An investigation into the nature and prevalence of musculoskeletal conditions among women attending a community clinic, and the effectiveness of an intervention programme for these patients

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Thesis Presented for the Degree of

DOCTOR OF PHYSIOTHERAPY

in the Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

UNIVERSITY OF CAPE TOWN

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October 2016

DECLARATION

I, Roline Barnes, hereby declare that the work on which this thesis 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 at the University of Cape Town or any other university.

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ABSTRACT

The thesis set out to document the process of developing and testing a non-pharmacological biopsychosocial intervention programme which included exercise and health education for women with musculoskeletal conditions attending a clinic in a poorly resourced area of the Free State Province in South Africa. To inform the development of an appropriate intervention, several sub-studies were undertaken. Systematic reviews on the use of exercise and health education in adults were undertaken, one on the impact of these interventions on adults with chronic diseases of lifestyle (diabetes mellitus type II, hypertension) and the risk factor obesity, and the other on the impact on adults with musculoskeletal conditions. The selected research tools, which were chosen based on the framework of the International Classification of Functioning, Disability and Health (ICF) were subjected to a rigorous translation process. A facility-based descriptive observational cross-sectional study was undertaken to determine the prevalence and nature of musculoskeletal conditions amongst women between the ages of 40 and 64 years attending a community clinic. The gathered information was then used to modify and adapt existing non-pharmacological programmes and develop an intervention programme tailor made for these patients. Finally, an experimental randomised controlled trial was undertaken to determine the effectiveness of usual care against a non-pharmacological intervention utilising a workbook for the women identified in the survey.

A total of 16 studies met the inclusion criteria for the review of non-pharmacological interventions which included exercise and education for the Chronic Diseases of Lifestyle listed above. Of the seven papers which reported adequate information to calculate effect sizes, four of the better quality studies reported a medium or large effect size in either the physical or mental components of HRQOL or both. Three articles met the criteria for inclusion in the systematic review of randomised control trials in adults living with musculoskeletal conditions reporting on Health-Related Quality of Life, function and participation. The methodological quality of the studies was high and all three reported medium to large effects on the outcome variables related to pain at the cessation of the intervention.

The observational epidemiological study of 1 376 respondents revealed that the 'typical' respondent spoke Sesotho, was married, owned her own brick home and stayed in a household with about five other people. They could read and write and had attended secondary school. As they were unable to find work, they were unemployed. They did not receive any benefit grants. They were visiting the clinic

either to collect medication or to consult with a health professional. They were obese but did not take any harmful substances. The prevalence of joint pain (musculoskeletal conditions) was 62% and 53% had joint pain (musculoskeletal conditions) in conjunction with either hypertension and/or diabetes mellitus type II. People with joint pain (musculoskeletal conditions) were less likely to have diabetes mellitus type II, but there was no association between hypertension and joint pain (musculoskeletal conditions). The Body Mass Index (BMI) was significantly higher in those who reported joint pain (musculoskeletal conditions).

Those with joint pain (musculoskeletal conditions) reported a poorer quality of life, both with regard to the EQ-5D-3L index score and the more global VAS score. Those with joint pain (musculoskeletal conditions) experienced a mild effect on participation restriction such as family life, work and social life and a moderate effect on their financial position. They had to stop working or alter their employment. They experienced fatigue and depression. They did report significantly more difficulty with concentration, walking long distances, washing and dressing and interacting with unknown people and friends, than did those without joint pain (musculoskeletal conditions).

The WHODAS-2 yielded counterintuitive results and after a post-hoc analysis indicated poor convergent and divergent validity, the data were not included in further analysis.

Utilising the above information an exercise programme and workbook for the six weeks exercise and education intervention was developed. The six-week intervention programme utilized physical exercise in group format, health education, facilitated the development of self-management, problem-solving skills, decision-making skills and how to maintain a balanced lifestyle. The aim of the intervention was to explore the effectiveness of a non-pharmacological six-week intervention programme for middle aged women presenting with only musculoskeletal conditions or musculoskeletal conditions and at least one of the following co-morbidities: hypertension, obesity or diabetes mellitus type II. Enrolment was lower than anticipated and 20 participants were allocated to the control group, of whom five were not available for the six week follow-up. All 22 participants randomised to the intervention group remained in the study. The main findings of the study were that in general the intervention had little effect on the health conditions, physiological measures or BMI of the participants. However, there was evidence that functional improvement took place in items related to mobility (including distance walked), pain/discomfort (including a decrease in the number of pain sites and an increase in the percentage of

pain relief), anxiety/depression and fatigue (Self-efficacy for managing chronic disease 6-item scale). The Index Score, which is calculated from the EQ-5D-3L dimensions and reflects the QALYs (Quality Adjusted Life Years) gained, indicated that, if the intervention group maintained their improved health status for a year, they would have gained one third of a healthy life compared to those in the control group. The change in overall Self-efficacy score was also significantly higher in the intervention group. In addition, the high compliance with attendance, 88%, and the positive responses to the Acceptability Questionnaire, indicated that the intervention was well received and appropriate for this group of women.

It is concluded that the positive impact of the intervention programme suggests that the programme should continue at the clinic in question, but be offered at a more convenient time for participants who work. The workbook needs to be modified as it was not well received. The primary research recommendation is that, as the sample size was smaller than anticipated and the study may have been under-powered, further research should be undertaken before the intervention is rolled out to other clinics in the Free State or even nationally. The outcome measures will need to undergo further validation, particularly those based on numerical concepts and the Likert scale. The dosage of exercise would also need to be investigated to determine whether an intervention of longer duration (e.g. three months), greater dosage (twice a week for a longer period of time) and a better system of monitoring the extra-class exercise would result in a decrease in the impairments and an improvement in the health conditions of the participants. A large, multi-centre trial should assist in determining whether the results of this small study can be generalised to the larger population.

ACKNOWLEDGEMENTS

It is with appreciation that the researcher acknowledges the contribution of the following:

My Heavenly Father for answering my prayers.

Professor Jennifer Jelsma for her patience, guidance, support, encouragement and knowledge – without her this PhD would never have been possible.

Associate Professor Romy Parker for her guidance, support, encouragement and knowledge throughout the process.

My beautiful children Kristen and Dylan, for their love, encouragement and above all understanding in times when I had to work. I could not be prouder of you two.

My husband Daryl, for his love, support, prayers, always being there when I needed a shoulder to cry on and for believing that I could accomplish this when I was in doubt.

My parents for encouragement and support throughout the process.

My Cape Town Family, Diana Scholtz, Andrè and Suzanne Groenewald, who always supported and encouraged me. Thank you for welcoming me with open arms when I needed a place to stay.

My colleagues in the Department of Physiotherapy, University of the Free State, for their constant prayers, support and encouragement.

Professor Jonathan Jansen, Vice Rector of the University of the Free State, who planted the seed to spread my wings and embark on the PhD journey.

The Dean of the School of Medicine, Professor Gert van Zyl and Head of School of Allied Health Professions, Dr Santie van Vuuren, of the University of the Free State, for support.

Dr Corli Witthun, Vice Rector Research and Dr Glen Taylor from the Research Directorate, at the University of the Free State, for financial support when I needed it most.

The postgraduate school at the University of the Free State, in particular Dr Henriëtte van den Berg and Me Eleanor Nel for their support and sending me to attend SANTRUST to develop my research proposal.

Me Eleanor van der Westhuizen from the Research Directorate at the University of the Free State for her assistance with funding.

The National Research Foundation for funding through the Thuthuka grant (TTK14051167102) and Sabbatical grant (SGD150507117812).

Homemed (Pty) Ltd - Pretoria, South Africa for their generosity in supplying blood glucose monitors, glucose sticks, medlance needles and blood pressure monitors for the study.

Professor Kobus Marais and Ms Marlie van Rooyen of the Department of Linguistics and Translation, at the University of the Free State for managing the translation project.

The participants, who despite adversity were always there with a welcoming smile.

The research assistants: Mathuso Mosia, Vernon Adams, Dian Beukes, Annelize Bruwer, Elardie Oosthuizen, Adri Venter, Madie Wessels and the fieldworkers for their assistance.

Ms Petro Jonker from ER 24 who attended each session with the participants in case of an emergency.

Dr Andrè Rose, from the Department of Community Health at the University of the Free State for the screening of the intervention participants.

Miss Marizeth Jordaan from the Department of Dietetics and Human Nutrition at the University of the Free State, for compiling the healthy eating section in the workbook.

Ms Rothea Pelser and Me Annamarie du Preez from the Frik Scott Library at the University of the Free State who were always on hand to find a much needed article.

Ms Cindy Lewis, postgraduate and research officer at the University of Cape Town for her support.

My friends for their prayers.

"It was the best of times, it was the worst of times, it was the age of wisdom, it was the age of foolishness, it was the epoch of belief, it was the epoch of incredulity, it was the season of light, it was the season of darkness, it was the spring of hope, it was the winter of despair."

— Charles Dickens, A Tale of Two Cities —

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ABBREVIATIONS AND GLOSSARY

° - degrees
A1c- Glycated haemoglobin
ACSM – American College of Sports Medicine
AFPT – objective functional performance measured by the aggregated time of four common activities of daily living
AIDS – Acquired Immune Deficiency Syndrome
API - Autonomy. Preference Index
ASES – Arthritis Self-efficacy Scale
ATP - Adenosine Tri-Phosphate
BMI – Body Mass Index
B-PADS - Barriers to Physical Activity and Disability Survey
BUN – Blood Urea Nitrogen
CDL – Chronic diseases of lifestyle
Cf - compare
CINAHL – Cumulative Index of Nursing and Allied Health Literature
COMRADE – Risk Communication and Treatment Decision-Making Effectiveness
COPCORD – Community Orientated Programme for Control of Rheumatic Diseases
Country-years –The number of countries multiplied by number of years (1)
CST – Coping skills training
DALY's – Disability-Adjusted life years
DCP - Diabetes Care Profile
DCS-R - Diabetes Symptom Checklist – Revised
DDPRQ - Difficult-Doctor–Patient-Relationship-Questionnaire
DM – Diabetes Mellitus
DM II – Diabetes Mellitus type II
DSEQ – Diabetes Self-efficacy outcome expectancies questionnaire
DSMT – Diabetes Self-management Training
EIM - Exercise is Medicine
ExBeliefs - Exercise-related health beliefs and self-efficacy questionnaire
FEV1 - Forced Expiratory Volume in the first second

FVC - Forced Vital Capacity
GAT – Grip Ability Test
GWBI – General Well-Being Index
h –hour
HAART – Highly Active Antiretroviral Therapy
HADS – Hospital Anxiety and Depression Scale
HbA1c –Haemoglobin A1c (A stands for adult type)
HCCQ - Health Care Climate Questionnaire for health care provider support
HDL – High Density Lipoprotein
HDL-C – High-density Lipoprotein Cholesterol
HIV - Human Immunodeficiency Virus
HPCSA – Health Professions Council of South Africa
HRQOL – Health-Related Quality of Life
ICD10 - The World Health Organisation's International Statistical Classification of Diseases and Related Health Problems
ICF – International Classification of Functioning, Disability and Health Framework
ICIDH - International classification of impairments, disabilities and handicaps
ILAR – International League of Association for Rheumatology
K – kappa score
kg – kilogram
LDL – Low-density Lipoprotein
LDL-C- Low-density Lipoprotein Cholesterol
m – metre
MACTAR - McMaster Toronto Arthritis Questionnaire
MET – Metabolic Equivalent of Task
mg – milligram
MHCCQ – Modified Health Care Climate Questionnaires
min – minutes
mmHg - millimeters of Mercury
MOS – Medical Outcomes Study
MOS-SF-36 - The Medical Outcomes Study 36-Item Short Form

MSC – Musculoskeletal conditions
OA – Osteoarthritis
OSA – Obstructive Sleep Apnea
PADS - Physical Activity and Disability Scale
PAID – Problem Areas in Diabetes Survey
PEDro – Physiotherapy Evidence Database
PEP – Personalised Exercise Programme
PHC – Primary Health Care
QALY – Quality Adjusted Life Years
QWB – Quality of Well-Being
RDP - Reconstruction and Development Program me
SANTRUST – a South Africa-based educational trust, has developed its “pre-doctoral proposal development programme”.
SF-36 - Short Form 36-Item Health Survey for health-related quality of life
SIJ – Sacro-iliac Joint
SOLEC - Standing One Leg Eyes Closed
SOLEO - Standing One Leg Eyes Open
SWT – Shuttle Walking Test
TLC – Telephone-linked care
USA – United States of America
VAS – Visual Analogue Scale
WHO – World Health Organisation
WHO-5 - WHO-Five Well-being Index for health-related conditions
WHODAS 2.0 - The World Health Organisation Disability Assessment Schedule II
WHO-QOL26 – World Health Organisation Quality of Life 26
WHOQOLBREF-THAI – World Health Organisation Quality of Life Instrument – Thailand
WOMAC - Western Ontario and McMaster Universities Osteoarthritis Index
y – years
YLD – Years Lived with a Disability
YLL – Years of Life Lost

"A health condition is an umbrella term for disease, disorder, injury or trauma and may also include other conditions, such as ageing, stress, congenital anomaly or genetic predisposition. It may also include information about pathogeneses and/or aetiology" (1).

"Body functions are defined as the physiological functions of body systems, including psychological functions. Body structures are the anatomical parts of the body, such as organs, limbs and their components. Abnormalities of function, as well as abnormalities of structures, are referred to as impairments" (1).

"Impairments are defined as a significant deviation or loss (e.g. deformity) of structures or/and functions (e.g. reduced range of motion, muscle weakness, pain and fatigue" (1).

"Activity is the execution of a task or action by an individual and represent the individual perspective of functioning" (1).

"Participation refers to the involvement of an individual in a life situation and represents the societal perspective of functioning" (1).

"Activity limitation refers to difficulties at an activity level (e.g. limitation in mobility such as walking, climbing stairs, grasping or carrying)" (1).

"Participation restriction is a problem an individual may experience in his/her involvement in life situations (e.g. restrictions in community life, recreation and leisure)" (1).

Life course - "a sequence of socially defined events and roles that the individual enacts over time". In particular, the approach focuses on the connection between individuals and the historical and socioeconomic context in which these individuals have lived (2).

1 INTRODUCTION

1.1 Background

Musculoskeletal conditions (MSC) are a major cause of disability in both low- and high- income countries and consume a large amount of health and social resources (3-5). It is anticipated that the impact of MSC will continue to increase and aging populations will require more and more relief from chronic pain and disability (6). However, the field of musculoskeletal conditions is hampered by a lack of epidemiological data across a range of geography and treatments (6).

1.1.1 Extent and nature of the problem

In the United Kingdom MSC are the most common cause of pain and this high prevalence is mirrored around the world (3). Collaborative studies by the World Health Organisation (WHO), the International League of Association for Rheumatology (ILAR) and the Community Orientated Programme for Control of Rheumatic Diseases (COPCORD), conducted worldwide have provided substantial evidence regarding the burden of MSC, particularly the impact of joint pain on communities (3).

Burden of disease information is an important component required for health planning as it can be used to identify the health gaps in the population to improve population health status (7). Fifty four percent of Disability Adjusted Life Years (DALYs), could be attributed to non-communicable diseases and MSC account for 6.8% of the total DALYs. Undoubtedly, the burden is growing. In the 2004 Global Burden of Disease study, MSC accounted for only 2.0% of the burden (8). In addition, females seem to carry a larger proportion of the burden with the females carrying 56% of the DALYS attributed to MSC (9). In low to middle income countries ("developing countries") the burden is considerably higher, i.e. 21,076 thousand DALYS as compared to 8,723 thousand in high income countries.

Musculoskeletal conditions impact negatively on physical health and there is evidence that individuals with musculoskeletal conditions are more likely to experience activity limitations, not only in the short but also in the long term. There is a strong association between pain and decreased physical activity and ultimately to being overweight (10, 11). The resulting combination may increase the pain associated with MSC and can add to the stress of daily life, making even simple tasks difficult and affecting the cognitive ability of the individual. These factors can negatively affect the quality of life of the person with MSC (12). With the increasing longevity of the population, it is likely that the prevalence of musculoskeletal pain in the community will continue to rise (3, 6, 13). The prevalence of MSC is higher in women (3, 14, 15) and musculoskeletal conditions increase with age (6, 13, 14, 16).

Chronic diseases of lifestyle (CDL) are a group of diseases that develop over many years, have slow progression, are complex and have a poorly understood aetiology (17). The projected increase of CDL between 2010 and 2020 is estimated to be 15% globally (18-20). Inadequate physical activity has been linked to a wide variety of chronic diseases of lifestyle, and moderate intensity activity is viewed as being protective (17-20).

It is reasonable to assume that there might be an interaction between musculoskeletal pain and diminished levels of physical activity. However, the influence of musculoskeletal conditions on physical activity, and therefore indirectly on CDL, is not well documented, despite the high prevalence of these conditions; and the fact that HRQOL is the most important indicator of the impact the group of diseases has on a population (3).

Obesity, a major risk factor for CDL, is reaching epidemic proportions around the world. There is no difference in proportions between obesity and musculoskeletal pain (7). As the prevalence of obesity continues to grow, there is likely to be a considerable impact on the musculoskeletal burden globally in the foreseeable future (9).

It would appear that there is a need to interrogate not only the relationship between MSC, CDL and obesity within middle-aged women living in under-resourced areas in South Africa, but also preventative strategies to manage these conditions, especially with the increase in prevalence and the negative impact they have on the individual and society at large.

1.1.2 Management of co-morbidities and musculoskeletal conditions

The growing burden of disease due to ageing can be ameliorated to some extent by preventative strategies, for example encouraging moderate physical activity and weight loss, (9) eating nutritious foods, refraining from using tobacco products and avoiding consumption of alcohol (21). Moderate physical exercise and appropriate nutrition underpin many of the preventative strategies for both musculoskeletal conditions and co-morbidities. The prophylactic effects of physical exercise are well described and researched (6) and a large percentage of CDL are attributed to sedentary lifestyles (6).

Many studies have demonstrated the beneficial effects of exercise interventions which target behaviour. Improvement in health-related behaviours and HRQOL was recorded in employees of clothing/textile manufacturing companies in South Africa who participated in a six-week intervention programme utilising exercises, education, goal setting and pacing (22). Similarly, a six-week aerobic exercise programme in women with fibromyalgia syndrome showed improvement not only in cardiovascular fitness but also in flexibility and a decreased number of tender points (23).

The literature reports that there are a large number of disadvantaged women with co-morbid MSC and CDL. Self-management and exercises have been found to have a positive effect on these women and may also have an impact on their quality of life, self-efficacy and the self-management of their conditions.

Pragmatic trials are gaining greater acceptance and they (24) “are designed to evaluate the effectiveness of interventions in real-life routine practice conditions, whereas explanatory trials aim to test whether an intervention works under optimal situations. Pragmatic trials produce results that can be generalized and applied in routine practice settings (24).” As it is apparent that, in the clinical situation, relatively few women have MSC in isolation, developing and testing an intervention on women who do have co-morbid conditions, through the use of a pragmatic rather than an explanatory trial may yield information which will be of more use within the intended future context of such intervention.

In addition, there may be shared risk factors for MSC and CDL, such as obesity and lack of exercise, and a programme that addresses these risk factors may result in improvement in both health conditions.

The focus of this thesis was the management of MSC but as the CDL and risk factors included in the study are very commonly co-morbid in this group of women, and exercise has been found to have a positive impact on all these conditions, a secondary goal was to determine whether the intervention, which was aimed at MSC primarily, would also have a positive influence hypertension, Diabetes Mellitus type II and obesity.

1.1.3 Research questions

The primary research question was whether a non-pharmacological intervention designed to manage MSC in middle-aged women would result in an improvement in pain, functioning and HRQOL. However, as this was a pragmatic trial, it was necessary to address the frequent co-morbidities and risk factor of obesity. The research questions thus included the following. What is the evidence base for non-pharmacological interventions for the management of MSC and hypertension, Diabetes Mellitus Type II and obesity? What is the prevalence and impact of MSC within female patients attending clinics who are likely to have co-morbid MSC and CDL? Can a holistic approach to the management of women with MSC and in some cases, co-morbid CDL, be developed? How should intervention programmes be modified to meet the cultural and functional needs of these patients? Would the participants attend and find such a programme enjoyable? What would be the impact of such an intervention on pain, functioning and HRQOL?

1.2 Aims and objectives of the thesis

The ultimate aim of the study was to develop and test a non-pharmacological intervention which included exercise and health education for women with MSC attending a clinic in a poorly resourced area of the Free State in South Africa. Before this could be achieved, however, several other objectives had to be met, and these are set out below.

- The current practice and impact of such programmes for those with CDL and MSC needed to be established through systematic reviews. The objectives of these reviews were to:
    - determine what exercises or education are used for adults with diabetes mellitus type II, hypertension or obesity and musculoskeletal conditions and to ascertain what the

impact of exercises or education is on the HRQOL, function and participation of adults with diabetes mellitus type II, hypertension or obesity and musculoskeletal conditions.

- In order to plan or modify an intervention, it was necessary to establish the prevalence and nature of musculoskeletal conditions within the target population of adult middle-aged women. The specific objectives of the epidemiological sub-study were, within women between the ages of 40 – 64 years, attending a community clinic in the Free State, to:
    - determine the prevalence of joint pain (musculoskeletal conditions) as measured by the COPCORD Phase I and II questionnaire;
    - determine the nature of joint pain (musculoskeletal conditions) as measured by the COPCORD Phase I and II questionnaire;
    - establish the most common clusters/patterns of co-morbidities in women experiencing joint pain (musculoskeletal conditions) as measured by the COPCORD Phase I and II questionnaire;
    - determine the relationship between diabetes type II, hypertension and musculoskeletal conditions; and
    - determine what demographic risk factors (e.g. smoking, obesity) are associated with joint pain (musculoskeletal conditions) in these women as measured by the COPCORD Phase I and II questionnaire;

- The second aim of the sub-study was to determine the impact of musculoskeletal conditions on activity limitations and participation restrictions within the target population. The specific objectives were, within women between the ages of 40 to 64 years, attending a community clinic in the Free State, to:
    - determine the health-related quality of life as measured by the EQ-5-3L;
    - determine the functional impact of joint pain (musculoskeletal conditions) on middle-aged women presenting with joint pain (musculoskeletal conditions) as measured by the WHODAS 2.0; and
    - establish the prevalence of dysfunction and/or participation restrictions of participants to inform the content of the intervention programme.

- The next aim was to modify and adapt existing non-pharmacological programmes into a non-pharmacological intervention programme for the target population, with the programme designed to educate, empower, maximise functional status and improve the quality of life of the women.

  The objectives of the development of the intervention component were to:

  - modify and adapt existing programmes into an intervention programme based on the results of the systematic reviews and the needs of the participants identified in the survey;
  - compile and design a visually attractive, understandable and explanatory intervention programme incorporating education, behavioural changes and exercises for women attending a community clinic with joint paint (musculoskeletal conditions), diabetes type II, hypertension and obesity;
  - compile the intervention programme according to existing guidelines, but to tailor the programme to the environment and culture of the participants; and
  - include the participants identified in the survey of the study in the decision-making regarding the appropriate programme with regards to their environment and culture with the aim of increasing compliance with the programme, and to maximise functional status and the improvement of quality of life of the participants.

The final aim was to explore the effectiveness of a non-pharmacological six-week intervention programme for middle aged women presenting with only musculoskeletal conditions or musculoskeletal conditions and co-morbidities.

- The objectives were to determine:

  - whether the intervention would result in a significant difference between the intervention and control groups with respect to joint pain, as measured by the Brief Pain Inventory (Short Form); HRQOL in women with only joint pain or joint pain and at least one of the following co-morbidities: diabetes type II, hypertension and obesity as measured by the EQ-5D-3L; the functional impact of joint pain on the individual and co-

morbidities as measured by the Simmonds battery of functional tests and the six-minute walk test; and

- determine the interrelationship between joint pain (musculoskeletal conditions) and co-morbidities of individuals as measured by blood pressure, body mass index, venous glucose readings and cardiovascular fitness using the three-minutes step test.

The long-term aim of the study was either to make available an appropriate, effective workbook or an appropriate, sustainable, community integrated, peer-led exercise and education programme for the inclusion in the management of musculoskeletal conditions in middle aged women. The workbook and the programme should also take the specific needs of the target group into account, and should be feasible, effective and acceptable to the community.

1.3 Significance and justification of the study

As this was to be a pragmatic study, it made sense to investigate whether there was an interaction between the CDL, obesity and MSC.

1.3.1 Significance of the study

The influence of MSC on physical activity, and therefore indirectly on CDL is not well documented and the impact of joint disease on the functioning of people with CDL has not been adequately studied, despite the widespread prevalence of these conditions. The development of an effective exercise and education programme using cognitive behavioural principles targeting MSC as well as CDL through lifestyle changes and exercise may not only improve the quality of life of participants but may also improve their health conditions and in the long term encourage other community members to change their lifestyle and behaviour.

Due to the epidemiological transition that is rapidly occurring, primary health care systems should be developing an approach for the management of CDL, responding effectively to community and individual needs. Physiotherapists should target primary level care to minimise the impact on functioning and quality of life of those individuals with MSC who are unable to access therapy.

Establishing a quality primary health care service will ensure a comprehensive response to a growing health care burden, especially in resource poor settings and may have a potential economic impact (25).

For the optimal planning of quality primary health, care systems need to address the growing health burden of CDL, research studies are needed to determine the risk factors of health problems, as well as the distribution of health problems in South Africa (25, 26). It is therefore hypothesised that an intervention programme that targets MSC and which includes exercises, behavioural changes and education may result in not only improving function and also reducing the impact of diabetes mellitus type II, hypertension and obesity, and in addition may enhance the impact of medical interventions that are currently offered.

The impact of the study will be the formalisation of the role of rehabilitation within the primary health care setting. The study will provide a model for introducing and sustaining exercise programmes in the community, and will provide evidence for a programme that can empower a group of people who are often neglected by the health system.

1.3.2 Justification for the choice of study sample

Based on the review of the literature and the local context, the target population chosen for this research was middle-aged women (45-60 years of age) residing in under-resourced areas and attending a primary health care clinic. The justifications for the choice of these parameters are as follows.

People living in socially deprived areas are more prone to musculoskeletal symptoms and as a result of this have worse functional outcomes (27, 28). These reports, coupled with the BoD estimation of the considerably higher burden due to MSC in low to middle income countries, support the targeting of people living in under resourced areas. An obvious setting for the provision of interventions would appear to be the primary health care clinics, as these are accessible to those living in the less resourced areas of South Africa and service those with fewer resources who are unable to afford private health care.

The targeting of females was done on both epidemiological and pragmatic grounds. Several studies have indicated that females are more likely to utilise public health services (29, 30). Copley et al (2013) conducted a study on MSC at a health care centre in the Bloemfontein area and reported that 64% of

the attendees were female (31). In addition, there is evidence to suggest that females have a higher prevalence of MSC (3, 14, 15) and bear a disproportionately larger burden of disease due to MSC (56% of the DALYs due to MSC compared to 46% in males)(9). This appears to be true within local South African settings. In a similar setting in Cape Town, Parker and Jelsma (2010) screened 1005 individuals attending a primary health care clinic for MSC. Of these, 33% reported MSC not due to trauma or previous injury (32). Of relevance is that more than 80% of the individuals living with MSC were female, an even larger proportion than the 1.6:1 ratio of women to men who live with joint pain reported in a previous study (33). In the Bloemfontein clinic 46% reported MSC, of which 64% were female (31).

