be part of the decision making process, when deciding on which treatment option to go for. You are slowly becoming your own expert.

Appropriate use of medications

What is really important to understand well, is the analgesic ladder. Here you can see how and why the different groups of medications are prescribed at what stage of your pain. Therefore you must make sure that whatever level you are on in terms of medication, that you don't go ahead and start "prescribing" your own medication. You have to make these decisions together with your doctor by understanding them and communicating with him or her.

Link between a healthy lifestyle, good nutrition and exercise

It is really important to understand that medication is "only" one of the ways in which we can try and control your OA and high blood pressure. That is also why we are doing this course. By a combination of your medication, a healthy lifestyle with good eating and exercise, decreasing the stresses in your life and maintaining your social life, you are on a good path to being the "manager" of your disease.

Healthy food helps the uptake of your medication – remember you have more energy, which in turns will help you handle the many side effects. Also by eating a fibre rich diet, the side effects of NSAIDS will be less.

By adding exercise, activities and social engagements to your life, you become happier – remember the body's own production of endorphins (the happy hormone)? The more we can produce of these, the better we feel, the more we want to do and the less we think about the pain and the downsides to living with OA. Also, by becoming an active "manager" of our lives, we can decide which stresses we can do something about, and which we cannot do anything about. We make the choices and make sure that when life does become a bit too stressful and hectic, to take a step back and say: I need to take a break from that, and focus on myself. This ultimately makes us better at communicating with our surroundings.

Communicating effectively

If we understand ourselves better, we can communicate better – it is as simple as that. We will be able to explain what is going, we will be able to show we are in charge of our own body and mind and thereby condition. We will be able to say, that although we are making good lifestyle choices for ourselves, there are days and times when things aren't that great, where the pain is really bad, but we can still communicate and get ourselves back on track when the next "good" day comes along. This makes is easier for our loved ones, friends and colleagues to help and

support us. In this way, it becomes easier to say: I need a bit of space to cope, so I can get back on track again. Can you help me with this today? When they see you are making the positive changes, they are more willing to eager to help and understand.

Week 6: Continuing as a successful self-manager

Recap of key components of successful self-managing

Over the last six weeks you have learnt many skills which will help you to live positively with your condition. Research tells us that people living with any chronic disease who follow these steps have better quality of life, have fewer sick days and have better disease control. This is true for people living with high blood pressure, cancer or depression. You have learnt how to be a positive self-manager by being able to solve problems and set goals for yourself so that you can move forward with your life. You have learnt about the importance of exercise. How exercise can make you feel better, what exercises you should do and you have been doing those exercises too! You have learnt about the common symptoms that trouble people living with arthritis and you have learnt how to manage these symptoms. You have learnt about pain, what might be causing pain and how to treat and manage any pain you may have. You have learnt about food and eating well and how to make sure that your food is safe. With all of these you have also had the chance to practice doing things differently and to think about how this has made you feel.

- ### Action planning for the future

Now it is time to think about the future. People with long term illnesses often worry about what will happen if they get very sick, how they will manage their lives; how they will they look after themselves or their families. Worrying about these things can also make people feel sad, angry or depressed and helpless. These emotions may make everything feel even more difficult than they are. By working through this book you have already started to deal with these emotions. You have increased your knowledge and this is one of the main ways that we manage fear. If we are afraid of something, knowing more about it helps us to tackle the fear. If you know more about it, you can make a plan around it and making a plan helps us to get a sense of control over the very thing that we are afraid of.

Planning for the future means thinking about the things that might happen to you in the future and planning for them. You may never ever need to use the plan as the things that you worry about may not happen, but, having a plan will help you to worry less about these things and

stay in control should they happen. You can use the action planning forms you have been using in this workbook to think about the things which worry you about the future. You can then start making a plan about what you want to do if these things happen. If you are not sure about making a plan, you may want to talk to different people who might be able to help you with this.

Step 1:

To be able to plan for the future, you need to decide what it is that you are worried about happening. This can be the hardest step to think about. For example you might be feeling very sad and depressed. First you need to think about why you are feeling that way. It might be that you are worried about not being able to look after your family if you become ill, or you may be worried about making someone else ill, or you may be worried about not being able to look after yourself, or you may be worried about dying. Once you have identified what it is that worries you and makes you feel sad, depressed, angry or afraid then you can start to make a plan to deal with it. This will help you to feel less sad, depressed, angry or afraid.

Write down here some of the things that might happen in the future that you worry about:

1) _____

_____

2) _____

_____

3) _____

_____

Step 2:

Now that you have identified some of the things which worry you, you can start to think about different ways to manage these things. If you were worried about becoming ill and not being able to look after yourself, write down a list of things that you would need help with. Then write down who you could ask to help you with those things. The people who can help might be family, friends, social workers, counsellors, nurses, physiotherapists, occupational therapists or doctors. If you are not sure who could help you, you may want to talk to someone you trust to help you identify who could help.

Write down here three different things you could do to help plan for the things in the future that you worry about:

1) _____

2) _____

3) _____

There are many organisations and people who you can approach for help in planning for the future. These organisations include the Treatment Action Campaign (TAC), the Family and Marriage Society of South Africa (FAMSA), your church as well as the health care practitioners at your local clinic. The contact details for these organisations are included at the end of this section.

Once you have completed Step 2 and written down three different things you could do to help plan for the things in the future that you worry about, choose the one which seems to suit you the best (this might be one which is easier or is cheaper or you know has worked for someone else). Now use this action plan form to work out what you will do if the thing which you worry about happening should happen. ***You can use this method to plan for any of the things which worry you.***

Action Plan Form for Future Worries

I am worried that in the future I will not be able to:

_____

_____

My plan to manage this if it happens is to:

_____

_____

_____

_____

_____

_____

_____

(what, who, how, when?)