Based on both international and local studies, it therefore seemed reasonable to investigate the prevalence and impact of MSC in this particular group of women. In a situation where resources are limited, it was suggested that intervention aimed at this group might possibly be more cost effective and reach a greater number of the target group. As the intervention was to be culturally appropriate and include traditional forms of activity, the decision was made to exclude men as their interests and preferred physical activities were likely to be different to the women (34-36).

The age range was chosen to reflect the evidence that musculoskeletal conditions increase with age (6, 16, 26, 37). In the Parker and Jelsma (2010) study, the mean age of those with joint pain was 51.7 years (eight years older than those without pain) and in the Copley study, the average age was 53 years. As the inclusion criteria for the intervention study was middle aged women, the upper limit of 64 years was chosen. According to the World Health Organization most developed countries have accepted the chronological age of 65 years as a definition of 'elderly' or older person (38). Unfortunately, like many westernized concepts, this does not always adapt well to the situation in Africa. According to the World Health Organisation, if a definition in Africa is to be developed, it should be either 50 or 55 years of age, but this is somewhat subjective and introduces additional problems of data comparability across nations as there is not set age limit for old age in the literature for Africa (38). The more traditional African definitions of an elder, correlates with the chronological ages of 50 to 65 years, depending on the setting, the region and the country. Adding to the difficulty of formulating an accurate definition, actual birth dates are quite often unknown to individuals in Africa, as many individuals do not have an official record of their birth date. In addition, definitions of ageing can differ widely from traditional or community definitions. Therefore the researcher decided to follow the lead of the developed worlds and use the chronological age of 65 years as a definition of 'elderly' or older person (38). In addition, the

systematic reviews discussed in Chapters 3 and 4, almost all include participants within this age range, although several studies do include older participants.

The inclusion of co-morbidity information in the current study was based on the two local studies cited above which indicated that co-morbidities were very common in women with MSC and that the most common were hypertension (59.1%) and diabetes (24.8%) (32). The Copley study additionally reported that the participants reporting MSC had a higher prevalence of hypertension and Type II Diabetes than their counterparts. According to the National Demographic and Health Survey of South Africa 1998 30% of women in South Africa were obese and those more affected were black women (39). Obesity is very common in people living in under-resourced areas in South Africa. Puoane et al (2005) indicated that obesity is a major public health problem among black women living in urban areas in South Africa (40). A study conducted by van Zyl et al (2012) found that 26.2% of women in urban and rural settings in South Africa were obese in 2011(41). Twenty three percent of women in KwaZulu-Natal, South Africa enrolled in a HIV prevention trial were obese according to a study conducted by Wand et al (2013). A total of 5 495 women were enrolled in the programme(42). As this was to be a pragmatic study, it made sense not to exclude participants with joint pain (musculoskeletal conditions) who had these co-morbid conditions as the pool of eligible participants was likely to have one or more co-morbidities.

In summary, primary health clinic based interventions target those living in under-resourced areas in South Africa and the majority of the attendees are women. A large proportion of these women have MSC, CDL, obesity or a combination of these conditions. The focus of the present study was on joint pain but as co-morbidities including diabetes mellitus type II, hypertension and obesity are so common among the populations as described above, the development of the intervention needed to address these conditions as well.

1.4 Research setting for the proposed study

The study was conducted at a community clinic situated in the Bloemfontein area. The clinic is also a referral centre for primary health care clinics and serves as a centre for the follow-up of down-referrals. The clinic is situated in Mangaung in a peri-urban environment serving patients from both formal and informal settlements (43). Most of the patients attending the clinic are black and the services at the clinic are free of charge and easily accessible for community members in the area. The clinic was chosen

due to its location in the Bloemfontein area and due to the large patient population, ranging between 19 000 – 22 000 people utilising the centre/clinic services (31).

1.5 Outline of the thesis

The thesis consists of the following chapters:

Chapter 1 briefly outlines the background and motivation for the study, and then presents the aims and objectives of the different components.

The following three chapters report on literature reviews. Chapter 2 presents a narrative review providing a conceptual framework for the study, and discusses the literature on CDL, including obesity and MD. The role of exercise is examined with regard to the physiological effects of exercise and its impact on different CDL. Finally the research setting is discussed within the context of the primary health care system. Chapters 3 and 4 are systematic reviews on the role of exercise and health education in CDL and MSC.

As the use of validated instruments is essential to ensure internal validity, Chapter 5 describes the process of identifying and translating the outcome measures used in the study. As the majority of the participants spoke Sesotho, a rigorous translation process was followed, including cognitive debriefing of respondents.

Chapter 6 describes the epidemiological sub-study which was undertaken to establish the prevalence and impact of CDL and MSC. In Chapter 7, the process of integrating the relevant data gathered in the previous studies to develop an intervention is described. Chapter 8 presents the pragmatic intervention sub-study, including the methodology, results and discussion.

Finally, in Chapter 9, the research questions and aims and objectives of all components are revisited and recommendations regarding clinical practice, policy and further research are offered.

2 NARRATIVE LITERATURE REVIEW

2.1 Introduction

Two aims were addressed during the narrative literature review. The first was to provide an overview of the prevalence of musculoskeletal conditions and common chronic diseases of lifestyle, more specifically hypertension, diabetes mellitus and obesity. The second aim of the narrative review was to describe the role of exercise as a primary health care intervention in addressing the International Classification of Functioning, Disability and Health Framework (ICF) constructs of impairment, functional limitation and participation restriction (including Health Related Quality of Life) for each of the conditions.

The International Classification of Functioning, Disability and Health Framework (ICF) will be discussed as an introduction to the narrative review as it is an accepted model of the interaction between functioning, disability and health. The ICF is a meaningful way to communicate the functional limitations that individuals experience, especially with CDL, and it also structures the patient's problems for rehabilitation purposes. This chapter, therefore, describes the health conditions and impairments which fall under the umbrella term of chronic diseases of lifestyle and discusses the bidirectional relationship between functioning (physical activity), impairment and health condition. The contextual or environmental factors and the impact of these on access to health care are also briefly discussed.

Chronic diseases of lifestyle (CDL), also known as non-communicable diseases, are a group of diseases that develop over many years due to lack of moderate, regular exercise and the unhealthy diets of modern lifestyles (44) and are increasing substantially in all strata of South African society (45). These diseases include amongst others hypertension and diabetes mellitus type II. Obesity, a major risk factor for CDL, is reaching epidemic proportions around the world and there seems to be a definite association between obesity and musculoskeletal pain (7). Obesity and CDL also share the same modifiable risk factor of decreased physical activity.

Musculoskeletal conditions(MSC) are one of the main causes of disability in developed and developing countries worldwide (3, 9, 46) and the management of both MSC and CDL consumes a large amount of health and social resources and will become increasingly important as aging populations require greater

relief from chronic pain and disability (3-5). As mentioned previously, it would appear that there is a need to interrogate the relationship between MSC, CDL and obesity within middle-aged people living in under-resourced areas in South Africa.

Therefore, hypertension, diabetes mellitus type II, obesity and musculoskeletal conditions are discussed below within the ICF framework, with an emphasis on health condition and impairments. In addition, possible interaction between MSC and CDL, the risk factor obesity, the physiological effects of exercise as well as the role of exercise in each of the conditions are addressed. The environmental factors that influence the development and management of CDL, particularly the role of primary health care are also included in this chapter. Finally the research setting is described to provide contextual information to the study.

The electronic databases Africa-Wide, CINAHL, The Cochrane Library, PEDro, PsychArticles, PsycInfo, PubMed (which includes Medline), Scopus (which indexes Embase), Web of Science, Science Direct and SportDiscuss were searched. The only limit to the searches was in the inclusion of English articles. No limits were set regarding dates of articles as important information could have been missed if excluded. Cross-referencing and hand-search methods were also utilised. Suitable academic books were also included in the search. In the case where articles were not available, inter-library loans were utilised (national and international) to minimise loss of possible secondary sources of data. The search terms used included “prevalence”, epidemiology” or “incidence” of “diabetes”, diabetes mellitus type II”, diabetes mellitus type 2”, “type 2 diabetes mellitus” of “hypertension”, “high blood pressure” of “obesity” of “joint pain”, “chronic joint pain”, “musculoskeletal condition”, “musculoskeletal disorders”.

2.2 International Classification of Functioning, Disability and Health Framework (ICF)

The World Health Organisation’s International Statistical Classification of Diseases and Related Health Problems (ICD10) has been used worldwide to classify health conditions and to gather epidemiological data for different countries (47), but the ICD10 does not describe the overall the functioning and disability attendant on the health conditions. To address this need the WHO developed a new tool in 1980 for the classification of the consequences of diseases, called the International Classification on

Impairments, Disabilities and Handicaps (ICIDH) (47). This was subsequently revised and in 2001 the International Classification of Functioning, Disability and Health (ICF) was launched. The updated version was endorsed by the 54th World Health Assembly in 2001 as the framework for measuring health and disability at both population and individual level (48). The ICF presented a new conceptual framework for the understanding of health, functioning and disability (49) that can serve as the starting point for the understanding of the human experiences of functioning and disability. The framework emphasises the non-linear relationship and the interrelatedness of health condition, physical function, social function and environment in which the person lives in the determination of the well-being of the individual, in that all components may influence, and in turn be influenced by, each of the other components (49).

The ICF clarifies the concepts of "health" and "disability", and acknowledges that each and every individual can experience a decline in health and also experience some degree of disability. The ICF also allows for record keeping of the impact of the environment on the individual's functioning by including contextual factors in the classification system (48).

Diagnosis alone does not adequately capture the health outcome of individuals and populations, especially related to chronic diseases of lifestyle, and therefore the ICF is becoming more and more important in improving the quality of data on morbidity and diseases. The ICF is not limited to addressing Western concepts, but has worldwide cultural acceptability as it follows the principle of a universal model that covers the entire lifespan of an individual and is multi-dimensional. Most importantly the ICF addresses human functioning and not merely disability (49, 50).

The ICF framework provides a coherent view of the medical and social model (Figure 1)(51). The medical model views disability as a problem caused directly by trauma, disease or other health conditions, and utilises individual medical treatment and management of the disability, while the social model views disability as being caused by cultural, environmental and social factors (49). A third model is the biopsychosocial model which is viewed as an important conceptual framework behind the ICF and attempts to integrate the medical and social model. In this model the disability of the individual emerges as a result of the consequence of personal, biological and social factors (52).

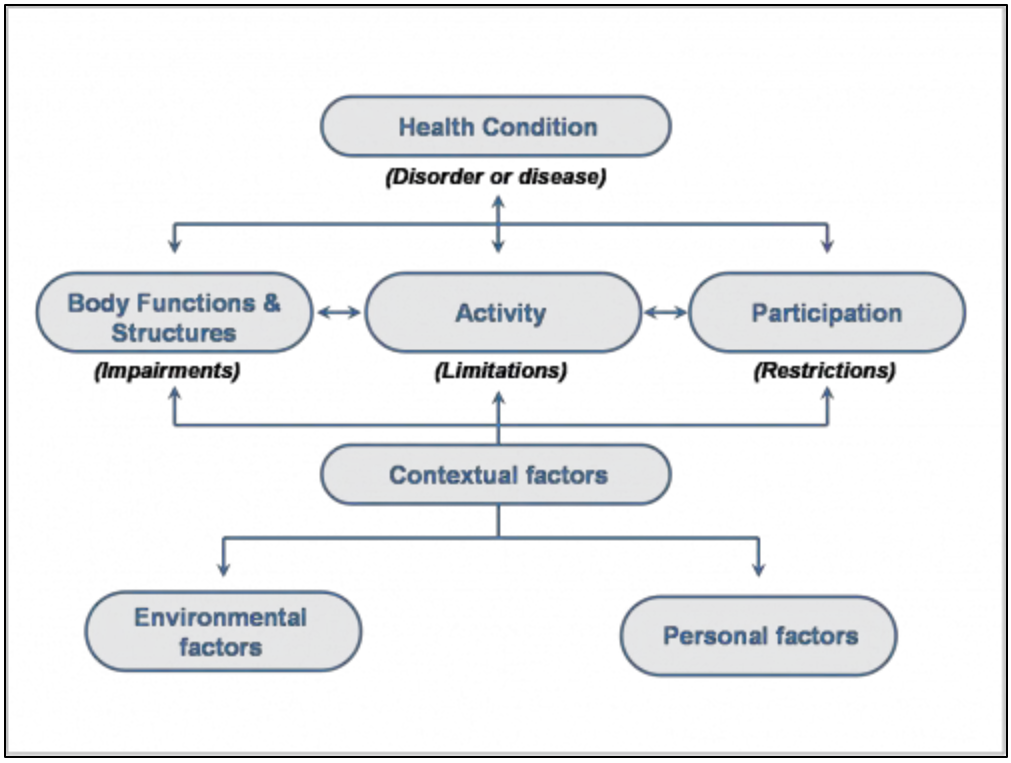


Figure 1: The model of functioning and disability upon which the ICF framework is based

The contextual component which forms part of the ICF framework represents the living situation of an individual and the individual's complete background. Within the contextual component the environmental factors include the social and physical environment of the individual as well as the attitude of a society in which they function (1). The factors are seen as external to an individual and can either act as a barrier or as a facilitator in the individual's life. Personal factors are the background of an individual's life and living situation and include gender, age, race, lifestyle and habits (1). Risk factors are mostly associated with the onset of the health condition, but also interact with the disabling process at each stage of the health condition. Risk factors could include personal factors including lifestyle and genetic predisposition as well as environmental factors which may include work and living conditions of the individual (1). As discussed below, the primary health care approach to the management of health conditions is an essential aspect of the context or environment of the participants of the study.

The uniqueness and strength of the ICF lies in the potential to improve clinical practice and health services, especially in the field of MSC. If utilised optimally, it may result in more efficient health

management and stimulation of research. The ultimate goal is to optimize participation not only from the individual's perspective, but also from society's perspective (1).

In conclusion, the ICF serves as a framework for understanding the impact of MSC on an individual and society (1)and is increasingly being used in clinical practice to formulate patient's problems effectively (1). The components of the ICF can form the basis for research which leads to better understanding of functioning, disability and health and their interaction (1). The non-linear relationship between the components and the recognition that each component can influence any of the other components (e.g. functioning in the form of physical activity can influence and be in turn affected by e.g. health condition) was central to the conceptualisation of this study (50). A further influence of the ICF on the study is that disability is seen as being aetiologically neutral and this allows for the common management of functional limitations, regardless of the specific health condition (diabetes mellitus type II or hypertension or obesity)(53).

2.3 Chronic diseases of lifestyle

The term non-communicable diseases or chronic diseases of lifestyle (CDL) is commonly used in studies investigating burden of diseases and represent a group of diseases that develop over many years due to lack of moderate, regular exercise and the unhealthy diets of the modern lifestyles (44) and which exclude injuries (54).

There is controversy in the literature regarding hypertension, diabetes mellitus and obesity which are classified as CDL by some authors and as risk factors for chronic diseases of lifestyle by others (44, 55-58). For example, obesity, diabetes mellitus type II, hypertension, coronary heart disease, stroke, cancer, chronic inflammatory bowel diseases , RA, chronic obstructive pulmonary disease, asthma, osteoporosis, eye diseases and dementia or Alzheimer disease have all been labelled as CDL by Boeing et al., (2012) during a critical review investigating whether vegetables and fruit are effective in the prevention of CDL (59). Contrary to this Coleman (1998); Beaglehole (2007) and the World Health Organisation (2010) do not view obesity as a CDL but as a risk factor for CDL (44, 55-58). Taking into consideration all the evidence any chronic condition excluding an injury could per operational definition be classified as a CDL, especially if contributing to the burden of disease and using resources related to all the other CDL listed in the literature.

Contrary to the widely held view that CDL are confined to those in higher income brackets, there is growing evidence that the prevalence of CDL are high in people living in lower income areas (45, 51) and the prevalence is increasing substantially in all strata of South African society (45, 51). In 2005 43% of total deaths in South Africa were attributed to CDL while CDL were responsible for 36 million deaths globally in 2008, and 80% of these deaths were in low-income countries (18). In 2010, 65% of the nearly 59 million deaths per year occurring in the world were due to CDL and the projected increase for CDL between 2010 and 2020 is estimated to be 15% globally (19, 20, 60, 61).

In the urban black population in South Africa the most common causes of mortality and morbidity associated with CDL are hypertension and DM type II (62). Data from South Africa indicated in 2000 that the burden of CDL, particularly diabetes and cardiovascular diseases, (which includes hypertension and stroke), is increasing in the urban Black African population (7).

CDL usually start in middle age after years of exposure to an unhealthy lifestyle, resulting in higher risk factors such as hypertension, dyslipidemia, diabetes and obesity that act independently and synergistically (63). These risk factors are often undiagnosed and inadequately managed in health services designed mainly to treat acute conditions. Chronic conditions are mistakenly considered to have a limited impact on burden of disease in Sub-Saharan Africa, mainly because of the high rate of infectious diseases (44) (63).

As the risk factors are similar in most of the CDL, it is becoming increasingly common for many patients to present with more than one chronic disease of lifestyle and the prevalence of co-morbidity conditions are increasing as the population ages (63).

In conclusion due to the epidemiological transition that is rapidly taking place, primary health care systems should be developing an approach to the management of chronic diseases of lifestyle (25). According to Steyn et al., (2012) “The pattern of chronic disease is changing as the determinants and risk factors for chronic diseases of lifestyle develop in this society in transition” – a process dubbed “the epidemiological transition” by Omran 1983 (64). Socio-economic development and rapid globalisation is altering the patterns of chronic diseases of lifestyle in South Africa and this transition is predicted by changes in demographics and nutritional needs of communities (44).

2.4 Chronic diseases of lifestyle (Prevalence and health conditions)

The literature reviewed, using the search terms as described above, reveal a trend towards an increasing prevalence of the CDL of diabetes mellitus type II, hypertension, musculoskeletal conditions and the risk factor obesity (Table 1). Not all of the papers were sourced but those in which the primary objective was to report on the prevalence of the condition worldwide and those that reported studies in South Africa were included. A spectrum of dates was included to indicate the increasing prevalence of each condition.

Table 1: Information related to prevalence of health conditions

Health condition	Country	Information related to prevalence	Reference(s)
Diabetes mellitus and diabetes mellitus type II	Worldwide	Age-specific diabetes prevalence estimated was applied to United Nations population estimates and projections for the number of adults by King et al (1998) and indicated that the prevalence of diabetes would rise from 4.0% in 1995 to 5.4% in 2025. In high income countries the estimated increase will be from 6.0% to 7.6% and in low and middle income countries the increase will be from 3.3% to 4.9%.	(65)
	Worldwide	A study conducted by Wild et al (2004) extrapolated diabetes prevalence data and estimated the prevalence rate of diabetes to be 2.8% in 2002 and 4.4% in 2030.	(66)
	Low- and middle-income countries	According to the Diabetes Atlas (2006) which is viewed as a flagship publication by the International Diabetes Federation around 246 billion people live with diabetes type I and II.	(67)
	199 countries and territories	Trends were estimated by Danaei et al (2011) from health examination surveys and epidemiological surveys. The authors concluded that the diabetes prevalence doubled from 1980 – 2008.	(68)

Health condition	Country	Information related to prevalence	Reference(s)
	Worldwide	The findings of the estimate study of Danaei et al (2011) also indicated that In 2008, 9.8% men and 9.2% women were living with Diabetes mellitus.	(68)
	Worldwide	According to the National Diabetes Federation In 2014, 415 million adults were living with diabetes and in 2040 an estimated 642 million will be living with diabetes.	(69)
	Yonchon county, South Korea	A population based cross-sectional study with random cluster sampling was performed by Park et al (1994) on 3804 residents and the prevalence rate for diabetes was 7.2%.	(70)
	Australia	A cross-sectional survey was conducted by Dunstan et al (2002) on 11 247 participants older than 25 years of age in Australia and found that the prevalence rate of diabetes was 8.0% in men and 6.8% in women.	(71)
	China	A national study was performed from 2007 to 2008 by Yang et al to determine the prevalence of diabetes in China. A nationally representative sample indicated that the prevalence rate for diabetes was 9.7%. The prevalence was 10.6% among men and 8.8% among women.	(72)
	South Korea	According to Vital Statistics Korea, diabetes is ranked in the top five causes of death (2011).	(73)
	USA	According to the Centre for Disease Control and Prevention diabetes is the seventh leading cause of death in the USA (2011).	(74)

Health condition	Country	Information related to prevalence	Reference(s)
	Africa	Published prevalence rates for diabetes in different populations and projected age distributions were used by Amos et al (1997) to estimate that by the year 2010 the total number of people with diabetes is projected to reach 221 million. The regions with the greatest potential increase are Asia and Africa where diabetes rates could rise 2-3 times those experienced currently.	(75)
	Cape Town, South Africa	A three-stage proportional, stratified, random cluster method was used by Levitt et al (1993) to determine the age-adjusted prevalence of diabetes in urban settings to be 8% age-adjusted to world population figures.	(76)
	Durban, South Africa	A modified glucose tolerance test was performed on 479 urbanised South African black individuals in a study conducted by Omar et al (1993). The results of the study indicated that the prevalence rate of diabetes was 4.2%, with 5.2% in women and 2.3% in males.	(77)
	South Africa	A cross-sectional study in which an oral glucose tolerance test was performed was conducted by Erasmus et al (2001) on 374 Xhosa speaking factory workers. The results indicated that the age-adjusted prevalence using a standardised world population was 4.5% amongst peri-urban Xhosa speaking individuals.	(78)
	South Africa	A multi-centre, observational study was conducted by Connor et al (2005) on patients attending general practices in South Africa. The results of the study indicated that diabetes was the most common risk factor in Asians (24%) but least common in whites (8%).	(79)

Health condition	Country	Information related to prevalence	Reference(s)
	Kwa-Zulu Natal, South Africa	A cross-sectional study conducted by Motala et al (2008) on 1 025 subjects using an oral glucose tolerance test indicated that the overall age-adjusted prevalence rate of diabetes was 3.9% amongst rural dwellers.	(80)
	South Africa	According to the World Health Organisation the age standardised mortality rate for diabetes is the 25th highest in the world (2007).	(81)
	South Africa	The World Health Organisation (2007) also indicated that the age standard mortality rate for diabetes is 50 per 100 000 of the population.	(81)
	Southern Free State, South Africa	A study conducted by van Zyl et al (2012) utilising interviews conducted by trained researchers found that the prevalence of self-reported diabetes mellitus was 11.1% in rural and 8.1% in urban.	(41)
Hypertension	High, Low- and middle-income countries	Different data from different regions of the world were pooled together by Kearney et al (2005) during a published literature review. The estimated total number of adults with hypertension in 2000 was 972 million, 333 million in economically developed countries and 639 million in economically developing countries. The predicted increase in 2025 is about 60%.	(82)
	90 Countries	Systematic analysis of population-based studies from 90 countries from 1995 – 2010 was conducted by Mills et al (2016). In 2010, 31.1% of adults in the world had hypertension in high income countries and 31.5% in low- and middle income countries.	(83)

Health condition	Country	Information related to prevalence	Reference(s)
	Portugal	A population-based cross-sectional survey was conducted in 2011–2012 by Polonia et al (2014). The overall prevalence of hypertension was 42.2%.	(84)
	Bogota, Columbia	Using data from previous studies, Cano-Gutierrez et al (2015) estimated that the prevalence of hypertension in 2012 in adults 60 years and older was 56.9%.	(85)
	Henan Province, China	A cross-sectional survey was conducted by Fan et al (2014) in 2012 on 18 772 randomly selected 15-74 year old individuals. The crude prevalence of hypertension was 24.9% and the standard rate was 26.6%, meaning that 25 million were hypertensive in the Henan Province.	(86)
	South Africa	A multi-centre, observational study was conducted by Connor et al (2005) on patients attending general practices in South Africa. The prevalence of hypertension was 59% in Black African people in 2001.	(79)
	South Africa	A multi-centre, observational study was conducted by Connor et al (2005) on patients attending general practices in South Africa indicated that hypertension was the most common risk factor in all population groups (55%).	(79)
	South Africa	A World Health Organisation comparative risk assessment was performed by Norman et al (2007) and the results indicated that hypertension caused 9% of all deaths in South Africa in 2000.	(51)
	South Africa	Data from 59 227 individuals who participated in the 2010 household survey was analysed by Hasumi et al (2012) which that self-reported hypertension for adults 18 years and older was 10.4%. The prevalence increased significantly with age for both male and females.	(87)

Health condition	Country	Information related to prevalence	Reference(s)
	Eastern Cape, South Africa	A cross-sectional survey utilising a structured interview was conducted by Igumbor et al (2011) indicated that the prevalence of self-reported hypertension was 24 % in rural villages.	(26)
	Free State, South Africa	A study conducted by van Zyl et al (2012) utilising interviews conducted by trained researchers found the prevalence of self-reported hypertension in rural areas was 62.6%.	(41)
	Free State, South Africa	A study conducted by van Zyl et al (2012) utilising interviews conducted by trained researchers found the prevalence of self-reported hypertension in urban areas was 48.3%.	(41)
Musculoskeletal conditions	Indonesia	During a COPCORD survey conducted by Darmawan et al (1992) in urban and rural populations in Indonesia it was found that the incidence of joint pain was 23.6% in rural areas and 31.1% in urban areas.	(88)
	Bighwan village, India	During a COPCORD survey conducted by Chopra et al (1996) 4096 adults were interviewed and 746 (18.2%) indicated that they were living with a rheumatic disease.	(89)
	United States of America	Data were reviewed from available surveys by Lawrence et al (1998) which determined that the prevalence of arthritis is estimated to rise from 15% in 1990 to 18.2% for 2020, an increase of 57%.	(90)
	Grampian region, United Kingdom	During a survey conducted in the Grampian region of the UK conducted by Elliot et al (1999) it was found that 1817 individuals from 3605 individuals (50.4%) indicated self-reported chronic joint pain, equivalent to 46.5% of the general population.	(91)
		During a cross-sectional survey conducted by Bergman et al (2001) in a Swedish population it	(37)

Health condition	Country	Information related to prevalence	Reference(s)
	Sweden	was found the prevalence of chronic regional pain was 23.9% and chronic widespread pain 11.4% among 2425 subjects that responded to the survey.	
	Kuwait	A WHO-ILAR-COPCORD study was conducted by Al-Awadhi et al (2004) on 2 500 randomly selected Kuwaiti households. The results of the study indicated that more than 35% of females and 20% of males reported musculoskeletal pain.	(92)
	England	Two cross-sectional surveys were conducted over 40 years apart. The results of the studies were compared and presented by Harkness et al (2005). According to the authors the prevalence of musculoskeletal pain has increased between two and four fold over the last 50 years.	(93)
	United Kingdom,	According to Brooks, P (2007) in an editorial the high prevalence of musculoskeletal pain due to musculoskeletal conditions is observed in the United Kingdom and mirrored around the world in other populations.	(3)
	Cape Town, South Africa	A cross-sectional study was conducted by Parker et al (2010) in clinics in two resource poor communities, and 1005 people were screened. The prevalence of MSC in this clinic- based survey was 36%.	(32)
	World's population	According to a report from the World Health Organisation and The Bone and Joint Decade (2010) it is estimated that 10% of the world's population older than 60 have significant clinical problems that can be attributed to osteoarthritis.	(13)

Health condition	Country	Information related to prevalence	Reference(s)
	Primarily in Europe	According to a report from the World Health Organisation and The Bone and Joint Decade (2010) the prevalence of MSC is expected to increase in the next 10 years.	(13)
	Worldwide	A modelling approach was utilised by Bradshaw et al (2000) to provide the first burden of disease study for South Africa. According to the authors MSC is reaching epidemic proportions.	(7)
Obesity	Worldwide	According to the expert opinion of Brooks (2006) the prevalence of obesity continues to grow.	(9)
	Worldwide	According to the World Health Organisation fact sheet more than 1.9 million adults were overweight in 2014 and more than 600 thousand of these individuals were classified as being obese according to WHO classification guidelines.	(94)
	Worldwide	According to the World Health Organisation fact sheet 13% of adults were obese in 2014.	(94)
	Spain	A cross-sectional study carried out between 2008 – 2010 by Gutiérrez-Fisac et al (2012), indicated that the prevalence of obesity was 22.9%.	(95)
	South Africa	According to the expert opinion of Walker (1998) in a technical report indicated that the proportion of obese black women is double that of obese white women.	(96)
	Free State, South Africa	A study conducted by van Zyl et al (2012) utilising interviews conducted by trained researchers found 13.5% of men and 23.3% of women in 2011 were overweight and 8.6% of men and 26.2% of women were reported as being obese.	(41)

As is evident from Table 1, there is a high prevalence of CDL, MSC, musculoskeletal pain and obesity in both developed and developing countries with consistent findings in large population-based studies. It is clear that prevalence rates have increased and the prevalence rates and burden experienced are expected to increase due to the prolonged average life expectancy in individuals and the increasing number of elderly worldwide (3, 13). There is an indication that this trend will continue until 2025 and will impose a heavy financial burden on nations' health care systems (65, 97). This burden would include absolute disability-adjusted-life years (DALY's)(3). "Disability-adjusted life year (DALY) is defined by Murray as a summary measure of population health incorporating time lost due to premature death and healthy time lost as a result of non-fatal illness episodes." Therefore DALY's as a health measure are the sum of a mortality component referred to as years of life lost (YLL's) and a morbidity component referred to as years lived with a disability (YLD's)" (32, 98, 99). It is relevant to explore the South African data in more detail with particular reference to the environmental and personal factors which are specific to the country.

In South Africa the burden of CDL, MSC, musculoskeletal pain and obesity will be affected by the rapid changes in the health profile of the country, conditions related to poverty, and under-development (7). Therefore older South African women who are obese and have lower levels of education (who represent a large proportion of the population, due to culture and the previous apartheid regime in South Africa) are at particular risk. Through this literature review, a definite need was identified to obtain estimates on the prevalence of CDL, MSC and obesity in this population, accounting for global and geographical differences to make these estimates as accurate as possible (13, 32). It is also imperative to establish comprehensive health and economic indicators, to incorporate an assessment of the quality of life of individuals (13) and to inform the provision of the necessary support to the patient (9, 32).

2.4.1 Diabetes mellitus type II

Diabetes mellitus (DM) type II is the most common form of diabetes mellitus, which occurs mostly in people 50 years and older (100) and is characterised by high levels of glucose, caused by the inability of the pancreas to produce insulin or in some instances the reduced capacity to produce insulin. (101) DM II has reached epidemic proportions globally and is associated with an increased risk not only of cardio-vascular disease but also pre-mature mortality (69). DM II often goes undiagnosed and early symptoms of the disease may include increased thirst, urination, hunger, tiredness and weight gain (100). The

disease is associated with age, genetics, family history, ethnicity, nutrition and poverty (102). It is now thought that there are different combinations and multiple genes involved in individuals with DM II (103-105). Although diabetes mellitus is more prevalent amongst obese individuals (BMI>30), normal weight individuals can also develop the disease (106). Results from a variety of studies have shown that DM type II can be prevented through a healthy lifestyle including maintaining normal body weight, maintaining physical activity, eating a healthy diet, refraining from smoking and using alcohol moderately (107-111).

Modern medical care uses a variety of pharmaceutical interventions as well as lifestyle interventions in an attempt to control hyper-glycemia and to ensure the adequate delivery of glucose to the body tissue to prevent damage. The direct and indirect effect of hyper-glycemia on the human vascular tree, are the major cause for morbidity and mortality in DM II and can be divided into macro-vascular complications which include coronary artery disease and stroke, and micro-vascular complications which include neuropathies and retinopathies (112).

2.4.2 Hypertension

Hypertension or high blood pressure is a condition that affects almost 1 billion people worldwide and is a leading cause of morbidity and mortality (113). This condition is usually asymptomatic until the damaging effects such as stroke, myocardial infarction, renal dysfunction and visual problems are observed and therefore the disease is sometimes called “the silent killer”. Arterial blood pressure is "normal" when the systolic pressure is 90-119 mmHg and the diastolic pressure is 60-79 mmHg. When the arterial pressure is ≥120/80 mmHg, a diagnosis of hypertension is made. In 90 to 95% of patients presenting with hypertension, the cause is unknown and this is called primary hypertension (113, 114). The remaining 5 to 10% of patients live with hypertension that is resultant from secondary renal disease, endocrine disorders, or other identifiable causes. This form of hypertension is called secondary hypertension (114). Regardless of the origin of the hypertension, the increase in the arterial blood pressure is caused by either an increase in systemic vascular resistance (SVR), or an increase in cardiac output (CO) (113).

If hypertension is left untreated, serious cardiovascular complications and threats to an individual's health can occur, including heart attacks and strokes. For this very reason hypertension is associated with high rates of mortality (115). Cardiovascular complications are associated with depression especially in older individuals, (116) while hypertension is closely related to obstructive sleep apnea (OSA) which affects multiple organs and systems within the individual particularly relevant to cardiovascular diseases which are closely related to hypertension (117).

2.4.3 Musculoskeletal Conditions

According to the literature (99, 100) musculoskeletal pain is a major problem associated with economic loss and disability for the individual [80]. The risk factors for musculoskeletal pain also include decreased physical activity which is the same as for the other chronic diseases of lifestyle. Therefore, musculoskeletal conditions could also be operationally defined as chronic diseases of lifestyle (101-105).

Musculoskeletal conditions (MSC) refer to a broad range of disorders and diseases of the musculoskeletal system including rheumatoid arthritis, osteoarthritis, osteoporosis, spinal disorders, severe limb trauma, fibromyalgia, gout, sprains and strains (13). Chronic musculoskeletal conditions are therefore defined as chronic pain and or/stiffness for three months or more during the last year and more than 15 days of symptoms during the last month (118).

MSC are one of the major causes of morbidity, with the exception of gout, sprains and strains, (13, 119) which limit function globally and impact negatively not only on individuals but also on communities (9, 120). In 2002 the magnitude of the impact of MSC was recognised in Australia when they were added as the country's seventh national health priority leading to the establishment of a National Arthritis and Musculoskeletal Disease Task Force (121). After a literature review, no information could be obtained regarding the impact of MSC in South Africa.

2.4.4 Obesity

Obesity is a broad public health problem and the term refers to the failure of natural physiological body weight control in the light of environmental influences that mostly favour a sedentary lifestyle and high energy diets (122). Obesity is defined as a body mass index (BMI) of more than 30kg/m^2 according to WHO criteria (123). In a person with normal body weight, weight is regulated by physiological signals that regulate appetite and satiety as well as energy expenditure of the individual. Obesity is viewed as a complex medical condition and is affected by a number of contributing factors including environmental, cultural, emotional and psychological factors (124).

The effects of the excess adipose tissue are exerted via the increased amount of production of adipokines and the increased release of free fatty acids. These products include leptin and adiponectin, both hormones; transcription factors and cytokines. In addition to these factors, enzymes are also produced in adipocytes and these enzymes are involved in the production of cortisol and oestrogen (125). Consequently the distribution of adipose tissue influences metabolism and disease risk (126).

There are several clinical problems that are associated with obesity and can be categorised into those associated with excess adipose tissue and those associated with the metabolic effects due to the increased adipose tissue (127). The diseases associated with increased adipose tissue mass include osteoarthritis, sleep apnoea and psychological problems, while diseases associated with the metabolic effects are coronary heart disease, diabetes mellitus type II, and hypertension as well as certain types of cancer including breast, colorectal and uterine cancer (122, 128-133).

2.5 Impairments and functioning

The impairments, activity limitations and participation restrictions of the health conditions diabetes mellitus type II, hypertension, musculoskeletal conditions and the risk factor obesity according to the ICF are presented below in Table 2. Supporting evidence for the occurrence of the ICF component is provided in brackets.

Table 2: Impairments, activity limitations and participation restrictions of CDL, MSC and obesity

ICF component	Condition			Risk factor
	DM II	Hypertension	MSC	Obesity
Impairments				
Pain	(134-136)	No evidence	(16, 93, 137) (138) (139) (114) (140) (141, 142) (143) (144)	No evidence
Vascular complications	(134-136)	(115-117)	No evidence	No evidence
Health state	Including physical and mental (134-136)	No evidence	(145)	No evidence
Depression and anxiety	(134-136)	(116)	(146) (147-149) (12, 150) (151, 152) (144) (153) (154)	(155-157)
Pain-related fear	No evidence	No evidence	(12, 150) (140)	No evidence
Decreased range of motion of joints	No evidence	No evidence	(147-149) (158) (141, 142) (143)	(159-161)
Muscle weakness	No evidence	No evidence	(147-149) (140) (162) (141, 142) (143) (143)	(163, 164) (159) (165)
Biomechanical changes	Due to peripheral neuropathy (166, 167)	No evidence	No evidence	(168, 169) (164, 169, 170) (171) (170) (164, 169, 172) (173)
Deformities	No evidence	No evidence	(147-149) (143)	No evidence
Decreased joint stability	No evidence	No evidence	(174-180)	No evidence
Physical fatigue	No evidence	No evidence	(152, 181) (143) (144)	No evidence

ICF component	**Condition**			**Risk factor**
	DM II	Hypertension	MSC	Obesity
Risk of falling due to poor balance	(166, 167)	No evidence	No evidence	(169, 170) (171)
Cardiovascular and respiratory changes	No evidence	No evidence	No evidence	(182, 183) (184)
Activity Limitations				
Sleep disturbances	No evidence	(115-117) (185)	(147-149) (152, 186) (144)	(187-189)
Problems with walking	Due to changes in balance and posture. (166, 167)	(190, 191)	(147-149) (158) (192, 193) (194) (31, 195) (31) (141, 142) (196) (197)	(159, 173) (161, 198-200) (171) (201)
Climbing stairs	No evidence	No evidence	(147-149) (158) (192, 193) (141, 142) (31, 195) (31) (141, 142) (197)	(171)
Grooming and getting dressed	No evidence	(190, 191)	(147-149) (31, 195) (31) (196) (197)	(171)
Upper limb function	No evidence	No evidence	(147-149) (158) (192, 193) (143) (31, 195) (196) (197)	No evidence
Executive-type cognitive deficits	No evidence	(185)	(152, 186) (144) (202)	(189)
Psychomotor retardation	No evidence	(185)	(144) (202)	(189)
Daily tasks	(203)	(190, 191)	(195) (141, 142) (204) (197)	(171)
Getting in and out of the car	No evidence	No evidence	(31)	No evidence

ICF component	**Condition**			**Risk factor**
	DM II	Hypertension	MSC	Obesity
Participation restrictions				
Social	(134-136)	(185)	(146) (147-149) (139) (205) (12, 206) (12)	(207, 208)
Interpersonal	No evidence	(185)	(139) (205) (151, 209, 210) (12, 206) (12)	(207, 208)
Work	No evidence	No evidence	(147-149) (139) (12, 206) (12) (202) (211)	(207, 208)

The impairments listed in Table 2 are not directly related to DM II or hypertension, but are rather due to the complications experienced by individuals and in older adults, the combination of common age-related disorders and complications (203) (115-117). All the impairments listed for DM II and hypertension have a moderate to severe impact on the health state of the individual, activities of daily living and they have an impact on the quality of life of the individual (134-136) (190, 191). Therefore, the impact is bi-directional as hypertension causes decreased activities, which then worsens hypertension. In addition, it is clear that functional limitations are influenced by a range of social, and economic as well as behavioural factors. Using the ICF framework allows for the exploration of the complex relationship between environmental factors and hypertension. Hypertension not only arises as a consequence of environmental and genetic factors but mostly from the interaction between these factors. Further, the relationship between socio-economic status and hypertension differs substantially in men and women. Men in lower economic status groups have a higher risk of hypertension, while women in lower and middle income groups have a significantly higher risk (212). The association between socio-economic status and hypertension varies according to a country's development and ethnic group (213). Modifiable socio-economic determinants associated with hypertension include education levels and occupation. Additional socio-economic determinants include urban or rural dwelling and individual, local or national economic conditions although these association are complicated and at times contradictory. Other possible explanations include awareness of hypertension prevention, better access and adherence to treatment among higher socio-economic groups and higher work strain among lower socio-economic status groups (212).

The bidirectional relationship between impairments and functional limitations is further demonstrated in the reciprocal relationship between depression and disability (214-216). Depression amplifies limitations from other health conditions, and worsens health behaviour including poor adherence to medication and physical inactivity (185). Life events that are perceived as negative, such as strained interpersonal relationships, due to the impairments and restriction of social activity may then amplify the depression (185). As is evident from Table 2 depression is an impairment experienced by all individuals living with a CDL, MSC or the risk factor obesity.

Also evident from Table 2, is that there are many impairments related to MSC and obesity. The most prominent impairment is pain. The prevalence of chronic MSC-related pain varies from above 20% in the Netherlands, Norway, Poland, Italy, Australia, and across 16 European countries to 11 % of adults in

Spain (3, 9, 217, 218). The range in pain rates is likely to be due to differences in the definition of chronic pain and using different time frames for reporting pain during the studies.

Patients with chronic pain conditions experience widespread negative consequences including depressive symptoms, sleep-related problems, significant pain intensity and decreased emotional well-being (147-149). The impairments and functional limitations experienced depend on the area and the joint(s) affected and may include decreased range of motion of a joint, muscle weakness and even deformities. In addition, disability and decreased physical performance in individuals with chronic MSC create a huge psychological burden which over time may progress into pain-related fear, anxiety and avoidance all of which impact on the quality of life of the individual (12, 150).

A coping style used by individuals living with MSC is to avoid physical activity, a passive pain-coping style which has been found to be associated with higher levels of disability (219, 220). The coping style can be explained using the conceptual framework of the avoidance model. The avoidance model states that an individual tends to avoid physical activity due to a fear of increased pain during the activity or anticipation of experiencing pain during the activity (221). This coping style may be effective in the short term to reduce pain, but unfortunately has long-term negative consequences which include deterioration of the individual's physical condition, especially muscle weakness, resulting in the joints becoming less stable leading to a decrease in the ability to carry a load. Consequently, the individual avoids physical activity more, following a vicious cycle towards further decrease in physical activity and resultant disability (140). The fear-avoidance model of chronic pain demonstrates how an impairment (pain) results in disuse, depression and disability and further pain, and it clearly illustrates the inter-relationships between impairments, function, participation, environmental and personal factors which impact on a person's health.

Pain is not the only impairment associated with MSC. Physical fatigue, inflammation and muscle weakness must also be considered as they interact with each other and are similarly intertwined causing activity limitations and participation restriction. The usefulness of the ICF model is further highlighted when the impact of emotional impairments experienced by individuals including frustration, irritability, resentment and tearfulness are explored (152, 186). The impairment has activity and participatory impact but likewise the activity limitation further has an impact on the impairment. The same is true for depression which, according to the ICF model, can also be viewed as a personal factor.

As is the case with DM II and hypertension, impairments associated with MSC, have negative impacts on the quality of life of the individual. According to Lawrence et al., (1998), an estimated 2.8% of the United States population in 1990 would live with arthritis or have a rheumatic condition as a major contributing cause of moderate activity limitations in their daily lives (90, 195).

The prevalence of activity limitation as a consequence of MSC, adjusted for age, was higher in women (3.4%) than in men (2.0%) and higher in Black populations (4.0%) compared to white populations (2.6%) (90). Musculoskeletal conditions, not only affect the body of an individual as recorded by individual impairments, but these disorders also affect their self-esteem, self-image, sexual relationships and their total emotional well-being (12, 206). Poor physical health can interfere with an individual's mental health and can contribute in the long run to an individual's poor physical condition (145). This once again emphasises that an impairment has activity and participatory impact, but likewise the activity limitation has a further impact on the impairment. Therefore, the ICF provides a framework for the multi-professional team to better understand the effect the chronic condition has on the overall well-being of the individual (12).

Figure 2 below is a representation of the ICF of an individual living with MSC. As can be seen from the representation this framework can then be used to develop multimodal interventions which address the inter-related components.

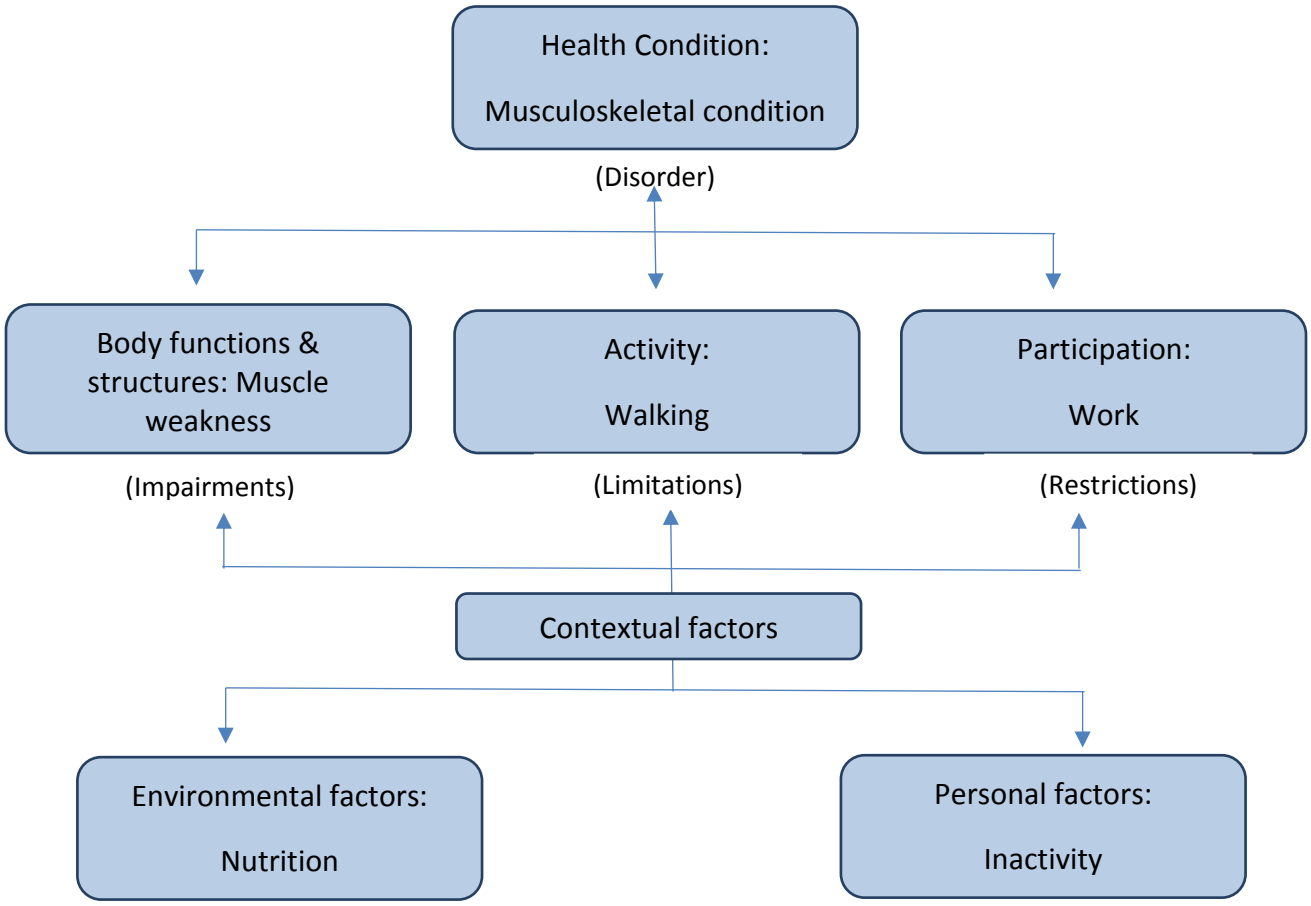


Figure 2: Representation of an example of the ICF concept applied to an individual living with MSC

In summary, there are many impairments related to MSC and obesity, as is evident from Table 2. In addition impairments associated with obesity which are predominately of a biomechanical nature due to the increase of the body mass index (BMI) and the effect it has on the body, will compound these (159-161). It is evident that personal and environmental factors also require consideration as they will

differ depending on the MSC as well as the environment in which the individual functions. Personal and environmental factors are summarised in Table 3 followed by a short discussion.

2.6 Context – environmental and personal factors

The environmental and personal factors of the health conditions diabetes mellitus type II, hypertension, musculoskeletal conditions and the risk factor obesity according to the ICF are presented below in Table 3. Supporting evidence for the occurrence of the ICF component is provided in brackets.

Table 3: Environmental and personal factors of CDL, MSC and obesity

ICF component	Condition			Risk factor
	DM II	Hypertension	MSC	Obesity
Environmental Factors				
Nutrition[1]	(102)	(222, 223)	(224) (225)	(226) (227)
Marital status	No evidence	No evidence	(228)	No evidence
Personal Factors				
Smoking	(203)	(185)	(229) (230, 231)	No evidence
Obesity	(232-234)	(222, 223) (235)	(174-180) (236) (194, 237-240) (230, 231)	No evidence
Inactivity	(203)	(185) (222, 223)	(140) (225)	(165) (226) (241)
Alcohol consumption	(110, 242, 243)	(222, 223) (235)	(230, 231)	
Availability of nutritional food	(102)	(222, 223)	(224) (225)	(226) (227)
Socio-economic status	No evidence	(222, 223)	(90) (174-180) (244) (245-248)	(122, 249, 250)
Age	(102)	(235)	(90) (174-180) (14, 15, 119, 251) (194, 237-240) (90, 120, 251-253)	No evidence
Ethnicity	(102)	(235)	(254) (194, 237-240)	No evidence

[1] Availability of nutritional food can be viewed both as a personal factor and an environmental factor. The justification being, that many disadvantaged people in South Africa live in an environment where their nutritional status is determined by what is available in their immediate vicinity to utilise as food sources rather than a personal lifestyle choice.

ICF component	**Condition**			**Risk factor**
	DM II	Hypertension	MSC	Obesity
Female sex	No evidence	(254) (194, 237-240)	(90, 120, 251-253) (255) (14, 15, 119, 251) (120, 121, 256)	No evidence
Family history/genetics	(104, 257-259)	(235)	(143)	No evidence
	DM II	Hypertension	MSC	Obesity
Other	Previous gestational diabetes mellitus (102).	No evidence	Stress (260-263)	Meet cultural expectations (264) (227, 265); low education levels (122) (250)

The last components of the ICF are those of environmental and personal factors which have an impact on the individual who is living with CDL, MSC or who has the risk factor of obesity. As can be seen in Table 3 several environmental factors and personal factors are common across the conditions. As previously mentioned, it is clear that functional limitations are influenced by a range of social, economic and behavioural factors. However, no specific interactions relating to DM II could be found in the literature (266-268). What is mentioned, is that nutrition, particularly poor nutrition related to poverty, plays a role in the development of DM II, yet the interplay is not well understood (102).

Social, lifestyle and cultural factors are all important determinants of the risk of functional impairments. In particular smoking; nutrition or diet; obesity; alcohol consumption and inactivity have been identified as contributing to impairment. However, all of these factors do not necessarily play a role in every condition; especially obesity.

Although older individuals are more prone to most of the conditions, excluding obesity, it is interesting to note that individuals living with MSC and perceiving themselves as having MSC were in poor agreement. Many of the participants believing they had a musculoskeletal condition could not be classified as having a diagnosis of any of the frequent MSC. On the other hand, people presenting with clear signs and symptoms of one of the MSC were actually never diagnosed (4). This phenomenon may be related to the general population's beliefs and associations that many MSC symptoms are part of the normal aging process, but may also be related to a poor level of health literacy amongst the general population (4).

In a South African setting, special mention needs to be made regarding the links between culture and obesity. In sub-Saharan Africa and developing countries, including in certain South African cultures, there is no definition for obesity, nor is obesity viewed as a disease (227, 265). Instead, obesity is seen as a sign of success, wealth, good health and happiness. Among African women, obesity is associated with being regarded as healthy and attractive due to cultural beliefs, while being thin is undesirable and is seen as a sign of poverty, deprivation, ill health and despair (227, 265); therefore, when designing a programme to approach obesity as a health problem, societal and cultural context should be considered and not merely personal factors.

In addition to the cultural attitude towards obesity, changes in culinary practices and eating habits also bear consideration in terms of body weight in South Africa. The socio-cultural paradigm shift described by Renzaho (2004) highlights the fact that consumption of high kilojoule foods, soft drinks, and frying of foods in vegetable oil is assumed to be the "foods of white people" (227) and therefore indicative of a higher social status to those who are struggling economically (227). It is evident that many of the health problems in South Africa are socially and culturally rooted and compounded by poverty, crime and violence. Efforts to promote healthy lifestyles (including regular, moderate physical activity and a sensible diet) will have to extend comprehensively to the very core of society and address different cultures (7). Therefore there is a need to develop an integrated intervention programme for CDL, MSC and obesity. This integrated intervention programme should include: exercise to increase physical activity levels; and health education to address low levels of health literacy, particularly in relation to diet/nutrition in the management of these complex and interrelated conditions.

2.6.1 Co-morbidity

As can be seen from Table 4 below, DM type II is commonly morbid with decreased pulmonary function and depression, while MSC occurs with obesity and DM type II. The risk factor obesity is commonly associated with co-morbidities including DM type II, hypertension, MSC, dyslipidemia and cardiac diseases. Comparison of studies is difficult due to the age, race, ethnicity and sex utilised in the study as well as the methodology followed, as in most instances self-reporting of co-morbidities is utilised. Hypertension and diabetes mellitus are commonly intertwined.

Table 4: Summary of co-morbidities

Reference	Population	Number	DM type II	Hypertension	MSC	Obesity	Other
DM type II							
(269)	Brazil	318 individuals	Primary condition	66.4%[2]	Not reported	Not reported	Vascular (53.8%) Hypercholesterolemia (60.8%) Ophthalmic (42.8%) Vascular (14.5%) Kidney (12.9%)
(270)	Rio de Janeiro, Brazil	105 individuals	Primary condition	Not reported	Not reported	Not reported	Anxiety (43.8%) Depression (38.1%)
(271)	Netherlands	772 individuals	Primary condition	Not reported	Not reported	Not reported	Depression (37%-43%)
(272)	Copenhagen	11 763 individuals	Primary condition	Not reported	Not reported	Not reported	Decreased pulmonary function
(273)	Framingham, Massachusetts	3 254 individuals	Primary condition	Not reported	Not reported	Not reported	Decreased pulmonary function
(274)	Western Australia	495 individuals	Primary condition	Not reported	Not reported	Not reported	Decreased pulmonary function

[2] In each instance the percentages under the co-morbidities refer to the percentages of those with the primary condition.