How confident are you that you can complete this action plan? *(Remember you are aiming for 7 out of 10 on the confidence line)*

_____

Not at all confident	| 1	| 2	| 3	| 4	| 5	| 6	| 7	| 8	| 9	| 10	Totally confident

- Reflection on changes

Over the last 6 weeks you have learnt many things about how to live with a chronic illness like osteoarthritis. You have learnt about the disease and how to be a successful self-manager. This does not mean that you should be managing your health on your own. What it does mean is that you now have the ability to manage your health and your life as part of the health team. Remember you are not alone but are part of a team of people whose aim is to help you get the most out of life. We encourage you to keep using the skills you have learnt in this workbook to live positively. There are extra "Action Plan Forms" and "Exercise Diaries" in the back of the workbook for you to use. Try to keep using these forms to help you remain active and give you a sense of purpose and accomplishment in your life. Being active and involved, using the skills you have learnt in this workbook are important steps in helping you achieve the best quality of life you can. In the box write down some of the important changes you have made in your life over the past few weeks.

Changes I have made in my life:

Now, your final task is to think about changes you still want to make in your life. Remember, this is about getting the most out of life, increasing your quality of life. Are there still some things missing in your life, things that you would still like to be able to do? In the box below, write down some of the things that are still missing. You can use this list to keep working on your goals from now on.

Things that are still missing in my life:

You have now completed this workbook. By working through this workbook you made an important commitment to yourself. You have chosen to spend time looking after yourself and you have taken steps to overcome the many challenges that people living with osteoarthritis face. Do not put this workbook away; keep it somewhere safe where you will be able to review it from time to time. We all forget things at times and it is useful to be able to look back and remind ourselves of things we may have forgotten. We can also look back and see how far we have come. We hope that the knowledge and the skills you have learnt by using this workbook will continue to have a positive effect on your life.

Appendix E-2: Exercise Diary

Exercise Diary

Use this exercise diary to keep track of your exercise goals and activities.

Start off by writing down your goal.

Write down here what you want to be able to do: _____

Now, what do you want to be able to do *this week* which will help you to reach your goal?

Remember from your action plan to include:

What you want to do

How much you are going to do

When you are going to do it

How many days a week you are going to do it

For example: This week, I will walk (*what*) around the block (*how much*) before lunch (*when*) three times (*how many*).

This week I will:

_____*(what)*

_____*(how much)*

_____*(when)*

_____*(how many?)*

	Exercise Planned	**Exercise I did...**	**How did I feel? Do you need to change anything?**
e.g.	*20 mins in a.m. after breakfast and in p.m. after supper*		*Very tired by the second session, I'm going to cut it down to morning only for this week.*
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

Appendix E-3: Acceptability of intervention

This questionnaire is for women between the ages of 45 -65 years attending the intervention programme at CHC's in Cape Town.

This questionnaire is about how you experienced the intervention programme.

This questionnaire is **completely voluntary.** You may choose not to participate or not to answer any specific question.

This questionnaire is **completely anonymous.** Please make no marks of any kind on the survey which could identify you individually.

INSTRUCTIONS

Give your honest opinion

Thank you very much for your co-operation

ID code _ _ _ _ _ _ _ _ _
Date: _

Age: _

THE FOLLOWING QUESTIONS ASK ABOUT HOW YOU PERSONALLY FEEL ABOUT THE PROGRAMME YOU ATTENDED FOR 6 WEEKS

Q1. What did you like the most about the programme?

Q2. What did you like the least about the programme?

Q3. What would you change about the programme?

Q4. What would you add to the programme?

Q5. What did you think about the self-management book?

APPENDIX F: Additional results of studies

Appendix F-1: Chapter 3-the validation of the adapted COPCORD questionnaire

Question	Responses	Expert 1 (MH)	Expert 2 (JJ)	Expert 3 RP)	Changes made
Home language	English, Afrikaans, isiXhosa and other	OK	Ok	Ok	Ok
Children	None 1 child, 2 children, 3 children, more than 3 children	Ok	Do not use categorical options. Change to how many children do you have?	I would go categorical – how many children do you have? Why are you asking the question? Are you interested in dependents – if so you may need to rephrase this	Changed it to an open question and change question to: how many children do you have?
Highest level of education	No schooling Grades R to 3 Grades 4 to 6 Grades 7 to 9 Grades 10 to 12 College, university or technickon	Separate out college option to college, technical training, college graduate, postgraduate education	Just ask for the number of years of schooling, or what the highest grade that you obtained at school? Maybe include post-schooling as a separate question	How many years of school have you completed? Or as suggested – what is the highest grade and then what is highest post school qualification.	Changed it to: what was the highest level of education that you obtained at school or after school?
Did you stop working due to any illness/ injury? If yes, why?	Musculoskeletal conditions (stiff joints/ spine) Chronic diseases Accident/ traumatic Injury Physical disability Other Illness	Ok	Will everyone know what chronic disease covers? What if someone is physically disabled due to a stroke (chronic disease)?	Ok	Changed- wrote high blood pressure, diabetes, cancer in brackets
Have you changed work due to any illness/ injury? If yes, why?	Musculoskeletal condition (stiff joints/ spine) Chronic diseases Accident/ traumatic Injury Physical disability Other Illness	Ok	Will everyone know what chronic diseases mean. Same point as above	Will everyone know what chronic diseases mean	Change- wrote high blood pressure, diabetes, cancer in brackets

Question	Responses	Expert 1 (MH)	Expert 2 (JJ)	Expert 3 RP)	Changes made
Do you receive a government pension or grant?	Yes No	Ok	Need to distinguish between a pension and a disability allowance. Also what about foster care grant or child support (if granny looking after child). So ask how many of the following grants do they get.	Also need to know if it's a permanent disability grant or a temporary one – they are often given temp ones	Changed to- Do you receive any of the following grants- tick all that apply- Answers: No grant, pension, temporary disability grant, permanent disability grant, foster care grant, child care grant, other grant
Are you the only provider for the family (breadwinner)?	Yes No	Ok	Ok	Ok	Ok
History of smoking	Never smoked Stopped smoking Currently smoke If smoking, how many cigarettes per day? If smoking, at what age did you start?	Ask when stopped	Details will not really help unless you want to analyse them specifically. Smoking/non-smoker/ex-smoker is most probably enough.	Why do you want to know this? Unless you are going to infer something from their pack history?	Add next to stopped smoking- how long ago, then create opening for number of years. Delete the last two options
History of alcohol use	Never used alcohol Currently drinking alcohol Stopped drinking alcohol If drinking alcohol, how many times per week do you drink? If drinking alcohol, at what age did you start?	if stopped, when?	Same point as above	Are you thinking of inferring something about behaviour change? Adherence? Otherwise you have plenty of other information and do you really need this?	Add next to stopped drinkng- how long ago, then create opening for number of years. Delete the last two options
Have your been diagnosed with any of these chronic diseases?	High blood (Hypertension) Sugar (Diabetes Mellitus Type II) Obesity (overweight) Cholesterol (hyperlipidaemia)	Ok	Ok	Ok	Ok

Question	Responses	Expert 1 (MH)	Expert 2 (JJ)	Expert 3 RP)	Changes made
How long (months/years) have you been diagnosed with these conditions?	High blood Sugar Obesity Cholesterol	Ok	Would change this to when were they diagnosed. And maybe categorise – last six months, over one year ago but less than 2, over two years ago. Include "If you have them	Would change this to when were they diagnosed. And categorise – last six months, over one year ago but less than 2, over two years ago.	When were you diagnosed with these conditions- create categories- last six months, a year ago, 2 years ago, over 2 years ago, 5 years ago, over 5 years ago
Did you use medication for these chronic diseases in the last 3 months?	Yes No	Don't you want to ask if on current medication as well as past use?	Combine this with question below. Do you use medication – tick all that apply. First option – no medication, then the others.	Combine this with question below.	Combined this question to one below- Do you use medication for your chronic diseases? If YES- tick all that apply
If yes, what medication did you use?	Over the counter pain killers Prescribed medication for high blood pressure Prescribed medication for diabetes Prescribed medication for high cholesterol Natural remedies, herbs, supplements Other	What about current medication?	Combine this with question above. Do you use medication – tick all that apply. First option – no medication, then the others.	What about prescribed pain killers? NSAIDs?	Combined this question to one below- Do you use medication for your chronic diseases? If YES- tick all that apply Answers: No medication, over the counter pain killers, will add prescribed pain killers and anti-inflammatories…. and add the rest of list
Do you use the prescribed medication on a regular basis as advised?	Yes No	Ok	Not sure whether people will answer truthfully – need to be more specific. E.g. in the last two weeks have you taken your medicine once or twice a day as the clinic sister told you to do.	Need to be more specific, in the last two weeks have you taken your medicine as the clinic sister told you to do.	Changed question- In the last two weeks, did you take your medicine every day as instructed by the clinic sister?
If no, what is the reason for not taking the medication on time?	I don't like taking too many pills I forget Some tablets make me feel sick, drowsy or sleepy Other reason	Don't you want to know if people cannot afford their medication?	Ok	Ok	Ok

Question	Responses	Expert 1 (MH)	Expert 2 (JJ)	Expert 3 RP)	Changes made
If yes, have you followed an exercise Programme yet?	Yes No	Are you currently following an exercise Programme? If so how often do uou do it?	Maybe need to find out what exercise Programme was prescribed. DO you mean simply being told to take more exercise or having a set of exercises specifically given to them?	Ok	Changed: If yes, did you follow the exercise Programme? Answers: No, yes, Had followed the exercise Programme, Had not followed the exercise Programme,
During the last 3 months have you experienced pain, aching, swelling, stiffness (tightness) in or around your joints or back which is not related to an injury / accident?	Yes No Not sure	Ok	Ok	Ok	Ok
During the last 7 days have you experienced pain, aching, swelling, stiffness (tightness) in or around your joints or back which is not related to an injury / accident?	Yes No Not sure	Ok	Ok	Ok	Ok