Reference	Population	Number	DM type II	Hypertension	MSC	Obesity	Other
(275)	United States	15 792 individuals	Primary condition	Not reported	Not reported	Not reported	Decreased pulmonary function
(276)	Mysore, India	90 individuals		Not reported	Not reported	Not reported	Decreased pulmonary function
Hypertension							
(277)	Poland	12 525 individuals	21.3%	Primary condition	OA (7.9%) Degenerative disc disease (11.9%)	Not reported	Coronary artery disease (21.6%) Gallstones (0.4%) Peptic ulcer (2.1%) Mood disorders (1.2%)
(278)	United States of America	No evidence	75%	Primary condition	Not reported	Not reported	Micro- and macro-vascular co-morbidities
(279)	Florida, United States of America	578 malignant cases of hypertension	12.6%	Primary condition	Not reported	1.7%	Hypercholesterolemia (5.1%) Lipid disorders (5.1%)
MSC							
(280)	Ontario, Canada	1 803 individuals	33.3%	Not reported	Primary condition	32.6%	Coronary Arterial Disease (56%) Depression (22.3%)
(281)	Ontario, Canada	No evidence	74.0%	Not reported	Primary condition	50.9%	Respiratory diseases (54.8%) Cardiovascular diseases (67.3%)

Reference	Population	Number	DM type II	Hypertension	MSC	Obesity	Other
(282)	Norwegian	No numbers provided	No evidence	Not reported	Primary condition	No evidence	Migraine and non-migraine headaches
Obesity							
(283)	Kampur, India	2 256 individuals	16.7% urban and 7% rural	17% urban and 14% rural	33.6% urban and 27% rural	Primary condition	Gall bladder (7% urban and 3% rural)
(284)	San Juan Metropolitan Area of Puerto Rico (2005 to 2007)	840 individuals	28.7%	Not reported	No evidence	Primary condition	Dyslipidemia Coronary heart disease (8.6%)
(285)	Kuwait	2 487 individuals (55.5%)	49%	55%	OA (46%)	Primary condition	Cardiac diseases (15%)
(286)	Germany	6 790 individuals	Condition only stated	Condition only stated	Condition only stated	Primary condition	Only stated no specific detail provided
(287)	BMI of ≥25 Canada's Aboriginal First Nation	483 individuals	35%	48%	No evidence	Primary condition	Dyslipidemia (38%)

Reference	Population	Number	DM type II	Hypertension	MSC	Obesity	Other
(288)	United States of America BMI =30-34.9	3 637 individuals	Not reported	Not reported	BMI of 30-34.9 (9.7%) BMI of 35-39.9 (13.5%)	Primary condition	Not reported
(289)	Not reported	Not reported	Not reported	Not reported	Not reported	Primary condition	Coronary heart disease Stroke Cancer Gallstones Urinary stress incontinence Gynaecological abnormalities Dyslipidemia

According to Dreher (2003) as cited by Jakovljević et al., (2003) co-morbidity is based on the interconnections of mind, neurotransmitters, endocrine and immune systems of the body which interact and influence each other both in health and in illness. Various pathways to co-morbidity are identified including shared pre-disposition and vulnerability (types of personality and personality traits), shared risk factors (stress, unhealthy lifestyles and negative emotions) and shared mechanisms (unsuccessful coping mechanisms, failed adjustment to situations, defence mechanisms, exhaustion) (290).

The high prevalence rates of co-morbidity and multi-morbidity have a significant impact on treatment responses and occurrence of adverse events in patients. Therefore, the focus on single diseases should be reviewed and replaced both academically and clinically with holistic treatment approaches (290).

2.7 Role of exercise and physical activity

This section examines the interaction between functioning (specifically exercise) health condition and impairments of function. The ICF model emphasises the non-linear nature of the disability process, in which there is an interaction between the components. The health condition and attendant impairments do not only cause activity limitations but in turn are influenced and modified by, functioning.

> "Lack of activity destroys the good condition of every human being, while movement and methodical physical exercise save it and preserve it." Plato as cited by King et al., (2010) (291).

Physical activity is defined as "any bodily movement produced by the contraction of skeletal muscles, which result in energy expenditure that is greater than that at rest" (292). This actually means that exercise is not limited to participating in sport, but includes activity of daily life which is associated with home life, and mode of transport as well as leisure activities (292).

There are several clinically important reasons to recommend exercise for patients with chronic disease. The first is that exercise may prevent the physical de-conditioning that patients typically experience; secondly exercise may optimise the functioning of the individual when used as adjunctive therapy to standard pharmacological treatments; thirdly exercise may reduce secondary cardiovascular risk factors and prevent other clinical consequences of the chronic disease and/or treatment. Lastly, improving

physical functioning will optimise quality of life, overall well-being and may possibly improve the overall long-term outcomes (291, 293-296). It is well established in the literature that exercise can improve emotional health, depression and self-efficacy, thereby improving chronic disease management (297-302).

As can be seen in Table 5 exercise has a beneficial impact across conditions. In addition, physical inactivity is one of the personal factors that contributes to activity limitations and participation restrictions of individuals living with CDL, MSC and obesity.

Table 5: Effects of exercise on CDL, MSC and obesity

Condition	Effect of exercise	Reference(s)
DM II	Improved sensitivity to insulin; possible improvement in blood glucose control; reduction in body fat and cardiovascular benefit.	(303-308)
Hypertension	Decrease in plasma nor-epinephrine levels; increase in the circulating vasodilator substances in the body; amelioration of hyperinsulinemia and changes in renal function.	(309-315)
MSC	Diminish the effect of inactivity, and effect of symptoms, but the effect of exercise on the disease process itself, has not been determined by research.	(316-324)
Obesity	Improved insulin sensitivity; changes in metabolic rate and lipid profiles, reduction in blood pressure, changes in glucose metabolism; improvement in the mood of the individual; preservation of lean body mass despite lower food intake and loss of abdominal fat deposits.	(325-331)

In summary, the main goals for exercise aligned with physiological principles are to improve and increase the overall functional strength and capacity of an individual; to increase daily physical activity and energy expenditure; enhance the metabolism of lipids and carbohydrates; promote the normalisation of the cardiovascular function, and to mediate the effects of limited functional ability (332).

Exercise is a treatment which works well within the ICF framework for CDL, MSC and obesity (1, 49, 50). If the individual has joint stiffness, then exercise addresses the loss of ROM and muscle weakness, which

then improves function and also improves participation. If it is structured around a goal or utilises exercise in groups (333), exercise also addresses personal factors and can assist people in managing their environment (334-337). Furthermore, exercise teaches people skills of goal setting, pacing and activity scheduling, all of which are health literacy skills needed for the management of CDL and MSC (338).

Thus, it makes sense to include exercise in the management of CDL, MSC and obesity, however, it is important to note that sequential goals should be developed and integrated into a lifestyle modification programme for people with co-morbidities (332).

2.8 Primary health care within the research setting

Contextual or environmental factors do not only include the physical environment in the ICF but also include access to products, such as pharmaceutical and other health management policies related to the provision of services, such as social grants, housing and transport. This section will deal exclusively with the research setting, which was within a primary health care clinic in a resource constrained area of the Free State.

Primary health care (PHC) was described in the 1978 Declaration of Alma-Ata as:

> "essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination" (339).

PHC consists of two systems in most low income countries. The first includes the hospital care system and the second the network of PHC clinics that offer basic, preventative services to low-income communities in urban and rural areas (340). PHC should form an integral part of both the country's health systems, which it is the central function and main focus, and also of the overall social and economic development of the community. It is the first level of contact of individuals, family and the community with the national health system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process (339). PHC is seen in

many countries as the best model for delivering basic health care to communities (340) and in many low and middle income countries disease burdens are mostly managed by these services. The services rendered encompass preventative, promotive, curative, supportive and rehabilitation services (341).

PHC forms the foundation of the health care delivery system in South Africa. With the onset of democracy in South Africa, PHC was seen as a model "whose time had come" and it was envisaged that a health care model with a people-orientated health care system would address the inequities that were created by apartheid (342). Primary care available at public sector clinics throughout South Africa was declared as a free share point of health care delivery.

The Pholela Health Centre model was used to develop the PHC in South Africa and the model was intended to provide comprehensive preventive and curative services in both urban and rural areas. From the onset the Pholela Health Centre was seen as innovative. It utilised population-based investigations to inform the health services provided and included health education and health promotion as essential elements of the health delivery system (343). A pioneering feature was the model's reliance on epidemiological and social information of the local community to inform the services provided at the centre. It was argued that an empirical understanding of the community's health profile based on evidence must be established in order to determine the appropriateness of the care at local health services to meet the needs of the specific community (343). One of the key elements of the Pholela model was the emphasis on community participation and empowerment in the delivery of health care and community members as well as the involvement of local authorities in the planning and decision-making.

The Community clinic forms part of the different models of primary care provision in South Africa and is defined as a facility at and from which a range of PHC services are provided (344). The clinics are open eight hours a day and are primarily run by nurses, although doctors do visit the clinics regularly. If a more specialised level of care is needed, patients are referred to District hospitals by clinic staff for further management (344). The physiotherapy services rendered at the clinics are provided by the newly graduated community service physiotherapists. The clinic renders a service to a monthly population ranging between 19 000 – 22 000 (31).

It is the personal observation of this researcher that the population of the current study is an impoverished, ethnically black community, most of whom rely on social grants and part-time employment. Many of the families are supported by one member and in most instances more than one family resides in a single informal or formal home depending on the settlement in which the family lives. No literature to substantiate the observation of the researcher could be found. Most of the informal settlements do not have access to running water or electricity. Due to the increase in the number of teenage pregnancies in the community as well as the HIV pandemic, the children in the community are often raised by the middle-aged women (31, 345). According to Copley et al., (2013) 89% of the population in the specific area of the clinic were literate and could read and write, while only 20.41% had obtained a Grade 12 level of education, which in South Africa is the final year of high school, usually attained by 18 years of age (31).

The transformation of the health system has posed an extreme challenge to the government due to health worker shortages, the migration of medical and allied health professionals, imbalances of resources, shortages in managerial capacity of health systems and leadership at all levels and the complex burden of disease which is still evolving with emerging infectious diseases and non–communicable diseases (346). Padarath et al., reported in 2004 that an estimated 40% of health positions in the public sector were unfilled and the numbers are increasing yearly (347). In 2010 56% of doctor posts in South Africa were unfilled as were 46% of nurses posts (348). Achieving the implementation of district-based health services in South Africa is hampered by the critical shortage of health care professionals and the inability to fill the vacant posts (249, 342).

The primary health care clinic where the research was conducted serves the formal and informal community settlements of Freedom Square, Namibia, Turflaagte, Chris Hani, JB Mafora, Kagisanong, Albert Luthuli, SE Jake, Buffer and Rocklands. Within the community there are several schools and police stations that also serve the community and there are also two smaller clinics the Freedom Square clinic and the Kagisanong clinic. During data collection for the current study, the Department of Health in the Free State Province had financial difficulties and were on the verge of national takeover. Essential services and medication were not being delivered to patients during this time and one clinic was closed due to the rent not being paid by the Department of Health (349, 350).

Therefore given the context, the setting, the ICF and the impact exercise and education has on CDL, MSC and the risk factor obesity, the treatment approach of the study is relevant.

2.9 Conclusion

The narrative review has highlighted the fact that the prevalence of health conditions and impairments of CDL (including obesity and MSC) is universally high and is increasing. Several studies have indicated that this is the case in South Africa, and that people living in under-resourced areas are particularly vulnerable to these conditions. The interaction between health conditions and risk factors was discussed and it is suggested that, as co-morbidity is very common in older persons, and as disability should be regarded as being aetiologically neutral, it makes sense to attempt to address therapeutically the impairments and activity limitations most commonly encountered co-morbidly through a common intervention.

A common protective factor amongst the CDL and obesity appears to be exercise (physical activity) as it has been found to improve impairments of body functioning at a physiological level. However, despite the high prevalence of CDL, including hypertension, diabetes mellitus type II and musculoskeletal conditions and the harmful influence inactivity has on these conditions, the functioning of people with these chronic diseases of lifestyle had not been adequately studied. As highlighted by the ICF, contextual and personal factors can have a major impact on functioning and, to the knowledge of this researcher; very little if any work has been done in severely under-resourced, rural areas of South Africa in terms of developing and testing appropriate interventions. The next two chapters concentrate on the impact of therapeutic programmes designed to improve the health-related quality of life (HRQOL), functional limitations and participation restrictions of persons living with CDL and obesity.

3 EXERCISE AND HEALTH EDUCATION IN THE MANAGEMENT OF CHRONIC DISEASES OF LIFESTYLE: A SYSTEMATIC REVIEW

3.1 Introduction

As demonstrated in Chapter 2 chronic diseases of lifestyle may have a major impact on the functioning of individuals that in turn may impact on their Health-Related Quality of Life. Health-Related Quality of Life (HRQOL) is defined as an individual's well-being and describes the perception of individuals regarding their health and functioning across social, physical and psychological domains. It refers to the self-reported standard of health and satisfaction experienced by a person or a community, regardless of illness or handicap (351). HRQOL is also related to the morbidity and mortality of an individual (352).

The aim of this chapter is to present the evidence for the use of exercise and health education in adults with chronic diseases of lifestyle (diabetes mellitus type II, hypertension) and obesity and the impact thereof on HRQOL. Although it would have been optimal to only deal with interventions which enrolled participants similar to those included in the current study, this was not possible. The search was not restricted to middle-age women as there were only three studies that dealt exclusively with women. The one study addressed obesity, the one study metabolic syndrome and the third study diabetes mellitus type II. Therefore the search had to be widened to include males and female of all age groups (adults) to ensure that the objectives of the review were addressed adequately.

3.2 Objectives

The objectives of the review were to address the following questions:

- What exercises are used for adults with diabetes mellitus type II, hypertension or obesity?
- What education is given to adults with diabetes mellitus type II, hypertension or obesity?
- What is the impact of exercises or education on the HRQOL of adults with diabetes mellitus type II, hypertension or obesity?

Information related to impairments of body structure and function, activity limitations and participation restrictions was also gathered but not included in this review as these outcomes differed considerably depending on the underlying health condition.

3.3 Methods

3.3.1 Criteria used for selecting studies for review

Criteria were identified in three categories to guide the selection of studies for the purpose of the systematic review. The following studies were included:

- Randomised controlled trials were included, while case-control studies, case reports, letters and cross-sectional studies were excluded.
- Studies on human adults with diabetes mellitus type II, hypertension or obesity were included.
- Studies reporting on the impact of interventions on health-related quality of life, function and participation were also included.

3.3.2 Search methods

The following electronic databases were searched from 2009/01/01 to 2013/12/31. The list of synonyms was developed in conjunction with a librarian the Health Sciences Library, at the University of Cape Town. The MeSH (Medical SubHeadings) database for the official MeSH headings as well as free language was used to identify synonyms for the specific search. The thesaurus (MeSH headings) provides suitable synonyms for the search in PubMed. Searching on the MeSH term automatically explodes, in other words includes all its subheadings and narrower terms. Despite including filters for example “human” and “adults” these filters would not filter out every article, possibly still in the indexing process, therefore articles still had to manually be filter out. When searching the MeSH database for Diabetes Mellitus Type 2, the search was directed to the MeSH heading Diabetes Mellitus Type 2 and upon exploring this term, further entry terms were provided to map to the initial heading. These terms can be used as synonyms for the systematic review search. The explanation for Diabetes

Mellitus Type 2 in the MeSH search was indicated as: "A subclass of DIABETES MELLITUS that is not INSULIN-responsive or dependent (NIDDM). It was characterized initially by INSULIN RESISTANCE and HYPERINSULINEMIA; and eventually by GLUCOSE INTOLERANCE; HYPERGLYCEMIA; and overt diabetes. Type II diabetes mellitus is no longer considered a disease exclusively found in adults. Patients seldom develop KETOSIS but often exhibit OBESITY." No definition or explanation was given for any of the other MeSH terms in this search.

Table 6: Search strategies utilised

Electronic database	**Limits to the searches**	**Terms excluded using the "NOT" Boolean search term**
Africa-Wide CINAHL The Cochrane Library PEDro PsychArticles PsycInfo PubMed (which includes Medline) Scopus (which indexes Embase) Web of Science Science Direct SportDiscuss	Journal articles English "human" "adult" "Diabetes "/ "Diabetes Mellitus" / "Diabetes Mellitus Type 2" / "Diabetes Mellitus Type II" / "Type 2 Diabetes Mellitus" OR "Hypertension OR "Obesity" AND "Health Education OR "Exercise"	"case-control studies" "letters" "cross-sectional studies" "children" "adolescents"

3.3.3 Data extraction and quality assessment

All the articles identified were imported into Mendeley® and duplicates removed. Mendeley® is a free desktop software reference manager tool (353), manufactured by Elsevier Publishing, United States of America, website https://www.mendeley.com . The researcher and a research assistant independently screened all the abstracts for possible inclusion. The full text of articles identified by either the author, or the research assistant as containing relevant information for the systematic review was obtained and the quality of the full text articles was then assessed.

Table 7: Criteria used for screening of abstracts

Category	Inclusion Criteria	Exclusion Criteria
Population	Human adults	Only children Only adolescents
Study design	Randomised clinical control trial	Case reports, case studies
Interventions	Exercise or health education/education	
Outcome	Reporting on the health-related quality of life of adults with diabetes mellitus type II or hypertension or obesity Activity limitation of adults with diabetes mellitus type II or hypertension or obesity Participation restriction of adults with diabetes mellitus type II or hypertension or obesity	Letters and cross-sectional studies

According to Woolf (2000), assessment is the utilisation of specific analytic criteria to judge the internal and external validity of studies (354). Controversy exists as to whether external validity should be included in the criteria (355-357). The Delphi list, as described by Verhagen et al., (1998), clearly indicated that internal validity and external validity as well as statistical considerations should form part of the concept of quality (355). Although there is no exact way of assessing the quality of research trials, a checklist, for example a Delphi list, is often used by authors with specified criteria rated and a total score calculated to estimate the quality of the trial (355-357). The total score can then be utilised to determine the inclusion and exclusion of studies in a meta-analysis, as a weighting factor in the statistical analysis (355, 358). The Physiotherapy Evidence Database (PEDro) scale was developed by the Centre for evidence-based Physiotherapy at the University of Sydney, Australia. The scale includes the Delphi list items, which were developed by means of a Delphi consensus, but includes two additional items to finalise the PEDro scale (359). The PEDro scale Table 8 consists of 11 criteria, of which criterion one assesses external validity, criteria two to nine measure internal validity and the final two assess the statistical information provided to interpret the results of the study (355, 360). The PEDro scale also contains a complete appendix on the definition and interpretation of each criterion (359).

Quality assessment of research articles relies on subjective assessment of content, and blinded quality assessment by more than one reviewer significantly reduces bias in systematic reviews (357, 361, 362). For this reason the researcher and a research assistant were masked reviewers, independently scoring the quality of included research articles (362). Each criterion was marked as yes when the reviewers were satisfied that the criterion had been met after reading the report and no when an unbiased decision could be made that the criterion stipulated was not satisfied. The page where the information was obtained was also noted on the scale. Scores for each study were then calculated as a percentage. Due to the fact that so few studies were eligible for inclusion in the systematic review, the decision was made that all studies would be included rather than calculating the mean score of the studies selected and only including those scored greater than or equal to the mean as described by Louw et al., (2007) (363).

Table 8: PEDro scale

No	Criteria	Yes	No	Where
1	Eligibility criteria were specified.			
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which the treatments were received).			
3	Allocation was concealed.			
4	The groups were similar at baseline regarding the most important prognostic indicators.			
5	There was blinding of all subjects.			
6	There was blinding of all therapists who administered the therapy.			
7	There was blinding of all assessors who measured at least one key outcome.			
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups.			
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated, or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”.			
10	The results of between-group statistical comparisons are reported for at least one key outcome.			
11	The study provides both point measures and measures of variability for at least one key outcome.			
	Total (%)			

Data were extracted from the studies identified and entered into spread sheets to create a summary that included the information listed in Table 9.

Table 9: Information included in spread sheet for study review

Author(s)
Year of publication
Study design
Aim or purpose of the study
Exposure (intervention/education) for both the control group and the intervention/experimental group
Sample size
Gender and age of the participants
Relevant demographic characteristics of the sample
Criteria for diagnosis/condition identification
Relevant co-morbidities
Contextual factors including setting and geography
Comparison of groups at beginning of study
Inclusion and exclusion criteria
Selection of participants
Allocation to the study
Concealment of allocation
Blinding method
Specific details of the intervention and control group
Measuring instrument
Observation period
Outcome measurement
Time points when the outcome was measured
Outcome definition identified for the study
Interpretation of the measurements
Effects (95% confidence interval)
Statistical methods used
Withdrawals/drop-out to allow and intention-to-treat analysis
Missing data/participants
Main findings which included the number for which the outcome was being reported and the authors' key conclusion (364)

3.3.4 Meta-analysis

Meta-analysis is described as quantitative pooling of data and results of studies reached by similar study designs on a specific issue. A meta-analysis involves several statistical methods of analysis (354, 358, 365), and increases the statistical power of individual studies by combining their findings, but unfortunately is not able to control for errors that have been built into the original set of data collection by the researchers. By performing a heterogeneity test, it can be demonstrated, how individual study results compare to the overall summary estimate. If significant heterogeneity is demonstrated it can indicate that the specific individual study possesses a factor that could have significantly influenced the results. Therefore, it is important to seek an explanation for the significant heterogeneity in order to identify any weak links in a study that should have been accounted for by the researchers during the interpretation of the results/findings (358, 366, 367).

In order to compare studies through meta-analysis, the studies should be similar in the following aspects: the studies should have the same hypothesis; the outcome of the studies must be similar; participants in the studies should be similar and comparable; the intervention of the studies should be similar; and a minimum standard of scientific quality should be met (362). Other aspects that should be considered are randomisation; blinding; adequate sample size of the study, measures taken to ensure quality during collection and management of data as well as statistical analyses (356-358, 365).

All studies for each separate condition were considered for meta-analysis regardless of the quality score that was achieved using the PEDro scale. All the studies looking at hypertension was grouped and considered for meta-analysis. Similarly all the studies looking at diabetes mellitus type II were grouped together and considered for meta-analysis as were the studies for obesity. Therefore, the all-inclusive method was chosen for the selected clinical trials (354, 365). The hypotheses of the studies, the intervention the outcome measures; to the characteristics of the study populations, sample size, and availability of the results were compared by two independent reviewers to identify the possible pooling of results (362). The researcher was one reviewer while a Biostatistician at the University of the Free State was the second reviewer for the meta-analysis section of the study. Heterogeneity among the study populations, the co-morbidities, quality of studies and the interventions utilised in the studies, did not allow for statistical pooling of results and therefore a meta-analysis was not performed.

3.4 Procedure

After the online search of the electronic databases as described in Section 3.3.2, the articles identified were imported into Mendeley by the researcher and duplicates were removed. A form developed by the researcher was used to determine the inclusion or exclusion of the articles. Even if QOL or HRQOL outcome measures were not mentioned in the abstract, the article was included for screening if quality of life outcome measures had been included in the studies as secondary measures and therefore not mentioned in the abstract. All abstracts, as well as the form developed by the researcher for the screening process were saved on a memory stick and handed to the research assistant (second reviewer). The second reviewer as well as the researcher was qualified physiotherapist with Master's degrees in the field of Orthopaedic Manipulative Therapy at the University of the Free State, both were trained in the process but had not previously conducted a systematic review.

The researcher and the second reviewer independently screened all the abstracts for possible inclusion. Once the screening process had been completed, the lists of possible inclusions were compared and finalised during a consensus meeting. Three articles were included by the second reviewer for reviewing but not by the researcher. These three articles were reviewed again during the consensus meeting and excluded as the studies did not report on the impact of interventions on impairment, activity limitation and participation restriction (including HRQOL) of participants. The full text of identified articles was then obtained. A meeting was held between the two reviewers to ensure that the interpretation of the PEDro score was done correctly and a trial scoring was done on two articles not included in the review. No problems were identified. Data were extracted from the studies identified and entered into the spread sheets. The PEDro scale was completed for each study and the total quality score noted. A table was compiled with the scores of each reviewer as well as the mean quality score of each article (Table 15). Not interaction between the two reviewers took place to influence the outcome of the quality scores during the process. Fleiss Kappa scores were calculated to determine overall inter-rater agreement between reviewers.

3.5 Results

The online search generated a total of 9 946 initial hits. A total of 9 533 articles were excluded as the title and/or the date of publication did not conform to the systematic review's objectives. Eight duplicates were removed and a total of 405 abstracts were screened by the researcher and the research assistant. A further 389 articles were excluded as they did not report on the impact of interventions on impairment, activity limitation and participation restriction (including HRQOL) of participants. 16 articles remained and full text copies were obtained (Figure 3). Following full text review, it was decided that all 16 articles would be further assessed using the 11 item PEDro scale.

Table 10: Number of articles obtained from electronic databases

Database	Number of records identified
Africa-Wide	459
CINAHL	345
Psychinfo	35
The Cochrane Library	82
PEDro	12
Scopus (which indexes EMBASE)	73
PsychArticles	15
PubMed (which includes Medline)	2 019
SportDiscuss	1 331
Science direct	5 575
TOTAL	9 946

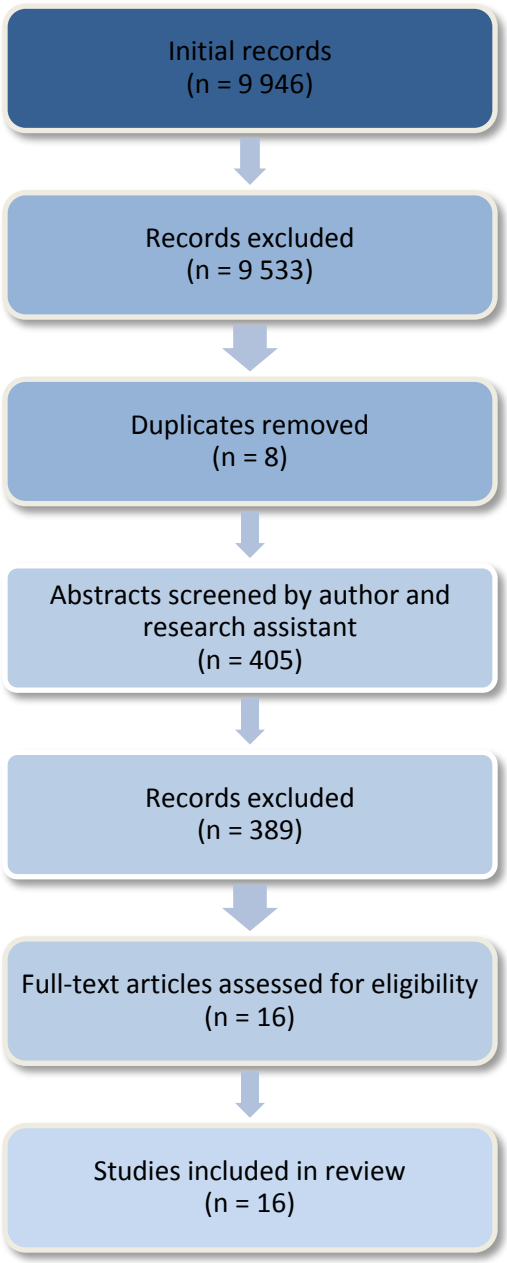


Figure 3: Flow diagram of the selection and review process

3.5.1 Description of the studies

A total of 16 studies met the inclusion criteria and were summarised in Table 12 below. The search was not restricted to middle-age women as there would be only three studies to be included in this category. One study addressed obesity, the other study metabolic syndrome and the third study diabetes mellitus type II. Therefore the search had to be widened to include males and female of all age groups (adults)

to ensure that the objectives of the review were addressed adequately. In total 2793 participants were included in the studies, of which 1492 (53.4%) were female. Sensitivity analysis comparing the impact on males compared to females was not performed for any study, and only one study compared the impact across age groups (Table 11). The mean ages of the participants in all studies ranged from 38 to 71, with seven reporting a mean age of between 60 and 68 years. Thus most studies included "middle aged" participants.

Table 11: Percentage of female participants in included studies

Author	**Percentage of female participants in each study**	**Sensitivity analysis**
Chaveepojnkamjorn et al., (2009) (368)	77.4%	None performed
Deinzer et al., (2009)(369)	66.2%	None performed
Rimmer et al., (2009)(370)	36.1%	None performed
Moriyama et al., (2009)(371)	51.5%	None performed
Bouchard et al., (2010)(372)	100%	None performed
Dyson et al., (2010)(373)	57%	None performed
D'Eramo-Melkus et al., (2010)(374)	100%	None performed
Oh et al., (2010)(375)	100%	None performed
Young et al., (2010)(376)	61%	None performed
Nicolucci et al., (2012)(377)	41.3%	None performed
Park et al., (2011)(378)	67.4%	None performed
Vadstrup et al., (2011)(379)	44.5%	None performed
Williams et al., (2012)(380)	37.5%	None performed
De Vico et al., (2013)(381)	40.3%	None performed
Espeland et al., (2013)(382)	55.5%	Only done for age (45-64 years and 65-76 years)
Sakurai et al., (2013)(383)	76%	None performed

Table 12: Summary of reviewed articles

Author (year)	Setting	Population (sample size)	Mean ± SD or range of age in years	Female %	Ethnicity (%)	Number of participants in each group	Details of intervention	Relevant co-morbidities	Measurement Outcomes
Chaveepojnkamjorn et al., (2009)(368)	Saraburi Province Thailand	Patients with diabetes mellitus type II (164)	48.9 (7.1)	77.4%	Taiwanese (100%)	80 (Intervention) 84 (Control)	Active learning was encouraged. (Education)	Missing	Interview: Quality of life using WHOQOLBREF-THAI.
Deinzer et al., (2009)(369)	Nuremberg Germany	Hypertension patients (86)	60.9±10.1 (Intervention) 61.1±9.3 (Control)	66.2%	Missing (German study)	40 (Intervention) 46 (Control)	Shared decision-making practice to empower patients. (Education)	Missing	Blood pressure Hypertension Questionnaire; Difficult-Doctor–Patient-Relationship-Questionnaire (DDPRQ); Short Form 36-Item Health Survey for health-related quality of life (SF-36); Autonomy. Preference Index (API); Combined Outcome Measure for Risk Communication and Treatment Decision-Making Effectiveness (COMRADE)

Author (year)	Setting	Population (sample size)	Mean ± SD or range of age in years	Female %	Ethnicity (%)	Number of participants in each group	Details of intervention	Relevant co-morbidities	Measurement Outcomes
Rimmer et al., (2009)(370)	New York, USA	Patients with severe obesity and mobility disability (92)	38.83	36.1%	African American (87%)	30 (Higher support group) 31 (Lower support group) 31 (Awareness group)	High and low levels of support to maintain physical activity. (Exercise)	Hypertension Cholesterol	BMI Blood pressure Blood tests Physical Activity and Disability Scale (PADS); The Barriers to Physical Activity and Disability Survey (B-PADS); The International Classification of Functioning, Disability and Health (ICF) Activity Measure; The Quality of Well-Being (QWB) Scale; CARDIA-2 for social support
Moriyama et al., (2009)(371)	Japan	Patients with diabetes mellitus type II (50)	66.4 ±9.2 (Intervention) 65.2 ± 8.5 (Control)	51.5%	Japanese (100%)	50 (Intervention) 25 (Control)	Acquisition of self-management skills. (Education)	Cholesterol Hypertension	BMI Blood tests Overall QOL scale in the WHO-QOL26; Generalised Self-efficacy Scale for the measurement of self-confidence and accomplishment.

Author (year)	Setting	Population (sample size)	Mean ± SD or range of age in years	Female %	Ethnicity (%)	Number of participants in each group	Details of intervention	Relevant co-morbidities	Measurement Outcomes
Bouchard et al., (2010)(372)	Canada	Obese women (48)	62.4 ± 4.4	100%	Missing	12 (Caloric restriction group) 12 (Resistance training group) 12: (Resistance training group) 12: (Caloric restriction + resistance training group) 12: (Control group)	Supervised weight loss programme with nutritional group and exercise group.	Wide range of conditions, from CDL to muscular dystrophy.	Functional tests BMI The Medical Outcomes Study Short Form-36 questionnaire for health-related quality of life (SF-36); Physical Activity Scale for the Elderly; modified version of the Older American Resources and Services questionnaire
Dyson et al., (2010)(373)	Oxfordshire United Kingdom	Patients with newly diagnosed diabetes mellitus type II (42)	60.8 (9.6)	57%	Missing	21 (Intervention) 21 (Control group)	Video education with expert opinions and case studies. (Education)	Hypertension	ADKnowl questionnaire, WHO-5 Well-Being questionnaire for quality of life; Dietary intake was measured by a validated three-day food diary Pedometer

Author (year)	Setting	Population (sample size)	Mean ± SD or range of age in years	Female %	Ethnicity (%)	Number of participants in each group	Details of intervention	Relevant co-morbidities	Measurement Outcomes
D'Eramo-Melkus et al., (2010)(374)	Urban Southern New England (USA)	Patients with diabetes mellitus type II (109)	48 ± 10	100%	Black American (100%)	57 (Intervention) 52 (Control)	Culturally appropriate education and coping skills. (Education)	Obesity High blood pressure Cholesterol	Blood tests Blood pressure Crown-Crisp Index for anxiety; 25-item Problem Areas in Diabetes Survey (PAID); Diabetes-specific social support was measured using a subscale of the Diabetes Care Profile (DCP); The Diabetes Self-efficacy Outcomes Expectancies Questionnaire (DSE-Q;)The Diabetes Knowledge Test; The Medical Outcomes Study for general quality of life; Modified Health Care Climate Questionnaire for health care provider support (MHCCQ); The Medical Outcomes Study (MOS)-SF-36 for quality of life

Author (year)	Setting	Population (sample size)	Mean ± SD or range of age in years	Female %	Ethnicity (%)	Number of participants in each group	Details of intervention	Relevant co-morbidities	Measurement Outcomes
Oh et al., (2010)(375)	South Korea	Patients with metabolic syndrome (52)	62.7 years (SD = 9.0;) range, 49-90	100%	South Korean (100%)	31 (Intervention) 21 (Control))	Comprehensive multi-component, therapeutic lifestyle modification programme (Education and exercise)	Hypertension Diabetes Cardiovascular disease Gastrointestinal disease	BMI Blood tests Medical Outcome Study Short Form-36 for health-related quality of life
Young et al., (2010)(376)	Baltimore, MD; Baton Rouge, LA; Durham, NC; Portland, OR, USA	Patients with Pre-hypertension or stage 1 hypertension (810)	50.2±8.9	61%	African American (34%)	268 Established Intervention 269 Established + DASH Intervention 273 (Control)	Multi-component lifestyle intervention. (Education)	Missing	BMI The Rand 36-item Health Survey for health- related quality of life; Stanford 7-day physical activity Recall
Nicolucci et al., (2012)(377)	Italy	Patients with diabetes mellitus type II (606)	Missing	41.3%	Missing	303 (Intervention) 303 (Control)	Training programme. (Exercise)	Missing	Blood tests 36-Item Short Form Health Survey for health-related quality of life (SF-36)
Park et al., (2011)(378)	Seoul, South Korea	Patients with hypertension (40)	71	67.4%	Missing	18 (Intervention) 20 (Control)	Patient tailored elastic band exercise and group health education. (Education and exercise)	Missing	Medical Outcomes Study Short-Form 36 for health-related quality of life (SF-36)

Author (year)	Setting	Population (sample size)	Mean ± SD or range of age in years	Female %	Ethnicity (%)	Number of participants in each group	Details of intervention	Relevant co-morbidities	Measurement Outcomes
Vadstrup (2011)(379)	Denmark	Patients with diabetes mellitus type II (143)	58.5 ± 9.0 (Intervention) 58.0 ± 10.3 (Control)	44.5%	Missing	70 (Intervention) 73 (Control)	Group-based rehabilitation programme and individual counselling programme and goal setting. (Education and exercise)	Albuminuria Retinopathy Peripheral neuropathy Cardio-vascular event	The Medical Outcome Study 36-item Short Form Health Survey for health-related quality of life (SF-36); The Diabetes Symptom Checklist – Revised (DCS-R)
Williams et al., (2012)(380)	Brisbane Australia	Patient with diabetes mellitus type II (120)	57.4 (8.3)	37.5%	Missing	60 (Intervention) 60 (Control)	Australian Telephone-Linked Care (TLC) Diabetes system. (Education)	Depression	Blood tests SF-36 version for health-related quality of life
Da Vico et al., (2013)(381)	Florence Italy	Patients with diabetes mellitus type II (263)	61 [54–68] (Intervention) 72 [65–78] (Control)	40.3%	Italian (100%)	150 (Intervention) 113 (Control)	Self-monitoring and enhancement of patients' motivation to change. (Education)	Unstated	Blood tests Short Form 36 for health-related quality of life (SF-36)

Author (year)	Setting	Population (sample size)	Mean ± SD or range of age in years	Female %	Ethnicity (%)	Number of participants in each group	Details of intervention	Relevant co-morbidities	Measurement Outcomes
Espeland et al., (2013)(382)	United States of America	Patients with diabetes mellitus type II (1 053 aged 65-76 and 4 092 aged 45 – 64)	Missing	55.5%	African American (14.6%) Asian (0.87%) Hispanic (11.3%) Native American (4.3%) Non-Hispanic white (66.8%)	2072 (Intervention) 2022 (Control)	Intensive Lifestyle Intervention. (Education and exercise)	Hypertension Prior cardio-vascular diseases Insulin use Depression	Interview BMI Blood pressure Blood tests The Medical Outcomes Study 36-item Short Form Health Survey (SF-36) for health status
Sakurai et al., (2013)(383)	Japan	Older individuals with obesity (127)	Group A (Exercise, diet, hot bathing): 59.9, SD 8.9 Group B (Exercise, diet): 61.0, SD 7.3 Group C (Hot bathing): 64.7, SD 7.6 Group D (Control – Health class): 61.3, SD 6.3	76%	Japanese (100%)	17 (Exercise, diet, hot bathing group) 16 (Exercise, diet group) 16 (Hot bathing group) 17 (Control – Health class)	Structured exercise classes, diet modification and hot bathing. (Education and exercise)	Hypertension High cholesterol	Physical tests Medical Outcomes Study Short-Form for quality of life (SF-36); The WHO-Five Well-being Index for health-related conditions (WHO-5)

All the studies included were randomised controlled trials including 7 961 participants. The smallest had 40 participants and the largest study had 1 053 participants between the ages of 65 and 76 and 4 092 participants between the ages of 45 and 64, the total number of participants in the study being 5 145 (378, 382). Both male and female participants were recruited in trials, except two trials which only recruited female participants (372, 375). The studies were all conducted in high income countries, except for two in the middle income countries (384)(according to the World Bank classification) of South Korea and Thailand (369, 376, 378)

As seen in Table 12 the majority of the studies (9) were conducted on patients presenting with diabetes mellitus type II (368, 371, 373, 374, 377, 379-382). Only three studies were conducted on patients living with hypertension (369, 376, 378) and three of the studies included in the review were conducted on obese individuals (370, 372, 383). One study was conducted on patients with metabolic syndrome which is seen as the precursor of diabetes mellitus type II (375). The interventions included in the studies in the review ranged from education, either individual or in groups, exercise and lifestyle interventions. Please refer to Appendix 1 for a detailed description of the interventions and education sessions utilised in the studies.

As can be seen in Table 13 a total of seven studies utilised self-help groups, shared decision-making, self-management training, coping skills, rehabilitation and health education as the intervention (368, 369, 374, 375, 379, 381, 382). Telephone delivered education was used by Moriyama et al., (2009) and Williams et al., (2012) for the intervention group (371, 380). Moriyama et al., (2009) focused on self-management skills (371) while the study by Williams et al., (2012) used the Telephone-Linked Care (TLC) diabetes mellitus system, an automated interactive telephone system (380). The content of the education and or exercises in the studies varied considerably as did the duration, frequency of the sessions and the number of session that took place. The education sessions varied from 30 minutes individual sessions to session lasting six hours. The exercise session ranged from the longest sessions of 175 minutes per week to the least of 75 minutes per week. The most frequent sessions were held once a week and the least frequent once per month for five months. The duration of the studies varied from four weeks to 12 months. A number of different health care professionals carried out the interventions and were also responsible for the exercise and education sessions of the interventions.

Table 13: Summary of interventions of included studies

Author	Country	Population	Exercise	Education topics	Duration of intervention	Intervention delivered by
Chaveepojnkamjorn et al., (2009)(368)	Thailand	Patients with diabetes mellitus type II	No evidence	Education regarding building good relationships, knowledge regarding diabetes mellitus, dietary control skills, physical exercise, self-monitoring of symptoms, motivation for self-care. Process of active learning (exploring, reflecting, sharing and finding personal solutions) was encouraged. One session per month for five months of two hours each.	16 weeks	Unstated
Deinzer et al., (2009) (369)	Germany	Hypertension patients	No evidence	Shared decision-making regarding treatment. No specifics were given. Five modules.	12 months	Physicians
Rimmer et al., (2009) (370)	United States of America	Patients with severe obesity and mobility disability	Personalised exercise programme or monthly exercise group. Personalised exercise programme included aerobic and resistance exercises (with a greater emphasis on aerobic exercise). Monthly exercise group lasting 90 minutes.	No evidence	12 months	Qualified fitness professional
Moriyama et al., (2009)(371)	Japan	Patients with diabetes mellitus type II	No evidence	Self-management skills, goal setting, knowledge about the disease and self-care. Thirty minutes once every two weeks.	12 months	Educator

Author	Country	Population	Exercise	Education topics	Duration of intervention	Intervention delivered by
Bouchard et al., (2010)(372)	Canada	Obese women	Resistance training as exercise with caloric restriction in one intervention group and the other two groups of the three arm intervention received either the resistance training or the caloric restriction. Three times a week and the education sessions one hour weekly sessions.	No evidence	3 months	Exercise physiologist and registered nutritionist.
Dyson et al., (2010) (373)	United Kingdom	Patients with newly diagnosed diabetes mellitus type II	No evidence	Lifestyle management education utilising 10-15 minute videos.	6 months	Practice nurse
D'Eramo-Melkus et al., (2010)(374)	United States of America	Patients with diabetes mellitus type II	No evidence	A culturally relevant group diabetes mellitus self-management training (DSMT), coping skills training (CST), diabetes mellitus care and cook book. 11 weekly consultations with the first six weeks session's duration of two hours while last five week sessions were only one hour.	12 week	Group leader; clinical psychologist or psychiatric mental health nurse practitioner
Oh et al., (2010) (375)	South Korea	Patients with metabolic syndrome	A standardised exercise programme in a supervised group included yoga stretching and rhythmic aerobic dance (Tae-Bo).	Monitoring of health, counselling, health education, exercise and diet. Health monitoring included blood pressure and body weight. Health education included information on metabolic syndrome and advice on lifestyle modifications. Educational booklet, poster and pamphlet were distributed. Intervention group followed a low-calorie and low-carbohydrate diet. Sixty sessions with three sessions per week during the first three months thereafter two sessions per week for next three months each session 90 minutes duration.	6 months	Community nurse practitioner.

Author	Country	Population	Exercise	Education topics	Duration of intervention	Intervention delivered by
Young et al., (2010) (376)	United States of America	Patients with Pre hypertension or stage 1 hypertension	No evidence	Physical activity up to 180 min/week, dietary recommendations. Behavioural skills, self-monitoring, social support, and goal setting. Eighteen sessions during first six months thereafter 12 sessions in remaining 12 months.	18 months	Unstated
Nicolucci et al., (2012)(377)	Italy	Patients with diabetes mellitus type II	Progressive mixed (aerobic and resistance) training for 150 minutes per week in two supervised sessions.	No evidence	12 months	Unstated
Park et al., (2011) (378)	South Korea	Patients with hypertension	Elastic band exercise twice a week.	Definition and symptoms of hypertension; possible complications; adherence to medication; blood pressure monitoring ; diet; exercise; stress management; emergency care; smoking and alcohol; self-management strategy and programme evaluation. Group health education (once a week) and individual counselling (once at the fourth week) for 30 minutes.	12 weeks	Health education by trained nurse and exercises supervised by exercise therapist.
Vadstrup et al., (2011)(379)	Denmark	Patients with diabetes mellitus type II	Programme included supervised aerobic and resistance exercise. 90 minute sessions twice a week.	Group-programme included: patho-physiology of diabetes mellitus, self-monitoring of blood glucose, dietary instructions, and importance of physical activity, weight loss, medication, co-morbidities, complications and individual counselling as well as goal setting. Ninety minutes group sessions once a week for six weeks.	6 months	Physiotherapist for the exercises sessions and a diabetes mellitus nurse specialist, dietician and a podiatrist for the education component of the intervention.
Williams et al., (2012)(380)	Australia	Patient with diabetes mellitus type II	No evidence	Self-management of blood glucose testing, physical activity, nutrition and adherence to medication. Weekly calls lasting 5-20 minutes, once a week for six weeks.	6 months	An automated interactive telephone intervention and coordinator.
De Vico et al., (2013) (381)	Italy	Patients with diabetes mellitus type II	No evidence	Group education included general information about diabetes mellitus, complications, nutrition, physical exercise	4 weeks	Physician, dietician and nurse.

Author	Country	Population	Exercise	Education topics	Duration of intervention	Intervention delivered by
				education and self- monitoring of blood glucose. Five sessions, a week apart; first session six hour duration and following sessions two hour duration.		
Espeland et al., (2013)(382)	United States of America	Patients with diabetes mellitus type II	No evidence	Intensive Lifestyle Intervention (ILI) with calorie goal and 175 minutes of physical activity per week.	4 years	Unstated
Sakurai et al., (2013) (383)	Japan	Older individuals with obesity	Three arm intervention: exercise, diet, hot bathing or exercise and diet or artificial hot bathing. 75 minutes twice a week.	Dietary modification and nutritional guidance classes. Participants discussed problems of dietary habits and settled issues in a group setting. Nutrition guidance classes comprised a total of five lessons.	3 months	Training instructor, physical therapist and nurse.

3.5.2 Outcome measures used

The following section will describe the outcome measures utilised in each of the studies included in the systematic review. The studies were once again grouped together, depending on the health conditions of the participants.

Table 14: Outcomes measures used in the included studies

Health Condition	HRQOL Outcome measure	Other outcome measures
Obesity	MOS SF-36 (372) CARDIA-2 (370) SF 36 (381)	BMI (370, 372) Ten physical tests (372) Isometric leg extension strength (372) % fat mass, lean body mass (372) Physical activity scale for the Elderly (372) Cholesterol (Total cholesterol; HDL-C; LDL-C) (370) PADS (370) B-PADS (370) ICF (370) Morphometric assessment (383) Timed Up & Go Test; Multiple-Sit-To-Stand Test; Stepping Test (383) Blood tests (HbA1c) (381) Dietary history (381)
Hypertension	SF 36 (369) Rand 36 item Health Survey (376)	BP measurements (369) DDPRQ (369) API (369) COMRADE (369) Stanford 7-day physical activity recall questionnaire (376) NDS-R 1998 (376) 24 hour urine collection (376) IPAQ short form (378) Self-care behaviour and self-efficacy for exercise (378) MOS SF-36 (378)

Health Condition	HRQOL Outcome measure	Other outcome measures
DM II	WHOQOLBREF-THAI (368) ADKnowl questionnaire (373) WHO-5 Well-Being questionnaire (373) MOS SF-36 ; (374) SF-36 (377, 379-383) WHO-QOL26 (371) DSC-R (379)	BMI (368, 371, 382) Blood test (A1c) (373); (triglyceride concentrations) (371, 373); (HbA1c) (371, 377, 380-382) (BUN), creatinine and thyroid function (374) Cholesterol (HDL and LDL) (373, 382) Three-day food diary (373) Pedometer (373) Crown-Crisp Index; (374) PAID (374) DSEQ (374) Diabetes knowledge test (374) MHCCQ (374) DSC-R (379) BP measurements (371, 382)

As can be seen from Table 14 the most common outcomes measures used in the studies are the SF-36 for quality of life and blood tests, BMI and blood pressure measurements as other outcome measures.

3.5.3 Methodological appraisal of the studies

The methodological appraisal of the studies consisted of firstly utilising the 11 item PEDro scale for critically appraising the studies. As mentioned previously the heterogeneity among the study populations, the co-morbidities, quality of studies and interventions did not allow for statistical pooling of results.

A summary of the quality scores of both reviewers and also the mean score of both reviewers are presented in Table 15. With the exception of two studies, all scored above 6 out of 11. A 6-10 score is viewed as a high quality score (385). In Table 16, the author's appraisal of the studies according to the PEDro scale is presented.

Table 15: Summary of the quality scores of individual studies

Author	Reviewer 1	Reviewer 2	Mean Score
Chaveepojnkamjorn et al., (2009)(368)	8	8	8
Deinzer et al., (2009)(369)	5	7	6
Rimmer et al., (2009)(370)	8	7	7.5
Moriyama et al., (2009)(371)	6	6	6
Bouchard et al., (2010)(372)	7	7	7
Dyson et al., (2010)(373)	7	7	7
D'Eramo-Melkus et al., (2010)(374)	7	7	7
Oh et al., (2010)(375)	7	7	7
Young et al., (2010)(376)	8	7	7.5
Nicolucci et al., (2012)(377)	7	6	6.5
Park et al., (2011)(378)	7	7	7
Vadstrup (2011)(379)	6	5	5.5
Williams et al., (2012)(380)	6	6	6
Da Vico et al (2013)(381)	6	6	6
Espeland et al., (2013)(382)	3	4	3.5
Sakurai et al., (2013)(383)	7	7	7
Mean quality score:	6.3	6.5	6.4

Table 16: Appraisal of articles using the PEDro scale

Author (year)	1.Eligibility criteria *	2.Random allocation	3.Allocation concealed	4. Groups similar at baseline	5. Blinding of all subjects	6. Blinding of therapists	7.Blinding of assessors	8.Measures of at least one key outcome	9."intention to "treat"	10. Results of between-group statistical comparisons are reported	11.Measure for at least one key outcome	SCORE (%)
Chaveepojnkamjorn et al.,(2009)(368)	1	1	0	1	1	0	0	1	1	1	1	72.7
Deinzer et al., (2009)(369)	1	1	0	0	0	0	0	1	1	1	1	45.5
Rimmer et al., (2009)(370)	1	1	0	1	0	0	1	1	1	1	1	72.7
Moriyama et al., (2009)(371)	1	1	0	0	0	0	0	1	1	1	1	54.5
Bouchard et al., (2010)(372)	1	1	0	1	0	0	0	1	1	1	1	63.6
Dyson et al., (2010)(373)	1	1	0	1	0	0	0	1	1	1	1	63.6
D'Eramo-Melkus et al., (2010)(374)	1	1	0	1	0	0	0	1	1	1	1	63.6
Oh et al., (2010)(375)	1	1	0	1	0	0	0	1	1	1	1	63.6
Young et al., (2010)(376)	1	1	0	1	0	0	1	1	1	1	1	72.7
Nicolucci et al., (2012)(377)	1	1	0	0	0	0	0	1	1	1	1	63.6
Park et al., (2011)(378)	1	1	0	1	0	0	0	1	1	1	1	63.6

Author (year)	1.Eligibility criteria	2.Random allocation	3.Allocation concealed	4. Groups similar at baseline	5. Blinding of all subjects	6. Blinding of therapists	7.Blinding of assessors	8.Measures of at least one key outcome	9."intention to "treat"	10. Results of between-group statistical comparisons are reported	11.Measure for at least one key outcome	SCORE (%)
Vadstrup (2011)(379)	1	1	0	1	0	0	0	0	1	1	1	54.5
Williams et al., (2012)(380)	1	1	0	0	0	0	0	1	1	1	1	54.5
Da Vico et al.,(2013)(381)	1	0	0	1	0	0	0	1	1	1	1	54.5
Espeland et al., (2013)(382)	1	0	0	0	0	0	0	0	0	1	1	27.3
Sakurai et al., (2013)(383)	1	1	0	1	0	0	0	1	1	1	1	63.6

1. Eligibility criteria were specified.
2. Subjects were randomly allocated to groups.
3. Allocation was concealed.
4. Groups similar at baseline regarding most important prognostic indicators.
5. Blinding of all subject.
6. Blinding of all therapists who administered the therapy.
7. Blinding of all assessors who measured at least one key outcome.
8. Measures of at least one key outcome were obtained from more than 85% of subjects initially allocated to groups.
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or data for at least one key outcome was analysed by "intention to treat".
10. Initial result of between-group statistical comparisons is reported for at least one key outcome.
11. Study provides both point measures and measures of variability for at least one key outcome.

There was moderate agreement in the scores between the two reviewers [kappa (K) =0.44] (386). In addition, in no case was there a difference greater than two between the scores allocated (Table 15). The reliability of score allocation was therefore judged to be fair/satisfactory (387) . The mean quality score among the trials were calculated as 6.4 out of a possible 11. Quality scores ranged from a minimum of 3 (allocated by reviewer 1) and a maximum of 8 (allocated by reviewers 1 and 2).

3.5.4 Risk of bias

Areas of bias that will be discussed include the concealment of allocation of participants, blinding of the researcher/physician or research assistant and management of incomplete data.

3.5.4.1 Blinding

Concealment of allocation of participants was unstated in almost all the studies except three (370, 373, 376). Blinding of the researcher/physician/research assistant was also unstated in most of the studies except in Rimmer et al., (2009) (research assistants were blinded)(370); Young et al., (2010) (research assistant was blinded)(376); Vadstrup (2011) (researcher was blinded)(379) and Nicolucci et al., (2012) (participants and researcher were not blinded) (377).

3.5.4.2 Incomplete outcome data

As can be seen in Table 17 below loss to follow-up varied within studies, with some studies not suffering any loss to follow-up and the most significant lost to follow-up 32.7% in an intervention group.