Appendix F-2: Chapter 3-validation of the adapted COPCORD phase II questionnaire

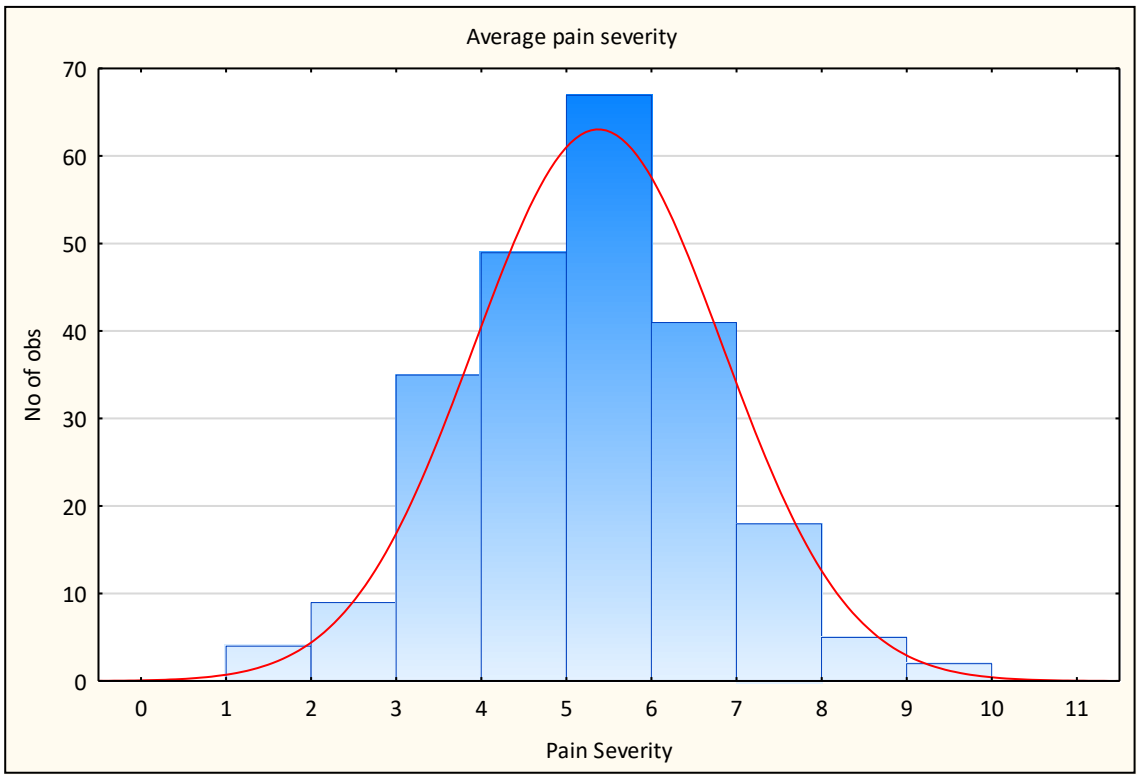
Question	Responses	Expert 1	Expert 2	Expert 3	Changes made
Please indicate on the figure below, with a ✓ all the sites where you have experienced **pain** in the last 3 months and with a X all the sites where you have experienced **swelling**.		Ok	Ok	Ok	Ok
Please indicate on the figure below, with a ✓ all the sites where you have experienced pain in the last 7 days and with a X all the sites where you have experienced swelling		Ok	Ok	Ok	Ok
When is the pain most intense?	In the morning After an activity (doing something) While resting at night Other	Ok	Ok	Ok	Ok
During the last year have you experienced stiffness in your joints in the morning after getting out of bed or after a long rest without movement?	Yes No Not sure	Ok	Ok	Ok	Ok
If yes, indicate the site/s of stiffness in the following joints	Neck Upper Back Shoulder Elbow Wrist Fingers Lower Back Hip Knee Ankle Toes	Ok	Why don't you include this on the body chart. X for pain O for stiffness?	Not sure that the body chart idea will work – may get confusing information	Did not change this question
Did the stiffness go away after exercise	Yes No	What if the stiffness did not	Ok	Ok	Ok

Question	Responses	Expert 1	Expert 2	Expert 3	Changes made
or movement of the joint?	Not sure	go away with movement but by some other intervention. There is no question to determine that			
Have you been diagnosed with arthritis or other joint diseases like rheumatism?	Yes No	Ok	Ok	Ok	Ok
Have you been taking any medication for joint or back pain, not related to an injury, in the last 3 months?	Yes No	Ok	This is again duplicated. Q25 and 26	Duplicated- Q25 and 26	This question will not be changed as it is not a duplication but asks for medication for joint or back pain
If yes, what medication was used?	Over the counter pain killers Natural remedies, herbs, supplements Over the counter anti-inflammatory drugs (NSAIDS's) Prescribed anti-inflammatory drugs (NSAID's) Injection Other	Ok	Same as Q25 and 26	Duplicated- Q25 and Q26	This question will not be changed as it is not a duplication but asks for medication for joint or back pain
Did the medication reduce your joint pain or back pain?	Yes No	Ok	Ok	Ok	Ok
Have you received any type of treatment, other than medication, for pain?	Yes No	Ok	You can cut down on questions by combining this and the next question as suggested above.	Combine with next question	Combined these two questions- have you received any other treatment for your joint pain? If yes- tick all that apply. Answers- NO, Yes, then add the list of therapies
If yes, please specify the type of treatment that you	Exercise □ Education	Ok	Have you received any other treatment for your	Can tick all that apply	As above

Question	Responses	Expert 1	Expert 2	Expert 3	Changes made
received at the day hospital	Massage Herbal/ natural Acupuncture Electrotherapy machines Joint mobilizations Strapping/ bracing Other		joint pain? If yes- tick all that apply.		
Did the above treatment reduce your joint pain or stiffness?	Yes No	If yes, for how long?	Maybe combine the above list with whether it made a difference as there is more than one treatment.	Maybe put it into a table with a yes no column and a it helped column	Added to question- If yes- how long did you have relief of pain? Add to answer- opening space for years
What treatment worked best in reducing your pain and stiffness?	Exercise □ Education Massage Herbal/ natural Acupuncture Electrotherapy machines Joint mobilizations Strapping/ bracing Medication Injection	What do you mean by worked best? Don't you want to know how long the relief lasted?	Include other	Add other	Changed- What treatment gave you longer relief of pain and stiffness? - tick all that apply Added other
Are you easily depressed or get anxious because of the pain/ joint stiffness?	Yes No	Ok	Ok	Ok	Ok
Do you experience abnormal sleeping patterns because of the pain /joint stiffness?	Yes No	Ok	Ok	Ok	Ok
Do you feel physically tired due to the pain / joint stiffness (not able to manage everyday tasks)?	Yes No	Ok	Ok	Ok	Ok