Table 17: Lost to follow-up and time of follow-up

Author	Population (sample size)	% loss to follow-up for intervention and control group	Time to follow-up
Chaveepojnkamjorn et al., (2009)(368)	Patients with diabetes mellitus type II (164)	Intervention: 6.2% Control: 5% Intervention: 9% Control: 13%	12 weeks 24 weeks
Deinzer et al., (2009)(369)	Hypertension patients (86)	Intervention: 2.5% Control: 2%	12 months
Rimmer et al., (2009)(370)	Patients with severe obesity and mobility disability (92)	High support: 10% Low support: 9.7% Control : 25.8%	6 months
Moriyama et al., (2009)(371)	Patients with diabetes mellitus type II (50)	Intervention: 16% Control: 8%	12 months
Bouchard et al., (2010)(372)	Obese women (48)	No specifics are provided regarding separate groups: 25%	12 weeks
Dyson et al., (2010)(373)	Patients with newly diagnosed diabetes mellitus type II (42)	Intervention: 0% Control: 14%	6 months
D'Eramo-Melkus et al., (2010)(374)	Patients with diabetes mellitus type II (109)	Intervention: 32.7% Control: 26% Intervention: 23% Control: 35%	12 months 24 months
Oh et al., (2010)(375)	Patients with metabolic syndrome (52)	0% 0% Intervention: 12.9% Control: 0%	3 months 6 months 12 months

Author	Population (sample size)	% loss to follow-up for intervention and control group	Time to follow-up
Young et al., (2010)(376)	Patients with Pre-hypertension or stage 1 hypertension (810)	Established: 13.1% DASH + Established: 12.3% Control: 14.3% for HRQOL scores Established: 10.8% DASH + Established: 9.3% Control: 9.9% for HRQOL scores	6 months and 18 months
Nicolucci et al., (2012(377))	Patients with diabetes mellitus type II (606)	Intervention: 8.3% Control: 14.2%	12 months
Park et al., (2011)(378)	Patients with hypertension (40)	Intervention: 18.2% Control: 4.3%	12 weeks
Vadstrup (2011)(379)	Patients with diabetes mellitus type II (143)	Intervention: 18.5% Control: 20.5%	6 months
Williams et al., (2012)(380)	Patient with diabetes mellitus type II (120)	Intervention: 5% Control: 8.3%	6 months
Da Vico et al., (2013)(381)	Patients with diabetes mellitus type II (263)	Not mentioned Not mentioned No specifics are provided regarding separate groups: 12.7% withdrew from the education group.	3 months 6 months 12 months
Espeland et al., (2013)(382)	Patients with diabetes mellitus type II (1 053 aged 65-76 and 4 092 aged 45 – 64)	Not stated	4 years

Author	Population (sample size)	% loss to follow-up for intervention and control group	Time to follow-up
Sakurai et al., (2013)(383)	Older individuals with obesity (127)	0%	3 months

The methodology regarding formal statistics including means and standard deviations and the outcome measured, in this instance quality of life of participants, might have allowed for pooling of data of the following studies: Deinzer et al., (2009); Bouchard et al., (2010); Young et al., (2010); Nicolucci et al., (2012); Vadstrup (2011); Williams et al., (2012); Da Vico et al., (2013) and Sakurai et al., (2013) (369, 372, 376, 377, 379-381, 383). However, the heterogeneity among the study populations, the variety of co-morbidities, quality of studies and interventions did not allow for the statistical pooling of results. Therefore, the studies are described in a narrative way for the purpose of the systematic review.

3.5.5 Effect of intervention on quality of life, function or participation of adults

Table 18 below summarises the effect of the interventions on the HRQOL of the participants and the effect size is included where possible. The standardized mean-difference effect size (d) is designed for contrasting two groups on a continuous dependent variable. The Campbell collaboration web-site calculator was used to calculate d (388).

Table 18: Summarised effects of interventions on HRQOL for adults with diabetes mellitus type II, hypertension or obesity

Author*	Condition	Number of participants in each group	HRQOL Mean, (SD) at conclusion	Effect size (Cohens d)	95%CIs	Effect size**	Study Score	Narrative Comments from text.
Espeland et al., (2013)(382)	Diabetes mellitus type II	1 053 aged 65-76 years and 4 092 aged 45 – 64 years)	Not reported				27.3	Older participants achieved high mean SF-36 scores on the domains of general health, mental health, social function and vitality than younger counterparts, but lower mean scores for physical function. The reason postulated is that older individuals had more free time to dedicate to lifestyle changes and were possibly more motivated to engage in those self-management behaviours which are required to make meaningful lifestyle changes.
Vadstrup (2011)(379)	Diabetes mellitus type II	268 (Established Intervention) 269 (Established + DASH Intervention) 273 (Control)	Physical: Rehabilitation group: 83 (18) Individual group: 87 (15) Mental: Rehabilitation group: 80 (18) Individual group: 82 (16)	Physical -9.24 Mental -0.12	Physical -0.41—0.07 Mental -0.29-0.05	Large negative No effect	54.5	The group-based rehabilitation programme did not improve the participant's HRQOL more than those in an individual counselling programme. Positive finding is that lifestyle intervention is an important part of managing a patient with diabetes mellitus type II
Deinzer et al., (2009)(369)	Hypertension	40 (Intervention) 46 (Control)	Not reported				45.5	There were no differences between the two groups regarding HRQOL.
Moriyama et al., (2009)(371)	Diabetes mellitus type II	50 (Intervention) 25 (Control)	Intervention: 3.0 (0.6) Control: 2.8 (0.5)	0.35	(-0.13-0.84)	Small	54.5	Intervention group showed significant improvement over time in QOL, and self-efficacy rating (Friedman's test).

Author*	Condition	Number of participants in each group	HRQOL Mean, (SD) at conclusion	Effect size (Cohens d)	95%CIs	Effect size**	Study Score	Narrative Comments from text.
Williams et al., (2012)(380)	Diabetes mellitus type II	303 (Intervention) 303 (Control)	Physical: Intervention: 45.6 Control: 45.2 Mental: Intervention: 51.7 Control: 48.7				54.5	The authors reported significant changes were found in the mental health domain of the HRQOL of those who participated in the intervention. The authors further stated that the physical domain of the HRQOL did not show any improvement during the six month intervention period.
Da Vico et al., (2013)(381)	Diabetes mellitus type II	18 (Intervention) 20 (Control)	Physical: Intervention: -0.28 Control: -0.30 Mental: Intervention: -0.31 Control: -0.33				54.5	The authors stated that no variations were observed in the quality of life scores either in the intervention of the control group, however, baseline scores for quality of life were similar to norms for the Italian general population, so there was no real margin for improvement. The authors stated that, In fact, uncomplicated diabetes mellitus is not sufficient to induce a marked deterioration of HRQOL.
Nicolucci et al., (2012)(389)	Diabetes mellitus type II		Missing				63.6	Experimental group: improved QOL, improvements in physical and mental HRQOL related to volume supervised exercise training. Control group: worsened QOL.
Bouchard et al., (2010)(372)	Obesity	12 (Caloric restriction group) 12 (Resistance training group) 12: (Resistance training group) 12: (Caloric restriction + resistance training group) 12: (Control group)	Post-objective: 86.2 (12.5) Pre-objective: 82.8(16.9)	0.25	-0.41 – 0.90	Small	63.6	Despite improvement in eight out of ten physical-capacity tests, no improvement was observed for the SF-36 physical function score.

Author*	Condition	Number of participants in each group	HRQOL Mean, (SD) at conclusion	Effect size (Cohens d)	95%CIs	Effect size**	Study Score	Narrative Comments from text.
Dyson et al., (2010)(373)	Diabetes mellitus type II	21 (Intervention) 21 (Control group)	Missing				63.6	No significant changes in general quality of life after six months and no significant differences between the two groups.
D'Eramo-Melkus et al., (2010)(374)	Diabetes mellitus type II						63.6	Experimental group: Significantly greater role-physical and physical function QOL and less diabetes-related emotional distress compared to control group. Both groups improved in the general health, vitality, and bodily pain QOL domains.
Oh et al., (2010)(375)	Metabolic syndrome	57 (Intervention) 52 (Control)	Physical: Intervention: 66.3 (4.0) Control: 56.0 (5.0) Mental: Intervention: 69.7 (3.9) Control: 57.2 (5.7)	Physical 2.29 Mental 2.58	Physical 1.80-2.80 Mental 2.07-3.09	Large Large	63.6	Intervention group: Greater improvement in physical function, general health, vitality and mental health HRQOL compared to control group.
Park et al., (2011)(378)	Hypertension	31 (Intervention) 21 (Control))	Physical: Intervention: 85.0(18.1) Control: 77.3(20.9) Mental: Intervention: 81.7 (11.9) Control: 71.6 (12.9)	Physical 0.40 Mental 0.82	Physical - 0.16-0.96 Mental 0.25 – 1.40	Small Large	63.6	Intervention group: Increases in scores of some of the health-related quality of life domains (general health, vitality, social functioning and mental health).

Author*	Condition	Number of participants in each group	HRQOL Mean, (SD) at conclusion	Effect size (Cohens d)	95%CIs	Effect size**	Study Score	Narrative Comments from text.
Sakurai et al., (2013)(383)	Obesity	70 (Intervention) 73 (Control)	Physical: Intervention A: 48.6 (4.9) Intervention B: 49.6 (6.1) Intervention C: 51.3 (5.0) Control: 47.9 (6.30 Mental: Intervention A: 53.8 (6.9) Intervention B: 50.4 (7.8) Intervention C: 51.5 (6.9) Control: 50.8 (4.6)	Physical (Intervention C – chosen as largest difference) 0.60 Mental (Intervention Control) 0.12	Physical (Intervention C) 0.26- 0.93 Mental (Intervention Control) -0.21 – 0.45	Medium No effect	63.6	All three groups improved in the summary scores of the physical and mental domains of the SF 36 compared to the control group but effect was variable.
Rimmer et al., (2009)(370)	Obesity	30 (Higher support group) 31 (Lower support group) 31 (Awareness group)	Not reported				72.7	

Author*	Condition	Number of participants in each group	HRQOL Mean, (SD) at conclusion	Effect size (Cohens d)	95%CIs	Effect size**	Study Score	Narrative Comments from text.
Young et al., (2010)(371)	Hypertension	269 (Established + DASH Intervention) 273 (Control)	Physical: Intervention: 0.2 (0.5) Control: 0.8 (0.5) Mental: Intervention: 0.9 (0.6) Control: -0.1 (0.6) (Mean change ± SE) 6 month results.				72.7	Both intervention groups had modest improvement in the physical dimension of HRQOL (vitality) after 18 months. Participants losing at least four kg during the intervention either after six months or 18 months during the study showed improvement in most of the physical health dimensions of HRQOL. The authors concluded that their report is one of the first to indicate positive changes in HRQOL as a result of a multi-component lifestyle intervention. However, increased physical activity did not improve the HRQOL of the participants when controlling for dietary changes in the study.
Chaveepojnkamjorn et al., (2009)(368)	Diabetes mellitus type II	80 (Intervention) 84 (Control)	Intervention: 96.2 (5.8) Control: 79.2 (8.8)	2.28	(1.9-3.00)	Large	72.7	Intervention group: mean QOL scores increased significantly over 24 weeks. Control group: No changes in scores.

**Ranked according to PEDro score.*

***Key:*

(388)	*D value*
Small	*0.20*
Medium	*0.50*
Large	*0.80*

Despite the lack of information in some studies, it was possible to compare the HRQOL impact across most and in several of the better quality studies; a medium or large effect size was reported in either the physical or mental components of HRQOL or both. The narrative analysis indicates that except for three studies, the interventions improved the HRQOL of the participants. In most of the studies, mental function, vitality and general health improved, but not physical function. The three studies that did not show any improvement in HRQOL are; the study by Deinzer et al., (2009) (hypertension); Dyson et al., (2010) (DM II) and da Vico et al., (2013) (DM II). Despite HRQOL not improving in the Deinzer et al., (2009) study the authors concluded that the results of their study indicated that the implementation of patient education programmes for patients with hypertension empowers patients to participate in the management of their own condition (364). Dyson et al., (2010) utilised a short video intervention to deliver lifestyle education and this increased the overall knowledge of the diabetes mellitus type II individuals compared to the control group. The lack of difference between the control and intervention group for quality of life may according to the authors be due to the small sample size as a results of the problems associated with recruitment issues that were experienced during the study (368). The study conducted by da Vico et al., (2013) indicated that group educational programmes are a powerful tool in the management of DM II and according to these authors the lack of effect of the programme on the QOL of the individuals could be due to the limited sensitivity of the test, as the baseline scores for QOL in the participants in the study were similar to the norms for the Italian population and therefore there was no real margin for improvement. The authors also stated that uncomplicated diabetes mellitus is not sufficient to indicate a deterioration in the health-related quality of life of the individuals (376).

The studies reporting on interventions for people with DM II and metabolic syndrome indicated positive effects on both the physical functioning and mental functioning domains of health-related quality of life. Possible reasons why in certain studies the participants only improved in the mental domain of health-related quality of life and not in physical function could be that participants in the study could already consider themselves as being physically capable at baseline and that participants could also have adapted their physical environment to their physical capacity and physical limitations. This by implication would mean that they may perceive that they do not have any limitations when they actually have some limitations when measured objectively (367). It is thus imperative to realise that the measurement instrument used in research to quantify physical function after an intervention could potentially have important implications on the outcome of the study and should be carefully analysed in regards to the objectives set out for the specific study (367).

3.5.6 Implications for practice

Even small effect sizes of HRQOL improvement may be seen as having a clinical significance in the long term (390-392) and medium to large effect sizes were reported in several of the better quality studies. It appears that there is evidence to support the efficacy of lifestyle interventions including exercise (aerobic as well as resistance training) as well as health education with regard to improving HRQOL. These interventions should be utilized in practice but the emphasis should be on tailoring the program according to the needs of the community, to make it culturally acceptable and take into account the population for which the program is designed. Based on the conclusion of several authors self-efficacy, goal-setting and joint decision making should be encouraged in practice to ensure the sustainability of a lifestyle intervention (393-395) . It appears that exercise and education should be incorporated into intervention programmes designed for people with hypertension, diabetes mellitus and obesity.

3.5.7 Implications for research

It is generally believed that health-related quality of life improves after modification in the lifestyle of individuals, but little is known about whether the programmes used are actually improving the HRQOL or QOL of individuals (375). Therefore, studies need to focus on standardising the education and exercises used in intervention programmes for individuals with chronic diseases in order to allow for comparison of the studies. It is imperative that all studies conducted on individuals living with DMII, hypertension or obesity should include HRQOL or QOL measurement instruments in order to focus on the biopsychosocial aspects rather than just on the disease. In conclusion it appears that exercise and education interventions make a difference in the lives of the individuals living with the condition.

3.6 Conclusion

The first objective of the systematic review was to determine what exercises are used for adults with DM II, hypertension or obesity. Admittedly, the focus of this thesis is on middle-aged women and the majority of the papers in the review included both men and women. However, it is likely that the majority of conclusions may be of relevance to women as they were included in the majority of trials

and, formed slightly more than half of the participants. However, in the absence of sensitivity analysis, this assumption could not be tested. Due to the complex nature of the review and the search criteria set as exercise and health-education, this limited the studies identified and therefore limited the potential of learning about the content of individual parts of the intervention package.

Both traditional and less conventional exercise programmes were utilised. Traditional exercise programmes included warming up, cardio-vascular exercises, muscle stretches, and strengthening of upper and lower limbs, as well as abdominal muscles and finally cooling down. Less conventional exercise programmes included yoga stretching, Tae-Bo and hot bathing. Personalised exercise programmes were also utilised in the studies, depending on the disease.

The second objective was to determine what education is given to adults with DM II, hypertension or obesity. Most of the health education included information on the specific disease, advice on lifestyle modifications such as diet and self-care, and also coping skills training and self-management skills. Some of the studies issued participants with an educational booklet, poster or pamphlet. All of the health education sessions were culturally relevant for the participants.

The last objective was to determine the impact of exercise or education on impairment, activity limitation and participation restriction (including HRQOL) of adults with DM II, hypertension or obesity. Moderate changes were observed in the QOL of adults with hypertension or obesity and most of the improvement was noted in the physical health dimensions. Improvement was noted in the physical as well as the mental HRQOL dimensions of adults with DM II.

The findings of this review indicate that a limited number of randomised clinical control trials conducted on individuals living with DMII, hypertension or obesity include HRQOL or QOL outcome measures. In view of the ICF framework and the biopsychosocial model, it is imperative not only to include outcome measures that assess, the impact of the disease on the structures of the body, but rather to assess the impact the disease has on the individual's life and overall well-being. It is also evident that it is difficult to compare the results of studies due to the heterogeneity of samples, and to the fact of effect sizes not being reported, and the lack of standardisation of intervention programmes (either exercise or health education).

Moderate changes were observed in the quality of life of adults with hypertension or obesity and most of the improvement was noted in the physical health dimensions. Improvement was noted in the physical as well as the mental HRQOL dimensions of adults with diabetes mellitus type II.

Although the overall effect of the interventions in the studies on impairment, activity limitation and participation restriction (including health-related quality of life) at the end point of data collection were not significant, it is clear that even small effect sizes of improvement in HRQOL may be seen as having a clinical significance in the long term on the individual living with DMII, hypertension and obesity. Therefore, multi-component lifestyle modification intervention programmes should be developed which include exercise, health education, goal setting and cognitive behavioural principles for individuals living with chronic diseases.

4 EXERCISE AND HEALTH EDUCATION IN THE MANAGEMENT OF MUSCULOSKELETAL CONDITIONS: A SYSTEMATIC LITERATURE REVIEW

4.1 Introduction

The aim of the following section is to present the evidence of the current state of knowledge concerning exercise and health education in musculoskeletal conditions (MSC) and the impact thereof on impairment, activity limitation and participation restriction (including HRQOL) of adults. It is important to discuss critically the evidence, as MSC are important contributors to the burden of disability (4, 8, 29, 90, 396). As with the previous review, it would have been preferable to include interventions which exclusively enrolled participants similar to those included in the current study, this was not possible. The search was not restricted to middle-age women as there were no studies that dealt exclusively with women. Therefore the search had to be widened to include males and female of all age groups (adults) to ensure that the objectives of the review were addressed adequately.

4.2 Objectives

The objectives were to address the following questions:

- What exercises are used in the treatment of adults with MSC?
- What education is given to adults with MSC?
- What is the impact of exercises or education on impairment, activity limitation and participation restriction (including HRQOL) of adults with MSC?

4.3 Methods

4.3.1 Criteria used for selecting studies for review

The criteria were identified in three categories to guide the selection of studies for the purpose of the review. The following studies were included:

- Randomised controlled trials were included, while case-control studies, case reports, letters and cross-sectional studies were excluded.
- Work-related musculoskeletal studies as well as workplace interventions were excluded.
- Studies on human adults with MSC were included.
- Studies reporting on the impact of interventions on impairment, activity limitation and participation restriction (including HRQOL) as well as decrease in joint pain of participants were included.

4.3.2 Search methods

The following electronic databases were searched from 2009/01/01 to 2013/12/31. The same procedure as described in section 3.3.2 was used to develop and build the search using specific synonyms provided in the MeSH database.

Table 19: Search strategies utilised

Electronic database	**Limits to the searches**	**Terms excluded using the "NOT" Boolean search term**
MEDLINE with full text CINAHL with full text Academic Search Complete SPORTDiscuss with full text PEDro The Cochrane Library	Journal articles English "human" "adult" OR "midlife" AND "musculoskeletal dis" / "musculoskeletal" / "chronic joint "pain" / joint pain AND "rehab" / "rehabilitation" OR "fitness" OR "therapeutics" OR "physiotherapy" / "physical therap OR "exercise" AND "health knowledge" OR "patient information" OR "Health promot" / "health promotion" OR "health education" OR "patient education" OR "health literac" / "health literacy" AND "self manag" / "self management	"case-control studies" "case reports" "letters" "cross-sectional studies" "children" "adolescents"

4.3.3 Data extraction and quality assessment

All the articles identified were imported into Mendeley (353) and duplicates removed. The researcher and a research assistant independently screened all the abstracts for possible inclusion. The full text of articles identified by either the author, or the research assistant as containing relevant information for the systematic review were obtained and the quality of the full text articles was then assessed. Please refer to Chapter 3 (Section 3.3.3) for a description of the quality assessment procedure followed.

Table 20: Criteria used for screening of abstracts

Category	Inclusion Criteria	Exclusion Criteria
Population	Human adults	Only children Only adolescents
Study design	Randomised control clinical trial	Case reports, case studies
Interventions	Exercise or health education/education	
Outcome	Reporting on the health-related quality of life of adults with musculoskeletal conditions Activity limitation of adults with musculoskeletal conditions Participation restriction of adults with musculoskeletal conditions Decrease in joint pain	Letters and cross-sectional studies

Data were extracted from the studies identified and entered into spread sheets to create a summary that included the information listed in Table 9.

4.3.4 Meta-analysis

All studies were considered for meta-analysis, regardless of the quality score that was achieved using the PEDro scale, therefore the all-inclusive method was chosen for the selected clinical trials (354, 365). The hypotheses of the studies, the intervention and also the outcome measures; the characteristics of

the study populations, sample size, availability of the results were compared by two independent reviewers to identify the possible pooling of results (362). The researcher was one reviewer and a Biostatistician at the University of the Free State acted as the second reviewer. Heterogeneity among the study populations which targeted different health conditions, the co-morbidities, quality of studies and interventions did not allow for statistical pooling of results and therefore meta-analysis was not performed.

4.4 Procedure

After the online search of the electronic data bases as described in Section 4.3.2, the articles identified were imported into Mendeley by the researcher and duplicates were removed. A form developed by the researcher was used to decide on the inclusion or exclusion of the articles. Even if QOL or HRQOL outcome measures were not mentioned in the abstract, the article was included for screening if quality of life outcome measures were included in the studies as secondary measures and therefore not mentioned in the abstract. All abstracts, as well as the form developed by the researcher for the screening process were saved on a memory stick and handed to the research assistant (second reviewer). The second reviewer was a qualified physiotherapist with a Master's degree in the field of Orthopaedic Manipulative Therapy at the University of the Free State, and has been exposed to the process of systematic reviews.

The researcher and the second reviewer independently screened all the abstracts for possible inclusion. Once the screening process had been completed the lists of possible inclusions were compared and finalised during a consensus meeting. The full text of identified articles was then obtained. A meeting was held between the two reviewers to ensure that the interpretation of the PEDro score was done correctly and a trial scoring was done on two articles not included in the review. No problems were identified. Data were extracted from the studies identified and entered into the spread sheets. The PEDro scale was completed for each study and the total quality score noted. A table was compiled with the scores of each reviewer as well as the mean quality score of each article (Table 27). No interaction between the two reviewers took place to influence the outcome of the quality scores during the process.

4.5 Results

The online search generated a total of 146 initial hits. A total of 98 articles were excluded as the title did not conform to the systematic review's objectives. Three duplicates were removed and a total of 45 abstracts were screened by the researcher and the research assistant. A further 24 articles were excluded as they did not report on the impact of interventions on impairment, activity limitation and participation restriction (including HRQOL) of participants. Twenty one articles remained and after the full text review by the researcher, another 18 were excluded as they did not report on the impact of interventions on impairment, activity limitation and participation restriction (including HRQOL) of participants.

Table 21: Number of articles obtained from electronic database

Database	Number of records identified
MEDLINE with full text	54
CINAHL with full text	12
Academic Search Complete	66
SPORTDiscuss with full text	10
Africa-Wide	1
PEDro	0
The Cochrane Library	0
TOTAL	146

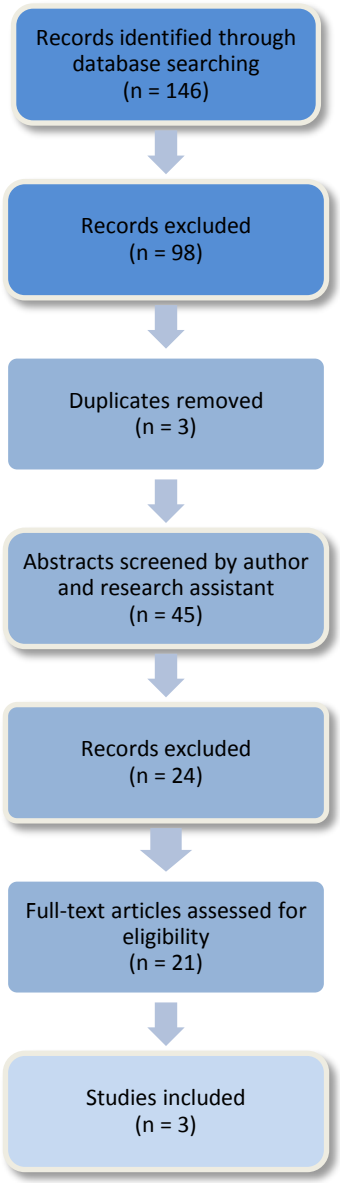


Figure 4: Flow diagram of the selection and review process

4.5.1 Description of the studies

A total of three studies met the inclusion criteria and were summarised in Table 23 and Table 24 below. The search was not restricted to middle-age women as there would be no studies to be included in this category. Therefore the search had to be widened to include males and female of all age groups (adults) to ensure that the objectives of the review were addressed adequately. The total number of participants was 4946, ranging from 114 participants (397) to 4 414 (398) in a single study. Both male and female participants were recruited in the trials and two of the three studies had a large preponderance of women but the third, large study, had approximately equal numbers of men and women. In total, 57% were female (397-399).

Table 22: Percentage of female participants in included studies

Author	**Percentage of female participants in each study**	**Sensitivity analysis**
Hansson et al., (2010)(399)	85%	None performed
Hurley et al., (2012)(397)	70%	Done for cost analysis
Kamada et al., (2013)(398)	55.3%	None performed

Table 23: Summary of reviewed studies

Author (year)	Setting	Population (sample size)	Age (years) (mean ± SD or range)	Female (%)	Ethnicity (%)	Number of participants in each group	Education / Exercise or Both	Relevant co-morbidities	Measurement Instrument
Hansson et al., (2010)(399)	Malmö Sweden	Osteoarthritis (114)	62 (9.43)	85%	Missing	61 (Intervention) 53 (Control)	Education	Missing	EQ-5D Arthritis Self-efficacy scale Balance and functional tests Grip ability test
Hurley et al., (2012)(397)	South East London	Chronic knee pain (418)	67(50-91) (Intervention) 67 (51-89) (Control)	70%	Missing	278 (ESCAPE-knee pain group) 140 (GP management group)	Both	Diabetes mellitus, cardiovascular or respiratory disorders	WOMAC
Kamada et al., (2013)(398)	Japan	Middle-aged and elderly (4414)	60.6 ± 10.5 (Intervention) 61.0 ± 10.6 (Control)	55.3%	Japanese	9 communities (Intervention) 3 communities (Control)	Both	Missing	Change in engagement in regular physical activity Visual Analogue Scale for pain

Three studies met the criteria set for the review. All three were randomised controlled trials. The total number of participants was 4946, ranging from 114 participants (399) to 4 414 (398) in a single study. Both male and female participants were recruited in the trials and two of the three studies had a large preponderance of women but the third, large study, had approximately equal numbers of men and women. In total, 57% were female (397-399). One study was carried out in the United Kingdom (397, 400), one in Sweden (399), and one in Japan (398).

The interventions included in the studies ranged from education, either individual or in groups, and exercise. Please refer to Appendix 2 for a detailed description of the interventions and education sessions utilised in the studies.

Not only did the content of the education and/or exercises vary between studies, but also the duration, frequency of the sessions and the number of sessions that took place. The education sessions varied from five group sessions, or three hours for each session (399) to 12 supervised sessions of 15 to 20 minutes each, twice weekly for six weeks (397) and outreach health education by professionals during medical check-ups of individuals as well as during community events including various sports events and festivals (398).

The exercise sessions in the studies ranged from simple individualised exercise regimes (397), to encouraging participants to increase their physical activity to at least 150 minutes per week (398). The frequency of sessions varied from once a week for five weeks (399); 35 to 40 minutes twice weekly for 12 weeks (397) and at least 150 minutes of physical activity per week (398). The duration of the studies ranged from five weeks of education (399) to one year exercise and education programme (398).

The interventions during the studies were carried out by different health care professionals and included physiotherapists (397) or occupational therapists (399) and also encouragement and support from various health care professions (398).