Appendix F-3: Chapter 4 Results

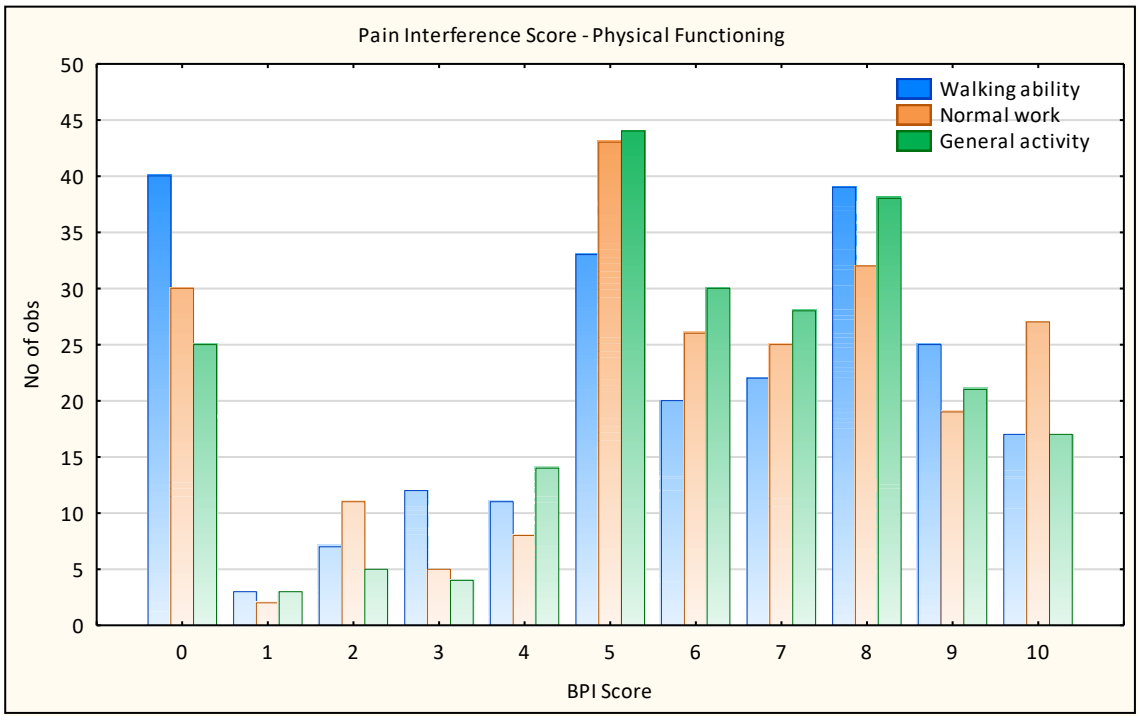
Further details regarding the normality of the Pain severity data and the histograms of the Pain interference-physical functioning and the psychological domains are reported. The first figure demonstrates that the PSS were normally distributed with most participants reported a score between three and seven.



Average Pain Severity on the BPI

N=229 reporting pain in the previous week

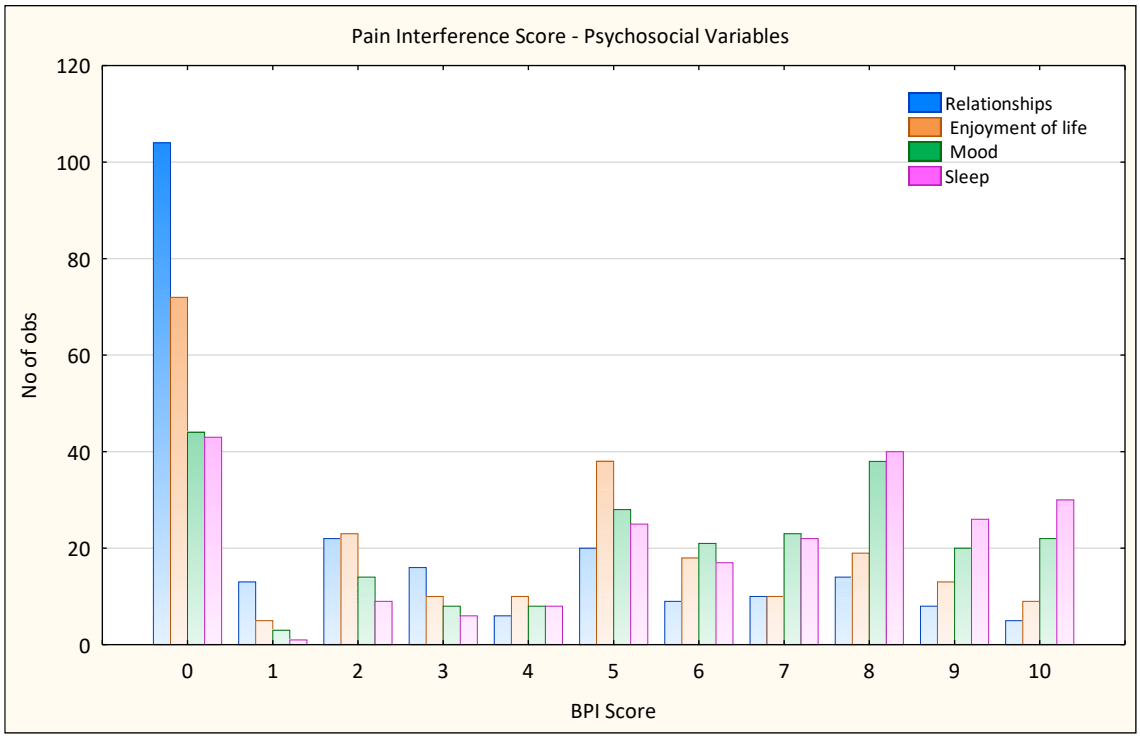
With regard to the physical activities, the second figure demonstrates that there was a range of scores from no interference through to extreme interference, and although more participants reported no interference in walking ability than in normal work of general activity, the patterns of responses were similar with peaks at five and eight.



Histogram of Pain Interference Score – Physical Functioning

N=229 reporting pain in the previous week

Relationships and enjoyment of life were not as affected as mood and sleep with regard to psychosocial functioning and, in those reporting pain interferences, these two peaked at a score of eight in the third figure.



Histogram of Pain Interference Score – Psychosocial variables

N=229 reporting pain in the previous week

Appendix F-4: Chapter 6- RCT results

Comparison of WHODAS between experimental and control groups at each time point

	Experimental Group (31)		Control Group (32)	
WHODAS	**Median**	**IQR**	**Median**	**IQR**
Week 0	14	7-20	14	9.5-18
Week 6	10	5-18	13	10-16.5
Week 12	6	2-14	14	11-19.5

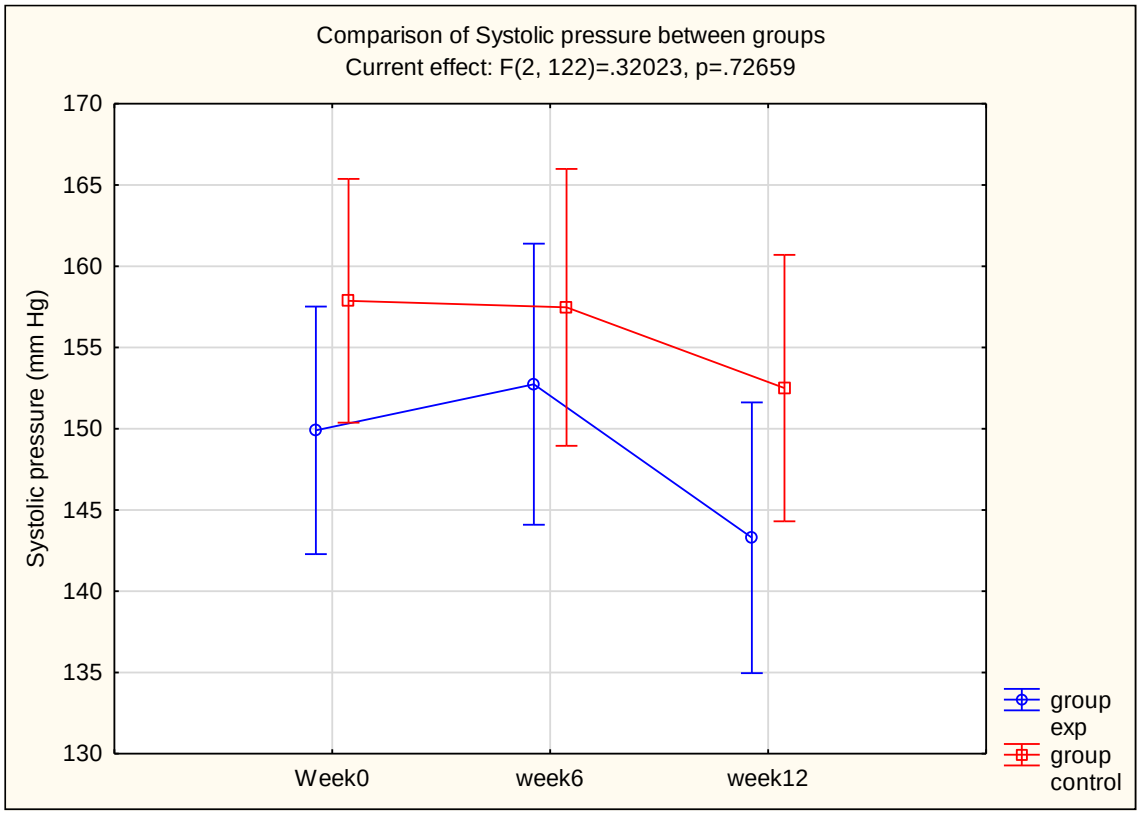
Comparison of ALF scores between experimental and control groups each time point

	Experimental Group (31)		Control Group (32)	
ALF: Functional ability	**Median**	**IQR**	**Median**	**IQR**
Week 0	23.29	21.7-27.4	23.97	20.9-30.4
Week 6	17.49	15.9-19.8	19.49	17.7-22.7
Week 12	19.51	17.7-21.8	20.61	17.2-23.1