Table 24: Summary of interventions of included studies

Author	Country	Population	Nature of intervention	Exercise	Education topics	Duration of intervention	Intervention delivered by
Hansson et al., (2010)(399)	Sweden	OA	Patient education programme for OA with focus on self-efficacy.	Exercise and physical activity for the lower limbs including home-training exercises. Practical exercises for the hands.	Education included human anatomy, physiology of pain and coping with pain, OA, medication, diet and current research in field. Participants were advised to use heat and cold when needed. Brainstorming session to determine what patients found difficult to do. Demonstration of orthopaedic aids for the lower limbs. Ergonomic advice. Hand advice including using paraffin wax.	5 weeks	Physiotherapists, occupational therapists and dieticians.
Hurley et al., (2012)(397)	England	Chronic knee pain	Exercise-based rehabilitation programme integrating exercise, education and self-management,	Integrating exercises to encourage regular physical activity.	Education and self-management strategies to change inappropriate health belief and alter behaviour.	6 weeks	Physiotherapist
Kamada et al., (2013)(398)	Japan	Middle-aged and elderly	A community wide programme to promote exercise	Walking was encouraged as aerobic exercise for all the groups. The stretching exercises for the two groups were stretches for the back muscles, the adductor muscles, gluteus maximus, the knee extensors and flexors, while the strengthening exercises included strengthening of the trunk flexors, knee flexors and extensors.		12 months	Medical professionals

A detailed description of the interventions was critically appraised by the researcher during the development of the six-week intervention programme as well as the workbook that was adapted from previous studies and summarised in table format. (Appendix 2)

4.5.2 Outcome measures used

As is evident from the outcome measures summarised in Table 25 various outcomes were explored with no consistency between studies.

Table 25: Outcome measures used in the included studies

Health Condition	HRQOL Outcome measure	Other outcome measures
MSC	EQ-5D (399) Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (397)	Arthritis Self-efficacy Scale (399) Lower limb functional tests (399) Grip Ability Test (GAT) (399) Participating in physical activity (398) Standing One Leg Eyes Open (SOLEO) and Standing One Leg Eyes Closed (SOLEC) balance tests (399) Hospital Anxiety and Depression Scale (HADS) (397) Body Mass Index (BMI) (398) Perceived health (398) Physical activity levels (398) objective functional performance measured by the aggregated time of four common activities of daily living (AFPT) (397) Exercise-related health beliefs and self-efficacy questionnaire (ExBeliefs) (397) McMaster Toronto Arthritis Questionnaire (MACTAR) (397) Muscle strength (397) Voluntary muscle activation (397)

4.5.3 Methodological appraisal of the studies

The methodological appraisal of the studies consisted of firstly utilising the 11 item PEDro scale for critically appraising the studies. As mentioned previously, the heterogeneity among the study populations, the co-morbidities, quality of studies and interventions did not allow for statistical pooling of results.

A summary of the quality scores of both reviewers as well as the mean score of both reviewers is presented in Table 26. None of these papers have been scored previously by PEDro but using the same scoring system, all the articles achieved a score or 7 or more. As previously stated a 6-10 score is viewed as a high quality score.(385). In Table 27 the author's appraisal of the studies according to the PEDro scale is presented.

Table 26: Summary of the quality scores of individual studies

Author	Reviewer 1	Reviewer 2	Mean Score
Hansson et al., (2010)(399)	8	8	8
Hurley et al., (2012) (397)	9	8	8.5
Kamada et al., (2013)(398)	8	7	7.5
Mean quality score:	8.3	7.6	7.8

Table 27: Appraisal of articles using the PEDro scale

Author (year)	1.Eligibility criteria *	2.Random allocation	3.Allocation concealed	4. Groups similar at baseline	5.Blinding of all subjects	6. Blinding of therapists	7. Blinding of assessors	8.Measures of at least one key outcome	9."intention to "treat"	10. Result of between-group statistical comparisons are reported	11.Measure for at least one key outcome	SCORE (%)
Hansson et al., (2010)(399)	1	1	0	1	0	0	1	1	1	1	1	73%
Hurley et al., (2012)(397)	1	1	1	1	0	0	1	1	1	1	1	82%
Kamada et al., (2013)(398)	1	1	0	1	0	0	1	1	1	1	1	73%

1. Eligibility criteria were specified.
2. Subjects were randomly allocated to groups.
3. Allocation was concealed.
4. Groups similar at baseline regarding most important prognostic indicators.
5. Blinding of all subject.
6. Blinding of all therapists who administered the therapy.
7. Blinding of all assessors who measured at least one key outcome.
8. Measures of at least one key outcome were obtained from more than 85% of subjects initially allocated to groups.
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or data for at least one key outcome was analysed by "intention to treat".
10. Initial results of between-group statistical comparisons are reported for at least one key outcome.
11. Study provides both point measures and measures of variability for at least one key outcome.

4.5.4 Risk of bias

Areas of bias that will be discussed include concealment of allocation of participants, blinding of the researcher/physician or research assistant and management of incomplete data.

4.5.4.1 Blinding

In terms of blinding, consideration was given to participant blinding and researcher blinding. Concealment was unstated in two studies. Blinding of the researcher was clearly stated in the study conducted by Hansson et al., (2010)(399) and the assessors were blinded to the allocation of the participants in the study conducted by Hurley et al., (2012)(397). The researchers were also blinded in the study conducted by Kamada et al., (2013) as the staff members who were responsible for the allocation of the clusters were not involved in the execution of the research study (398).

4.5.4.2 Incomplete outcome data

Loss to follow-up was variable within the studies, with some studies suffering larger numbers of loss-to follow up than others. The least lost to follow-up was in the study of Hansson et al., (2010) with 12.3%. Table 28 below summarises the lost to follow-up of all the studies. The loss to follow-up was calculated for the entire study and not for individual groups.

Table 28: Lost to follow-up and time of follow-up

Author	Population (sample size)	% loss to follow-up	Time to follow-up
Hansson et al., (2010)(399)	Osteoarthritis (114)	Intervention: 16.4% Control: 7.5%	6 months
Hurley et al., (2010)(397)	Patients with chronic knee pain (418)	ESCAPE knee group: 15% Control: 9% ESCAPE knee group: 18% Control: 19% ESCAPE knee group: 25% Control: 29% ESCAPE knee group: 32% Control: 33%	6 weeks 6 months 18 months 30 months
Kamada et al., (2013)(398)	Middle-aged and elderly individuals (4 414)	Aerobic activity group: 18.9% Flexibility and muscle strengthening group: 22.4% Aerobic, flexibility and muscle strengthening group: 19.3% Control: 21.7%	12 months

4.5.5 Effect of intervention on quality of life, function or participation of adults

Hansson et al., (2010) showed that there was a statistically significant difference between the two groups in the five domains of the EQ-5D-3L, with the intervention group having a higher number of participants indicating that they had no problems after six months of the intervention in all the dimensions of the EQ-5D-3L (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). The VAS score of the EQ-5D-3L also improved significantly more in the intervention group than in the control group (399).

The WOMAC function score, as well as all other secondary outcomes, showed large improvements immediately after the intervention, in the participants who completed the ESCAPE- knee pain programme in comparison to the usual care group in the study by Hurley et al., (2012). Unfortunately, at all subsequent follow-up assessments there were no differences between the ESCAPE-knee pain group and the usual care group, except for improvement in the ESCAPE-knee pain participants' exercise

health beliefs and self-efficacy and physiological measures of sensori-motor muscle function which showed no improvement during any stage of the study.

The results of the study conducted by Kamada et al., (2013) revealed that the programme did not improve physical activity levels of middle-aged participants, but significant differences were observed in awareness and knowledge between the two groups in the short term (398). Please refer to Table 29 and Table 30 for a summary of all the effects of the interventions.

The large number of drop-outs in the Hansson et al., (2010) study did not have an impact on the results of the study as intention-to-treat analysis was utilised (399). Hansson et al., (2010) observed an improvement in the EQ-5D-3L domains, but not in the physical tests included in the study. The reason for this could be that the study only included education and no exercise under supervision which is the only way to change behaviour (399, 401).

The community wide campaign study of Kamada et al., (2013) with its robust design and community wide coverage revealed that the programme did not increase the physical activity levels of middle-aged individuals, but did improve their knowledge and awareness regarding increased physical activity levels. There were also no significant changes between pain outcomes of the control and the intervention group. The results found were short-term changes and it might be that changes in behaviour towards increased physical activity is rather a long-term change which was not observed and, as previously mentioned, individuals have to be supervised to see improvement in exercise and not just encouraged to exercise (398, 401, 402).

In summary the review of the studies reveals shortcomings in the research that affected the outcome of the studies. There appears to be definite merit in the education programme utilised by Hansson et al., (2010) to be effective in increasing the HRQOL of individuals with MSC as well as the ESCAPE-knee pain programme of Hurley et al., (2012) that improved the physical function of the participants with chronic knee pain in the short term.

Table 29: Effect of interventions for adults with musculoskeletal conditions summarised

Author (year)	Outcome measure	Mean Intervention (SD)	Mean Control (SD)	d	95% CI	Effect size	Narrative
Hansson et al., (2010)(399)	EQ-5D, other tests of function	Not reported					Changes in score were reported. Statistical improvement only shown in the EQ-5D VAS and the standing one leg eyes closed test
Hurley et al., (2012)(397) Baseline: ESCAPE knee pain group n = 278 GP group: n = 140 6 weeks: ESCAPE knee pain group n = 237 GP group: n = 128 6 months: ESCAPE knee pain group n = 229	WOMAC (Baseline)	27.1 ± 6.7	27.2 ± 7.0	-0.015	(-0.2178, 0.1884)	No effect	ESCAPE-knee pain, produced considerable improvements in physical function that declined over time, but were still evident 30 months after completing the programme, and was more cost effective than usual care.
	WOMAC pain	7.5 ± 1.7	7.7 ± 1.7	-0.118	(-0.3209, 0.0856)	No effect	
	WOMAC (6 weeks)	20.0 ±5.9	25.9 ± 6.3	-0.976	(-1.2027, -0.75)	Large	
	WOMAC pain	5.2 ± 1.7	7.1 ± 1.8	-1.0947	(-1.3239, -0.8655)	Large	
	WOMAC (6 months)	21.7 ± 6.7	23.4 ± 7.5	-0.39	(-0.6172, -0.1628)	Small	
	WOMAC pain	5.7 ± 1.9	6.5 ± 2.1	-0.4065	(-0.6338, -0.1791)	Medium	

GP group: n = 113 18 months: ESCAPE knee pain group n = 209	WOMAC (18 months)	21.9 ± 7.5	24.3 ± 6.6	-0.3323	(-0.5721, -0.0926)	Small	
	WOMAC pain	5.7 ± 2.0	6.4 ± 2.1	-0.3444	(-0.5842, -0.1045)	Small	
				-0.1878	(-0.4357, 0.06)	No effect	
GP group: n = 100 30 months: ESCAPE knee pain group n = 189 GP group: n = 94	WOMAC (30 months)	22.3 ± 8.7	23.8 ± 6.3	Not reported		Large	
	WOMAC pain	5.9 ± 2.6	6.4 ± 2.0	Not reported		Large	
Kamada et al., (2013)(398)		Group A (Aerobic activity)	Group FM (Flexibility and muscle strengthening)	Group AFM: (Aerobic +Flexibility + muscle strengthening)			
Effect size reported	Changes in physical activity	Effect size : 1.02	Effect size: 0.94	Effect size: 0.97		Large	Intervention group: Although the effect sizes ranged from Medium to Large in most case, no significant improvement in physical function, decrease in regular physical activity, increased awareness and knowledge in short term was found. Control: Decrease in regular physical activity; no other changes.
	VAS pain score low back pain*	Effect size: 0.66	Effect size: 1.53	Effect size: 0.54		Medium to large	
	VAS pain score knee pain*	Effect size: 0.49	Effect size: 0.81	Effect size: −0.15		No effect to large effect	
	Low back pain at follow up	Effect size: 0.92	Effect size: 0.91	Effect size: 1.04		Large	
	Knee pain at follow up	Effect size: 1.20	Effect size: 1.23	Effect size: 1.00		Large	

4.5.5.1 Implications for practice

All of the studies were of high quality and the results, although not statistically significant in most cases, did indicate some positive effects of the interventions. Due to the limited number of articles that were included in the review it is difficult to determine the clinical significance or implications for practise utilizing exercise in musculoskeletal conditions. Although the evidence supporting lifestyle interventions including exercise is limited it seems to still be useful to include exercise (aerobic as well as on strengthening exercises) as well as health education in practice. However, the programs should be tailored according to the needs of the community and take into account the population for which the program is developed, in this instance middle-aged women between the ages of 40 – 64 years. It is clear that self-efficacy, goal-setting and community involvement should be encouraged in practice to ensure the sustainability of any intervention program.

4.5.5.2 Implications for research

Due to the lack of evidence regarding the effect of education and/or exercise on MSC, it is imperative that further research be conducted to determine the clinical significance of exercise on musculoskeletal conditions with special emphasis on determining the effect the intervention or education has impairment, activity limitation and participation restriction (including HRQOL) of individuals living with musculoskeletal conditions. There is also a need to conduct similar studies on elderly populations. It is also clear that the population and the needs of the community should be taken into account when developing interventions studies to make the intervention programme culturally acceptable and appropriate.

4.6 Conclusion

The objectives of this review were firstly, to identify what exercises and education are used for adults with musculoskeletal conditions. Due to the complex nature of the review and the search criteria set as exercise and health-education, this limited the studies identified and therefore limited the potential of learning about the content of individual parts of the intervention package. Two of the studies provided information regarding the exercise programmes followed while one study did not specify the exercises

included in the programmes. Different models of education were provided in all three studies depending on the study population. The last aim of the systematic review was to determine what the impact of exercises or education was on impairment, activity limitation and participation restriction (including HRQOL) of adults with musculoskeletal conditions. One study on patients with OA indicated that there was an improvement in HRQOL and self-perceived health while another study indicated that there was an immediate improvement in function after the programme but that the effect declined over time. The community wide campaign study did increase knowledge and awareness regarding increase physical activity in middle-aged and elderly individuals in the community.

A limitation of the review is that the participants were not restricted to women, and the focus of this thesis is on middle-aged women. However, it is likely that the majority of conclusions may be of relevance to women as they were included in the majority of trials and, formed slightly more than half of the participants. However, in the absence of sensitivity analysis, this assumption could not be tested.

The information obtained from the two systematic reviews was utilised in conjunction with the prevalence, nature and impact of musculoskeletal conditions discussed in Chapter 6 as well as existing intervention programmes as discussed in Chapter 7 to modify and adapt an exercise programme and workbook for the intervention component of the study.

5 INSTRUMENTATION

5.1 Introduction

Associated with the exponential increase in health sciences research, the number of measurement instruments available has increased dramatically and the choice of whether to choose a measurement instrument or a questionnaire to be used in research has become a major challenge to researchers.

Measurement tools in rehabilitation are generally aimed at recording functioning and disability which includes impairment of body structures and function, activity limitations and participation restrictions, according to the principles of the ICF as discussed in Chapter 2. The measurements may further include environmental and personal factors that may affect the functioning and disability of the individual or the group. All of these need to be taken into consideration when selecting a measurement tool.

A description of the measurement instruments chosen for the specific research study will follow in this chapter as well as an explanation of the translation project which was a collaborative initiative between the Department of Linguistics and Language Practices and the researcher at the University of the Free State.

5.2 Measurement instruments

There are many instruments that could be used to measure the different constructs covered by the ICF domains. The choice of instrumentation was therefore challenging. After an extensive review of the literature, several candidate instruments were identified and these are listed in Appendix 3. The final list of instruments chosen for the current studies is given in Table 30. A detailed discussion on the included instruments follows the list. The criteria for choosing the instruments to be included in the study were:

- Availability – the measurement instrument had to be available to the researcher within the research context. The researcher had limited funds and was not in a position to purchase expensive measurement tools.

- Feasibility – the tests needed to be done within the environment of the research, i.e. within the clinic and within the community centre which was used for the intervention study. As the survey required testing of large numbers of people, the instruments chosen needed to be short and easy to apply.
- Complexity of language used was a big consideration. Bantu is a major branch of the Niger-Congo language family spoken by most populations in Africa. Bantu languages are spoken throughout central and Southern Africa and have a common root (403). English is an extremely rich language and the Global Language Monitor estimates that there are over one million English words (404). Although no reference could be found regarding the number of words in Sesotho, a Bantu language, the researcher and supervisors had had considerable experience in translating instruments into local South African languages. Other Bantu languages, Shona, isiXhosa (405, 406) and Zulu, for example, were unable to support the nuances and range of meanings of the English words in many cases. It was not always possible to find semantically and culturally equivalent words. Thus a primary consideration in the choice of self-report instruments was the relative simplicity of the language used to formulate the questions and the ease with which it was anticipated that comparable Sesotho words could be found.
- A further consideration, linked to the above, was whether the instrument had already been translated into another Bantu language and validated and used within a similar context to that of the current research. This would give the researcher confidence that the instrument could be translated into a Bantu language and that it had performed well when used with respondents from similar backgrounds. In addition, the data gathered from this study would be more readily compared to other South African studies.
- The psychometric properties, i.e. validity, reliability and responsiveness, had to be satisfactory and preferably tested within the South African context.

Table 30: List of examples of standardised instruments to measure the different components of the ICF

Component	Function	Instrument
Health component		Self-designed questionnaire based on self-report.
		COPCORD
Impairment	Blood pressure maintenance	Electronic table-model sphygmomanometer.
	Cardiovascular fitness	Kasch Pulse Recovery (407-409)
		6-minute walk test (410, 411)
	Random serum glucose levels	Check classic blood glucose monitoring unit.
	Maintenance of body weight: Weight	Calibrated electronic digital scale accurate to 0.05kg.
	Maintenance of Body height: Height	Stadiometer accurate to the nearest 0.1 cm.
	Pain	Brief Pain Inventory (412-414)
		Simmonds battery of functional tests (415-417)
		WHODAS 2.0 – components
Participation	HRQOL	EQ-5D-3L (406, 418-421)
		Pedometer (422) (423-425)
Personal factors	Demographic	Self-designed questionnaire
	Self-efficacy	Self-efficacy for managing chronic disease 6-item scale (426) (413, 427, 428)
		WHODAS 2.0 – component.
Environmental and contextual factors		WHODAS 2.0 – components
		Self-designed questionnaire

5.2.1 Health condition and impairment of body function

The choice of instrumentation to monitor changes in the health condition and impairment of body function was made based on availability and ease of administration. In all cases standard measurement practices were used.

5.2.1.1 Blood Pressure

An electronic table-model sphygmomanometer (Clever Chek TD-3250 – 2 in 1 blood pressure monitoring system) was used to measure blood pressure. It was manufactured by TaiDoc Technology Corporation, New Taipei City, Taiwan.

5.2.1.2 Blood glucose monitoring unit

The Gluco Check classic blood glucose monitoring unit TD 4255 was used to determine blood glucose levels. It is manufactured by TaiDoc Technology Corporation, New Taipei City, Taiwan. The Gluco Check classic blood glucose monitor uses new technology which means fewer steps is needed during the testing process and there is no risk of false readings due to the "no coding needed" technology which ensures correct coding and therefore more accurate results. Gluc Check system has a top-loading strip port with strip ejection capability, ensuring optimal safety for health-care providers. The strip eject function eliminates any blood contamination dangers associated with manually releasing a strip, offering the safest disposal possible. The system stores 450 readings with time and date which ensures more effective management of patients' blood glucose readings.

5.2.1.3 Weight measurement

The measurement of body weight was done through the use of Electronic Safeway digital scale accurate to 0.05 kg. Manufactured by Pure Pleasure (code: TF –SA 10155) of the Stingray Group, Cape Town, South Africa. The electronic digital scale is accurate to 0.05 kg.

5.2.1.4 Height

Height was measured by the Seca Leceister 214 portable stadiometer which is manufactured by Seca, Hamburg, Germany.

5.2.1.5 COPCORD epidemiological survey

In the 1980s WHO (The World Health Organisation) and ILAR (International League of Associations for Rheumatology) started the COPCORD (Community Orientated Programme for Control of Rheumatic Diseases) low cost and low infrastructure, locally based community programme. The aim of the programme was to record pain and disability, related to MSC in specific populations rather than focusing on diseases and syndromes (429).

WHO/ILAR/COPCORD studies conducted worldwide have provided substantial evidence regarding the burden of MSC, particularly the impact of joint pain on communities, and have been the drivers behind the development of the Bone and Joint Decade (3). Burden of disease information is an important component of health information required for health planning as it can be used to identify health gaps in the population that need to be addressed in order to improve the health status of a population (7).

The standardised COPCORD questionnaire Phase I and II was therefore selected for the epidemiological study, to identify the joint pain and disability related to MSC in the specific population, but supplementary questions were added according to previously conducted studies in South Africa to address those aims of the present study that were not covered by the standard COPCORD questionnaire (32, 41, 430, 431). (Appendix 4)

The COPCORD questionnaire has been used in studies in South Africa to determine the prevalence of joint pain and the present study was based upon the same methodology as the previously conducted studies in both Cape Town and Bloemfontein (31, 32).

This measure was thus chosen as it had been found to be valid and reliable and robust in similar settings both internationally (432-435) and within the South African context (31, 32).

5.2.1.6 Cardiovascular fitness tests

The Kasch Pulse Recovery test and the six-minute walk test will be utilised during the study to determine the cardiovascular fitness of participants (408, 410, 411, 436). Both the tests are used widely in clinical settings. The Kasch Pulse Recovery test is scored as the number of heart beats per minute over a period

of one-minute, taken after five seconds after cessation of a three-minute step test. A lower heart rate indicates better cardiovascular fitness (409). The six-minute walk test is used to measure the maximum distance that a participant can walk in six minutes and is used clinically in determining function in patients with cardiovascular or pulmonary diseases. The six-minute walk test is a useful instrument because of its similarity to the normal activities of daily living. The minimal clinically important difference for the six minute walk test in patients living with chronic obstructive pulmonary disease is an increase of 54 metres (437). The test, according to Cahalin et al., (1996) and Faggiano et al., (1997) is a better measure of exercise endurance than maximal exercise capacity. Studies have shown good construct validity and test-retest reliability for the test (438, 439). As discussed previously in Chapter 2, one of the impairments experienced by individuals living with musculoskeletal conditions, hypertension, diabetes mellitus type II and obesity is fatigue and consequently including the Kasch pulse recovery test and six-minute walk test would address the impact fatigue has on the function of individuals living with chronic diseases of lifestyle.

This measure was chosen as it was easy to administer within the constraints of the testing environment and required no specialised equipment.

5.2.1.7 Brief Pain Inventory (Short form)

There are numerous reliable and valid measurement instruments available to measure pain. The Brief Pain Inventory (BPI) is a self-administered questionnaire which was initially developed for use in the cancer patient population, but has since been validated for use in non-cancer pain and is now widely used in other chronic conditions in which pain plays an important role in the clinical presentation (413, 440). The BPI is available in a short and long format , with the short form primarily designed for research purposes, while the longer form enquires about the patient's illness history (440).

The short form contains three important elements which are not included specifically in other pain measurement instruments available. The first element takes the form of generalised questions which clarify to the participant that it is normal to experience some form of pain on a regular basis, but the aim of the questions is to determine whether the participant has experienced more pain than that he/she would normally expect. The second element is the assessment of the impact the pain has on various functional levels and the last element is to explore the effectiveness of medication through the Pain

Management Index (413, 441, 442). The severity of pain is measured by asking the participant to rate their "worst pain", "least pain", "average pain" and "pain right now" on a numeric scale from 0 – 10 during the previous 24 hours. "No pain" scored as 0 and "pain as bad as you can imagine" scored as 10. The four pain severity scores are then averaged to give a pain severity scale of the participant(s).The BPI short form also asks participants for information regarding treatments or medication they are receiving for pain and in the previous 24 hours how much relief these treatments have given them. The treatment relief is recorded on a numeric scale from 0% to 100%, with 0% being "no relief" and 100% being "complete relief". The last section of the BPI consists of seven questions exploring how pain during the previous 24 hours interfered with activities of daily life and quality of life. The seven questions address "general activity", "mood", "walking ability", "normal work" which includes both work outside the home and housework, "relations with other people", "sleep" and "enjoyment of life". The scale used is a 10-point scale with 0 indicating "no interference at all" to 10 "completely interferes". These seven scores are averaged to generate a pain interference score (443). The decrease in pain on a scale from 0 – 10 should be at least 2 points for minimal clinically important difference (444) .

The BPI has been translated and validated for use in several populations, including patients living with cancer, (441, 445-451) patients with non-malignant, chronic pain (414) and patients with painful diabetic peripheral neuropathy (452). The BPI demonstrates reliability as well as content and construct validity when used as a self-administered or interviewer administered instrument in North India, Taiwan, Germany, China, South Korea, Norway, Vietnam, Philippines, Mexico, France, the Dominican Republic and in South Africa in patients living with cancer (414, 440, 445-451). Although a Sesotho version of the BPI short form is available, no literature could be found to indicate that the translated Sesotho version had been validated. Due to the short BPI's value in exploring the presence and areas of pain, severity, treatment and functional impact of pain on individuals the measurement tool was selected for inclusion in the intervention phase as an outcome measure. The inclusion of the BPI also addressed the impairment of pain as discussed in Chapter 2 which in turn affects the functional limitations experienced by individuals living with MSC. (Appendix 8)

The BPI was chosen in preference to the Glasgow pain scale [362] and McGill pain questionnaires [363, 364] as both of these use very rich and descriptive language to describe the experience of pain. Translation would be unlikely to yield the same nuanced terms to discriminate between pain experiences. In addition, the BPI had been translated into isiXhosa and used successfully to monitor pain in women living with HIV (453) and had been previously been translated into Sesotho (454).

5.2.2 Activity limitations and Participation Restrictions

5.2.2.1 WHODAS 2.0

The World Health Organisation Disability Assessment Schedule 2.0 (WHODAS 2.0) is an instrument developed by the World Health Organisation (WHO). The WHODAS 2.0 is a generic instrument that was developed in order to assess activity limitations and restriction on participation experienced by an individual; and disability from a biopsychosocial approach. The WHODAS 2.0 is linked to the concepts of the ICF; it covers six domains of functioning including: mobility (moving around); self-care (hygiene and dressing); cognition (communication and understanding); getting along (interaction with other people); participation (taking part in community activities); and life activities (work, school, and domestic responsibilities) and has a recall period of 30 days. Each item is scored according to five levels - none, mild, moderate, severe and extreme/cannot do (455). (Appendix 5a)

The instrument has been validated and shows reliability in a wide range of settings and in different conditions (456-460). The WHODAS 2.0 displays good psychometric properties in rehabilitation and clinical samples, therefore confirming its suitability to measuring disability based on the ICF framework in the present study (460, 461).

The internal consistency and test-retest reliability of the WHODAS 2.0 are high in mental disorders (Europe, Australia, Americas, Middle East, Nigeria, Asia and New Zealand)(457, 458, 462, 463); early inflammatory arthritis (Canada)(456, 459); and ankylosing spondylitis (Netherlands)(460) as well as in older people with mental disorders in seven low and middle income countries (464), suggesting that the instrument can be used both in the assessment of individuals as well as to establish differences between groups. In comparison with other disability measures available, the WHODAS 2.0 has been validated not only in a wide range of patient populations (mental, arthritis, chronic back, neck and headaches, diabetes mellitus, heart disease and respiratory diseases), but also across different countries and languages (the Americas, Europe, the Middle East, Africa, South Africa, Asia and New Zealand)(463, 465). During the evaluation of responsiveness to change, the WHODAS 2.0 performed well across diverse chronic conditions and it performed equal to and sometimes even better than the SF-36 sub-scales (462).

The WHODAS 2.0 was chosen as a measurement instrument because it met many of the criteria listed above. It was available and compact so would not take too long to administer. The most important consideration, however, was that it had been translated and validated into both Afrikaans and isiXhosa (a Bantu language)(466). It had been found to perform particularly well in an under-resourced area of Cape Town. Similarly it had been used to describe the functional profile of people living with HIV in Rwanda after being translated into Kinyarwanda, another Bantu language. (467). In addition, the WHODAS 2.0 was specifically developed to capture information related to functional limitations and participation restrictions, as conceptualised by the ICF.