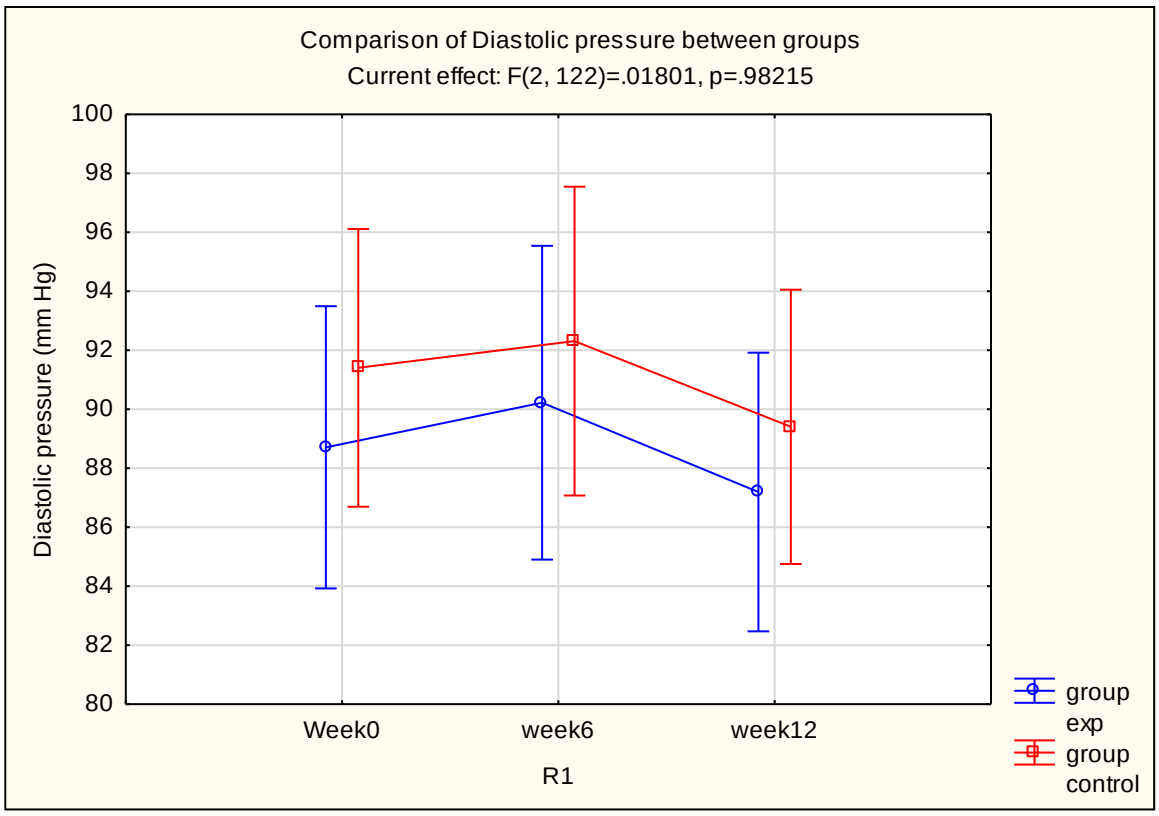
Comparison of Brief pain inventory scores (PSS and PIS) between experimental and control groups at each time point (n=63)

	Experimental Group (31)		Control Group (32)	
	Mean	**SD**	**Mean**	**SD**
Week 0				
PSS	5.2	1.8	5.6	1.9
PIS	5.7	2.2	5.7	2.0
Week 6				
PSS	4.2	2.1	5.6	1.9
PIS	3.8	2.5	6.2	1.6
Week 12				
PSS	4.2	2.1	5.8	2.3
PIS	4.3	3.0	5.3	2.2

Blood pressure and blood glucose results:



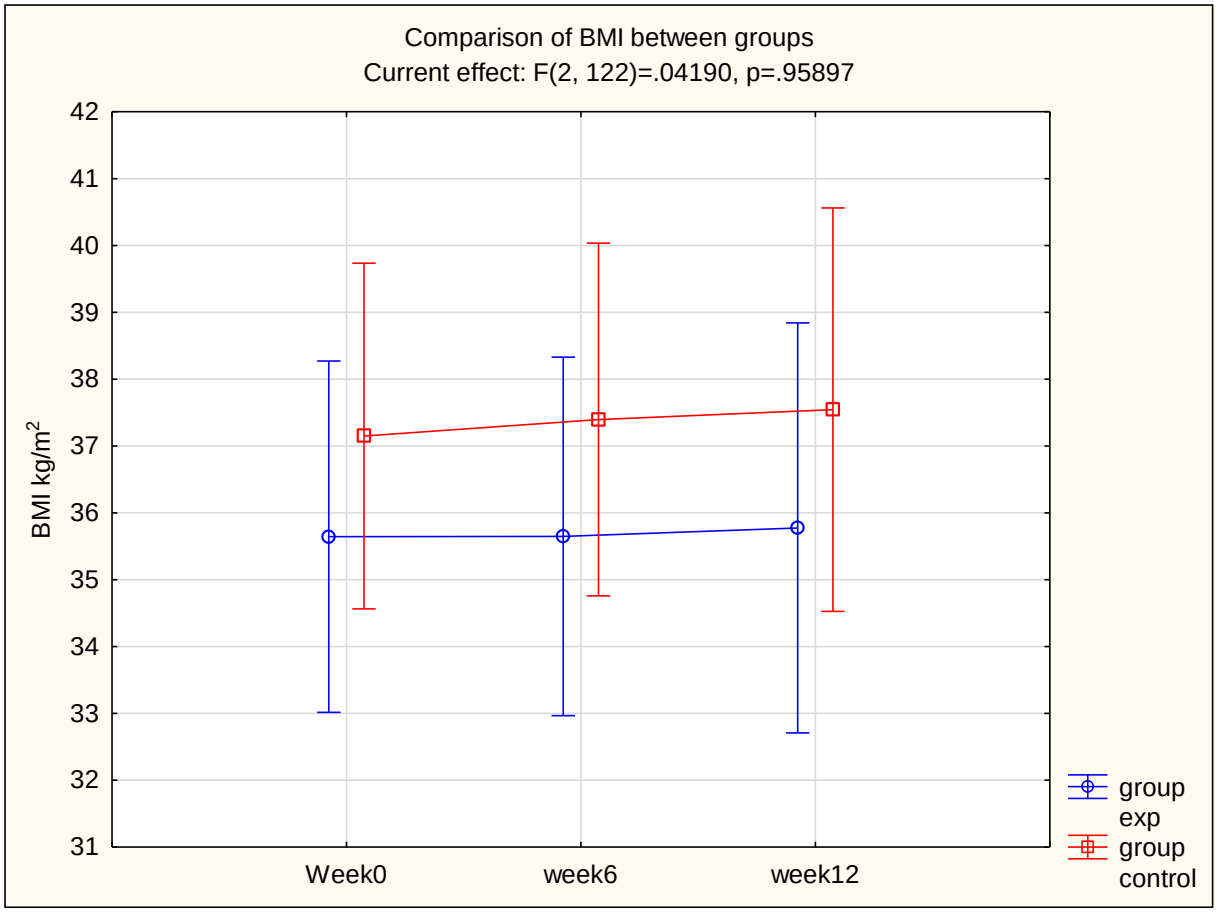
Comparison of Systolic pressure scores between groups over time



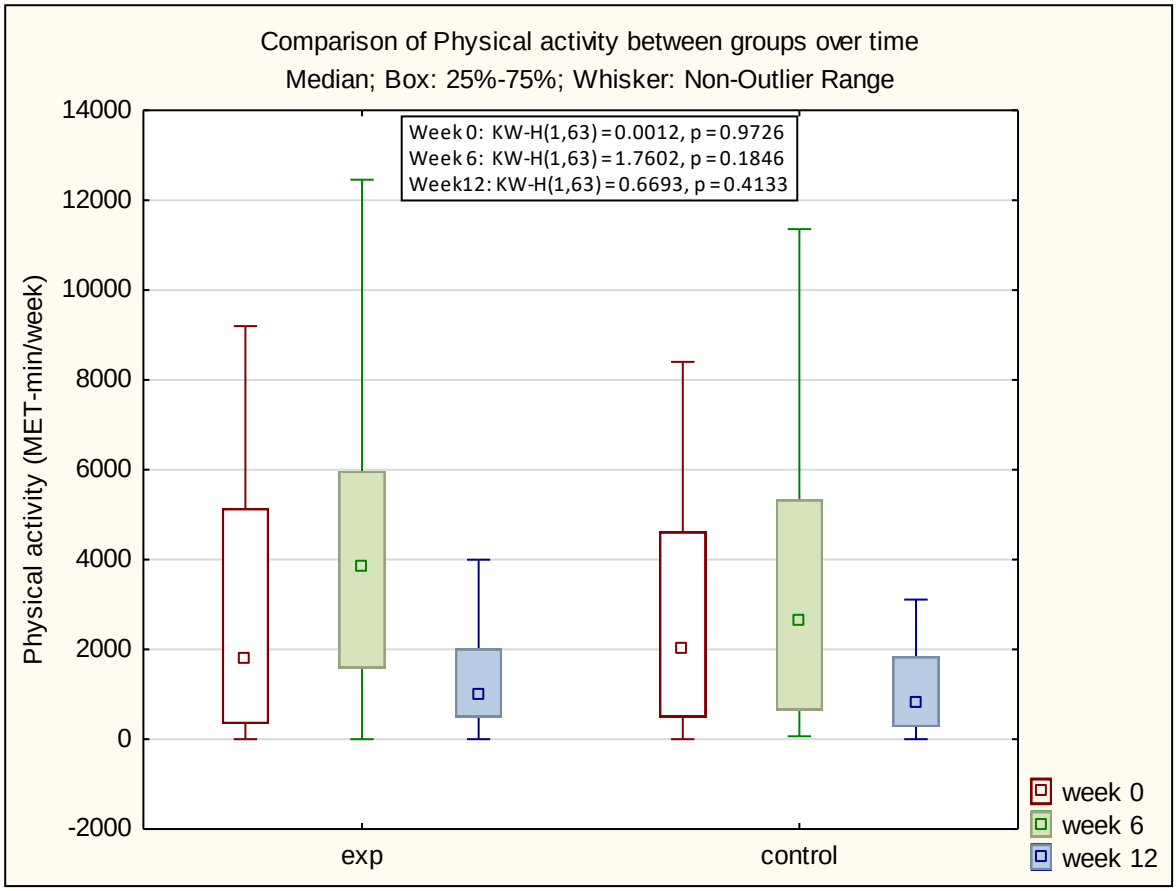
Comparison of Diastolic pressure scores between groups over time

Comparison of blood glucose values between experimental and control groups at each time point

	Experimental Group (31)		Control Group (32)	
Blood glucose scores	**Median**	**IQR**	**Median**	**IQR**
Week 0	6.3	5.2-7.1	5.6	4.7-7.6
Week 6	5.2	4.7-5.9	6.0	4.8-8.3
Week 12	5.8	5.0-6.7	5.4	4.8-6.7



Comparison of BMI scores between groups at each time point



Comparison of MET-min/week scores between groups at each time point

Comparison of EQ-5D-3L VAS and Index scores between experimental and control groups at each time point

	Experimental Group (31)		Control Group (32)	
	Median	**IQR**	**Median**	**IQR**
Week 0				
EQ-5D VAS	60	50-70	50	40-80
EQ-5D Index	0.62	0.19-0.72	0.62	0.15-0.69
Week 6				
EQ-5D VAS	80	50-100	60	50-80
EQ-5D Index	0.74	0.68-0.85	0.62	0.51-0.77
Week 12				
EQ-5D VAS	80	60-90	65	50-80
EQ-5D Index	0.69	0.58-0.85	0.63	0.39-0.76