The WHODAS 2.0 was translated by the researcher into Sesotho as part of the translation process of the study as no Sesotho version was available.

5.2.2.2 EQ-5D-3L

There are numerous Health-Related Quality of Life measurement instruments available, but one of the most commonly used instruments is the EQ-5D-3L (418). The EQ-5D-3L is a single index, generic measurement instrument devised to measure health of an individual developed by the EuroQol Group (419). The EQ-5D-3L is therefore an important tool to be used to unpack the health-related quality of life of an individual by using five domains of function: mobility, self-care, usual activities (which includes study, work, housework, family or leisure, pain or discomfort) and lastly depression or anxiety. The participants then had to indicate whether they perceive no problems, moderate problems or extreme problems. The instrument also includes a vertical visual analogue scale (VAS) on which participants rate their own perceived health state on a scale from 0 – 100 where the end points are labelled "worst imaginable health state" and "best imaginable health state"(468). The EQ-5D-3L instrument has been validated in a wide range of settings, including in South Africa and Zimbabwe (406, 420) and in patients with different conditions, such as cancer and arthritis (469). Another major advantage of the instrument is that there is a Sesotho version of the instrument available from the EuroQol Research Foundation which has undergone the rigorous translation processes required by the Foundation. (Appendix 6) Finally, the instrument yields disability weights or value sets which can be used to calculate Quality adjusted life years. This allows the researcher to use preference based measures to calculate a numerical value for each health state (470).

Although the SF36 (471) was a strong contender for incorporation, the EQ-5D was chosen as it met more of the criteria mentioned above. It is very brief and easy to administer. The language used is less idiomatic and simpler to translate. It had been translated into Sesotho by the EuroQol Foundation which requires rigorous adherence to a forward/backward translation process, followed by cognitive debriefing (472). Translated versions had already been validated in isiXhosa and Shona, two Bantu languages (406, 420). The availability of the value sets would also make it possible to calculate the number of QALYs that might be gained through the intervention.

5.2.2.3 Simmonds battery of functional tests

Impairments of pain and decreased movement or movement dysfunction are the most common signs and symptoms experienced as a result of a musculoskeletal disorder or other health problems. Movement dysfunction may be caused by pain, can be a co-morbid problem or may be a consequence of pain. Pain and movement are both multi-dimensional and complex and not as simple as generally believed. Cognitive, emotional and social factors play a major role in the complexity of pain or movement and therefore the limitations of a biomedical and biomechanical model as an explanation of pain and movement dysfunction have led to the biopsychosocial model of health and disability that is widely used (415). It was clear that the new model of management requires a new assessment approach that focuses on assessment and management at a functional level rather than an impairment level. The assessment at a functional level would require functional tests that assessed the ability of an individual to perform a series of movements (a specific task) rather than just a single movement of a single joint in a single plane. To achieve this assessment, Simmonds et al., (1998) developed a standardised, simple to perform battery of physical tests to be used in a variety of conditions (417). The tests can be used to quantify the impact of the specific conditions on the individual. The battery of tests has been tested on patients with back pain, and also on cancer patients and patients with HIV/AIDS (415-417).

The battery of tests have a strong test-retest as well as intra and inter-rater reliability and according to Novy et al., (2002), shows strong concurrent, construct, predictive and discriminative validity in adult patients with low back pain in an urban area in Texas, USA (473). The validity of the Simmonds battery of functional tests has been tested in musculoskeletal diseases as well as systemic diseases with optimum management predicted (415, 473).

Many individuals living with MSC as well as other systemic diseases often have an impairment of either central or physical fatigue. Although the mechanism of this has not been established, it is possible that the decrease of movement and performance in the individual might be contributors to the physical fatigue, but it is also possible that this might not be a consequence of the disorder, but rather an expression of the disorder in terms of motor function (474).

Two major constructs that underpin physical performance are speed and endurance and, therefore, individuals living with pain and certain illnesses such as cancer may move more slowly than matched cohorts across a variety of performance tests (415, 473, 474). They may move slower when they are actually attempting to move "as fast as they can" and move more slowly than their normal counterparts when they perform tasks such as walking and sit-to-stand (474).

The Simmonds battery of functional tests was included as a measurement instrument to determine the the physical performance of participants. The performance battery consists of a series of nine tasks (415, 474). There are several version of the battery of functional tests (415-417, 474). Refer to Table 31 for a description of the nine tasks included for this specific study and based upon the studies for individuals living with cancer (415) and patients living with HIV/AIDS (416). The individual tests which make up the battery have been separately validated for use in patients with OA (475) and were appropriate for use in our sample. The coin test was not included as part of the current study as it did not relate to lower limb balance or function. The coin test requires participants to sit at a table, while they are timed to pick up four coins (a quarter, a dime, a nickel, and a penny) and place them in a cup. Participants are required to pick up each coin individually. The pen pick up test was also not included in the present study. The test requires patients to stand and a pen is placed on the floor directly in front of their feet. They are timed as they bend down and pick up the pen as fast as they can (416). This test was also not included in the study conducted by Saw (2015) to determine the effects of a six-weeks physiotherapist-led exercise and education intervention in patients with osteoarthritis , awaiting an arthroplasty in South Africa (475). The six minute walk test was used as proposed by Simmonds (415) instead of the 5 minute walk test as previously proposed by Simmonds (417) due to literature supporting the psychometric properties of the 6 minute walk test (476-479).

The Simmonds test battery had been used previously within a South African population of women living in an under-resourced area and had performed well (447). The test battery does not require expensive equipment and could be performed in the space available to the researcher and participants. A further advantage is that the test yields numerical data which could be analysed using parametric tests.

Personal communication with Maureen Simmonds indicated that 15 metres is equivalent to 50 feet and is recommended for countries working in the metric system including South Africa.

Table 31: Description of the Simmonds battery of functional tests

Name of test	Description of test	Recorded as:
15 metres walking at preferred speed	Walk 7.5 metres turn around and walk back to the starting position at preferred walking speed.	Seconds
15 metres walking at fastest speed	Walk 7.5 metres turn around and walk back to the start as fast as you can.	Seconds
Unloaded forward reach	Stand adjacent to a wall on which a tape measure is positioned horizontally at shoulder height. Reach forward as far as you can.	Centimetres
Timed, repeated sit-to-stand	Sit in a standard chair, stand up and then sit back down. Repeat after a brief rest.	Seconds
Sock test	Sit in a standard chair. Put on one loose-fitting sock.	Seconds
Loaded forward reach	Stand adjacent to a wall on which a tape measure is positioned horizontally at shoulder height. Hold a weighted 4.46 kg bar with both hands close to your body and at shoulder height. Reach forward as far as you can with the bar in a horizontal position, maintaining hands at shoulder height.	Centimetres

Name of test	Description of test	Recorded as:
Timed, repeated reach-up	Stand facing a wall and reach up as high as you can with both hands. A mark is placed on the wall at the reached distance. You must reach up and return your hands to your side three times as fast as you can.	Seconds
Distance walked in six minutes	Walk as far and as fast as you can for six minutes. You are allowed to rest if necessary during the six minutes.	Metres
Timed belt tie	Sit in a standard chair and wrap a standard wrap bandage (approximately 1 metre) around your waist and tie it in front of you.	Seconds

5.2.2.4 International Physical Activity Questionnaire

Due to the modern lifestyle, physical inactivity of individuals has now become a global health concern contributing to an increase in chronic diseases of lifestyle as discussed in Chapter 2. Standardised approaches to measure physical activity are limited and the comparison of international data is difficult (480, 481).

The International Physical Activity Questionnaire (IPAQ) was developed in Geneva in 1998 to provide a measurement tool to obtain internationally comparable data on health-related physical activity. The validity and reliability of the questionnaire has been shown to have acceptable measurement properties for use in many settings, different languages, and these questionnaires are suitable for national population-based prevalence studies determining the level of physical activity of individuals in a specific population (335, 442, 482). These populations included those of Guatemalan, Australia, Brazil, United Kingdom, Canada, Finland, United States of America, Japan and South Africa. Most of the samples were middle-aged individuals in large cities, but rural populations with generally lower education levels were included in the South African and Guatemala samples (335, 442, 482). The questionnaire is suitable for use in young and middle-aged adults from 15 to 69 years of age (482). The age scope is well within the

bounds of the population of women being studies in the present study which has been identified as women between the ages of 40 to 64 years of age.

The short form of the questionnaire comprises four generic items. The questions are related to the physical activity of the participants in the previous seven days (335). Participants are specifically asked to consider all activities that they engage in at work, as part of their house and garden work, to think about how they get from place to place and also what they do during their spare time for recreation, exercise or sport. The first set of questions enquires about vigorous physical activities that the participant engages in and the term vigorous physical activity is referred to as "activities that take hard physical effort and make you breathe much harder than normal". Participants are asked to think about the activities that they did for at least 10 minutes at a time. The next set of questions enquires about moderate physical activities. Moderate physical activities refer to "activities that take moderate physical effort and make you breathe somewhat harder than normal". It is specifically mentioned that moderate physical activities should not include walking activities, but that participants should think about activities like carrying light loads, cycling at a regular pace or playing doubles tennis. The third set of questions requires participants to think about the time they spend walking. This includes walking at work, at home, walking to travel from place to place and any other walking that they do for recreation, sport, exercise or leisure. The last set of questions is about the time the participants spent sitting on weekdays. This includes time spent at work, at home, while doing work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading and sitting or lying down to watch television. In each instance participants are required to indicate how many days during the previous seven days they have engaged in the specific activities and also how many hours per day or minutes per day they spent on the activity during one of those days in the seven days. (Appendix 9)

The IPAQ was translated by the researcher into Sesotho as part of the translation process of the study as no Sesotho version was available.

The IPAQ was chosen as it had been used previously in a South African study to estimate the burden of disease attributable to inactivity in South Africa. It was reported to have been validated in both rural and urban South Africans. It had been used in the 2003 nationally representative set of data on inactivity in South Africa (483).

5.2.2.5 Pedometers

Pedometers are used to provide information on ambulatory activities (422) and are used in research to validate the physical activity levels of individuals (484) or to encourage individuals to increase their physical activity levels (423-425). One of the advantages of pedometers is that they provide an objective, accurate and low-cost measure of walking activities (422). The validity of questionnaires is often limited due to the individuals inability to give information accurately especially regarding moderate-intensity activities (422) and therefore pedometers are used to give an objective measure of these activities. The pedometers (model E01758, manufactured in China on behalf of Unilever by Supremia international Plc, Jubilee House, Merion Avenue, Stanmore, Middlesex, UK) used would be individualised for each participant according to the manufacturer's guidelines. This procedure includes entering the weight of the participant as well as the stride length of the participant – distance measured heel to toe as the participant walks. The stride length is set in centimetres.

5.2.3 Personal and Contextual Factors

5.2.3.1 Demographic information

Questions specifically related to demographic and environmental factors were included, as according to the ICF personal and environmental factors influence the impairments, activity limitations as well as participation restrictions of the individual living with the chronic disease (48-50). Demographic information included dealt with specifics regarding the age of the individual, ethnicity, home language, marital status, literacy, highest education level, type of dwelling and how many people were living with them. Further information would include their employment status and, if employed, their current job. If not employed, it would refer to the reason why they were not employed and whether they received social grants and if so what grant(s) did they receive.

5.2.3.2 Self-efficacy for Managing Chronic Disease Six-item scale

Self-efficacy refers to an individual's confidence about being able to perform a specific behaviour or to overcome a barrier to that specific behaviour (485, 486). It has been determined in various studies that self-efficacy plays an important role in the management of a chronic disease and it has been found that there is a definite correlation between self-efficacy and pain in MSC such as low back pain, rheumatoid arthritis and fibromyalgia, as well as other chronic diseases including diabetes mellitus (23, 335, 426, 440, 487-490).

Various studies have also reported that individuals with the same amount of pain, but with different levels of self-efficacy, have different levels of disability. The higher the self-efficacy levels, the lower the reported disability (488, 491-493). This is clearly indicated in a study conducted by Oliver and Cronan (2005) that reported that women with fibromyalgia with high levels of self-efficacy showed a decrease in their symptoms and an increase in their physical activity compared to their counterparts with lower levels of self-efficacy (23).

The present study explored the effectiveness of a non-pharmacological six weeks intervention programme, including exercise and educational sessions utilizing a workbook, for middle-aged women presenting with musculoskeletal conditions and either/or hypertension, diabetes mellitus type II and/or obesity. Therefore, the inclusion of a self-efficacy questionnaire was deemed appropriate based on the association between self-efficacy and musculoskeletal pain (491) and on self-efficacy and self-management in chronic diseases (426, 494, 495).

The measurement tool selected for the study was the Self-efficacy for Managing Chronic Disease six-item scale (SE-6)(426). The scale was specifically developed in the United States of America on arthritis patients to test the efficacy of chronic disease education programmes (427, 496). The scale was derived from the more comprehensive and burdensome Chronic Disease Self-efficacy Scales which consist of three sections. The sections include: the self-management behaviour section with 11 questions; the general self-efficacy section with five questions; and the self-efficacy section with 17 questions (497). The shorter version of the measurement tool includes the dimensions of symptom control, emotional functioning of the individual, the role of function in the individual and communication with the physician. Participants have to indicate on a numeric scale from 0 – 10 how confident they are about performing certain activities relating to their chronic disease. Zero indicates that they are "not at all

confident" and 10 indicate that they are "totally confident". The scale has been found to be valid and reliable for measuring self-efficacy in chronic conditions in several countries including: chronic conditions in France, China, England, Canada, Mexico and Australia (497-499); spinal cord injuries in Hong Kong (500); DM II in the USA (501); cancer patients in the UK (502); hypertension in United States of America (503), and China and South Korea (504) as well as in primary care patients in the United States of America (505). The chronic disease self-efficacy scale has been validated in German, English, Spanish, Afrikaans, isiXhosa and Zulu, but has not been translated or validated into Sesotho (475, 506-509). The instrument was translated into Sesotho as part of the collaborative translation project of the study. (Appendix 7)

This instrument was chosen as it had previously been translated successfully into a Bantu language (isiXhosa) and used in intervention studies aimed at reducing pain through improving self-efficacy and exercise (475). It is also brief and does not take long to administer.

5.2.3.3 Acceptability questionnaire

An acceptability questionnaire designed by the researcher using the available literature was included to determine the attitude of the participants in the intervention group towards the programme (334, 338). Five simple questions were formulated asking the participants what they liked most, liked least about the programme, what they would change or add to the programme and whether they liked the self-management booklet that had been developed and modified by the researcher from the available literature, and from the results of the epidemiological study as well as from existing programmes (364). (Appendix 10) Although no validity testing was done on the questionnaire, this method of evaluating acceptability of interventions has been used in previous research including people living with HIV, chronic low back pain and promoting physical activity (364, 510, 511).

5.3 Translation of measurement instruments

5.3.1 Introduction

As discussed, most questionnaires have been validated in English and within a very different cultural context to that of the current study. Translation of all standardised self-report questionnaires was therefore required. The translation process not only poses challenges due to differences in language, but also because of the cultural acceptability and validity of the translated questionnaire. The translation of the questionnaires from an English source text to a Sesotho text requires that three types of equivalence should be achieved between the source language text and the target language text: semantic, normative and conceptual equivalence (512, 513). Semantic equivalence refers to the extent that each item has the same meaning in the language or idiom of each culture. Normative equivalence refers to the capacity of the translated instrument to address successfully the difference between cultures and that the intended message is the same. Thirdly, conceptual equivalence addresses the degree to which a given concept is present in both the source and target text. Other requirements include that the content of each of the items in the questionnaire should be culturally relevant (content equivalence); the method of data collection should be equivalent in each culture (technical equivalence); that the interpretation of the instrument remains the same when being compared with the norm for each of the cultures (criterion equivalence); and lastly that the same theoretical construct is tested in each culture (513).

The main challenge of the project was the lack of terminology in Sesotho for formulating the questions and the cultural differences between English and Sesotho, as the target audience were mostly Sesotho speaking women.

5.3.2 Translation process

A multistep translation methodology has been developed although variations in the details of the steps are followed by researchers (514). In one variation, the proposed steps of the translation methodology include translating the questionnaire from the source language into the target language and this process

is called forward translation. The translation should be done by two independent professional translators with a third independent translator reconciling the two translated documents and resolving any discrepancies before proposing the final translation to be used for the second step in the translation process (515). The second step in the process is when the resulting target language version of the questionnaire is translated back into the source language, the so called back-translation. The back translation is seen as the quality-control step of the translation process. The process consists of the reconciled versions of the questionnaire being blindly translated back into the source text by two translators who have never seen the questionnaire before, either in the source language or the target language (515). These two back translations are then again compared by an independent moderator, after which a final translation is provided. In the translation process, it is essential to utilise different translators for the different roles (e.g. forward translation, back translation) for the sake of quality control. The moderator is the last person in the process who produces a synthesis. The moderator should not have been involved earlier in the process and should be an experienced language practitioner. In a second variation, the source text is translated by one professional translator, i.e. forward translation. This translation is then back translated into the source text by a second translator. A moderator then compares the back translations with the forward translation, pointing out and documenting discrepancies and suggesting a final translation. The first version needs more people during that translation process and the second variation fewer people (514, 515).

Therefore the methodological approached followed during the translation collaboration project of this study was mainly the first variation , but with the exclusion of a third independent translator, reconciling the two forward translated documents and resolving any discrepancies, before proposing a final translation to be used for the back translation process. The high cost involved in the translation process as well as the limited independent professional translators prepared to assist with the project, required the project manager to make adaptations to the process in order to ensure completion of the project within the set time frames of the study.

According to Breugelmans (2009), a common misconception is that once the back translation has been completed, the translation product is considered to have been validated (516). Cultural adaptation of a questionnaire, however, requires collaboration between professional translators of both the source text language and the target text language, and the researcher who developed the questionnaire as well as the population in which the questionnaire is to be used during the research study. This is done through testing of the questionnaire amongst patients who represent the target population of the study and the

process entails cognitive debriefing of the respondents on completion of the questionnaire (516). Cognitive debriefing is used to determine evidence of equivalence during the translation of questionnaires, linguistic validation of questionnaires and cultural adaption of the measurement instruments (517).

5.3.3 Translation collaboration project[3]

Four of the instruments selected for use in the present study had not been translated into Sesotho; these were the epidemiological survey questionnaire developed by the researcher; WHODAS 2.0 12 item self-administered questionnaire; Self-efficacy for Managing Chronic Disease six-item scale (SE-6), and International Physical Activity Questionnaire (IPAQ). Please refer to Appendix 11- 15 for the detailed summary of the translated and moderated texts. It was agreed with the collaborators from the Department of Linguistics and Language Practices that the translation should be standard language, with a register of language for general purposes, as the educational levels of the population had not been determined beforehand. It was emphasised in the plan that the translators should be sensitive to complicated ways of asking questions, technical terminology and culturally sensitive questions, and the layout of the translated questionnaires should be exactly the same as that of the original English source text to ensure comparability of the end products. Qualified translators were appointed based on their experience and expertise (Appendix 16). All the translators spoke Sesotho as their mother tongue, but regarded themselves as fully bilingual, having done translations in English as well as Sesotho. The moderator translator was a male freelance translator and was accredited.

It is recommended by several authors that the back translations should be performed by English first language speakers, but due to the translators being either free-lance or professional translators, it was deemed adequate that the back translators were fully bilingual and bicultural (405, 513, 518). This approach was judged to be effective in the translation of the EQ-5D-3L quality of life instrument (405). The process followed is illustrated in Figure 5 below.

[3] A concept paper describing the questionnaires and translation in the knowledge economy is in preparation.

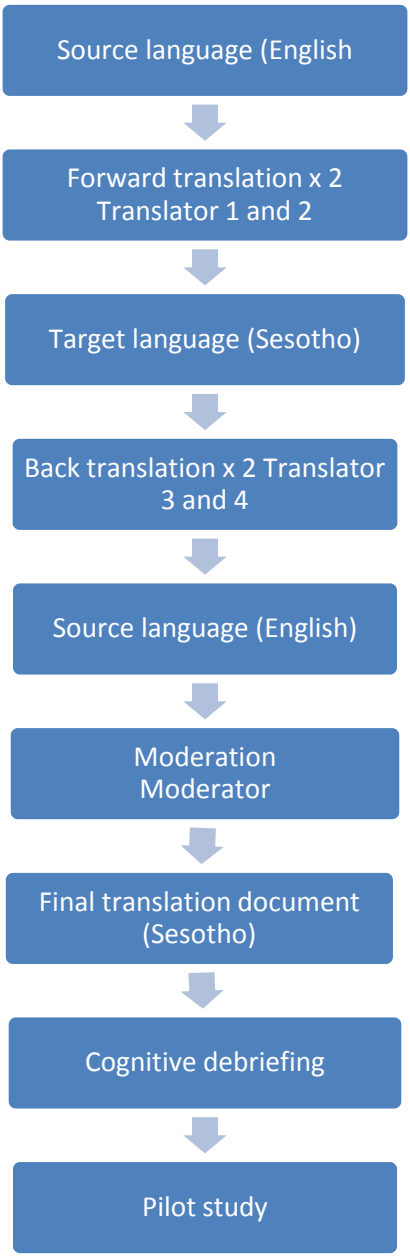


Figure 5: Flow diagram of methodology of proposed translation process

The two back translations utilised different translators than the forward translations and the moderation was performed once again by a different translator from the previous two translations. The moderator would be responsible for comparing the two back translations, with annotations and then

compiling a final translation. In this, translation project both moderators were accredited[4] in the language combination of English and Sesotho. A cognitive debriefing interview for the four translated questionnaires was conducted among five female participants whose native language was Sesotho. The interview was facilitated by a qualified physiotherapist who was fluent in both Sesotho and English. The interview was recorded by the researcher and the qualified physiotherapist assisted the researcher in the interpretation of the findings afterwards. Prior to the cognitive debriefing session, all the members of the cognitive debriefing session, including the facilitator, gave written consent for participation after they had been informed regarding the process and what was to be expected of them. The participants also specifically gave permission for the session to be audio taped. The results of the cognitive debriefing exercises are presented in Appendix 17. The last stage of the translation process was the observation of the pilot study conducted by the fieldworkers which involved the testing of the translated questionnaires combined with observations by the project managers and the researcher, as well as an informal focus-group discussion between the fieldworkers and the project managers to address any problems which might arise with the translated questionnaire.

5.3.4 Results

Unfortunately, despite the rigour of the planning process, the developed protocol could not be followed exactly due to a Sesotho forward translation that turned out to be inadequate and of poor quality. The methodology for the actual translation process that took place during the translation project is illustrated in Figure 6 below.

[4] Accreditation of a moderator is done by the South African Translators institute and the institute accredits the person as a professional translator in a specific given language combination. The accreditation is internationally recognised by the International Translation Federation. Accreditation, is however, not required to practise as a translator due to the industry not having a statutory body.

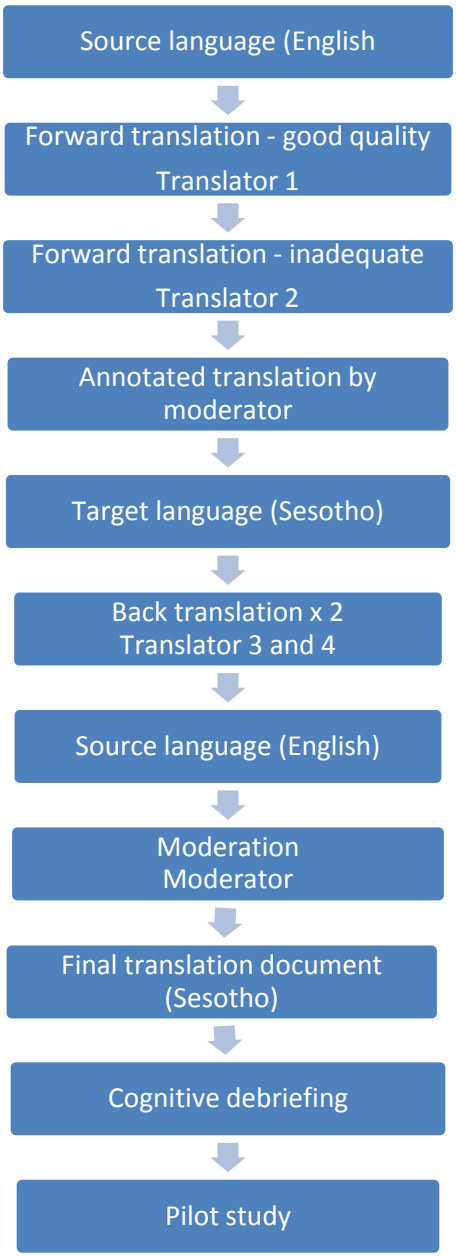


Figure 6: Flow diagram of actual methodology of translation process

The inadequate forward translation could not be redone because the back translator only reported the inadequacy of the translation late in the process, while the implementation date of the survey was confirmed with all stake holders. To resolve the situation in the best possible way, the moderator of the Sesotho project was asked by the project manager to produce an annotated translation using the one forward translation. The moderator then compared the one forward translation with the two back

translations and from this comparison, suggested a final translation, motivated by detailed annotations. These versions were then tested during the cognitive debriefing and pilot study.

A total of five participants (three with joint pain and two healthy individuals) completed the epidemiological survey, WHODAS 2.0 (12 item self-administered) questionnaire, IPAQ and SE-6. The questionnaires were initially given to participants to complete by themselves (self-administered) but the literacy level of some of the respondents was low, and after it came apparent that the participants were struggling with the questionnaires, the rest of the questionnaires were completed with the interviewer. Therefore, after the cognitive debriefing, it was agreed that utilising fieldworkers for completion of the questionnaires would be the best strategy. The fieldworkers were trained to minimize confusion with certain terms, phrases and concepts that were identified during the cognitive debriefing. Participants were all female with a mean age of 50.8 years. Participants were predominantly in the lower educational categories, with one participant having a higher education level than the other participants. The median time to complete the epidemiological survey was 17 minutes and to complete the WHODAS 2.0 seven minutes. The detailed description of the results is presented in Appendix 18. During the cognitive debriefing changes were only made to the COPCORD epidemiological survey.

The demographic details of the respondents are provided in Table 32.

Table 32: Demographic information epidemiological survey questionnaire

Age of each participant	**Gender**	**Profession**
R1: 46	Female	Supervisor for cleaning service
R2: 52	Female	General worker
R3: 42	Female	Unemployed
R4: 54	Female	Cleaning lady
R5: 60	Female	Retired
Mean age: 50.8 years		
Median age: 52 years		

There were few issues that arose out of the cognitive debriefing and these are presented in Appendix 19. No changes were made to any concepts in the translated version of the WHODAS 2.0 (12 item self-administered) questionnaire, the Self-efficacy for Managing Chronic Disease six-item scale (SE-6) and the International Physical Activity Questionnaire (IPAQ). According to the IPAQ website, it is recommended that no changes be made to the order or wording of the questions as this would affect the psychometric

properties of the instrument (482). Minor changes were made to wording and grammatical errors were corrected in the questionnaires.

No problems were identified during the observation of questionnaire administration and both the fieldworkers and the participants seemed comfortable with the process. This debriefing session of the fieldworkers did, however, serve to clarify some matters. These particular questions are discussed in the following paragraph. An informal focus-group discussion between the fieldworkers and the project managers did not identify deficiencies in the translation and no changes were suggested by the fieldworkers. The fieldworkers did mention that older participants did not feel comfortable answering questions regarding difficulties experienced during their sexual activities, and the researcher made it clear to the fieldworkers that participants had the right to refuse to answer questions that made them uncomfortable and that this would be noted as missing data. (Appendix 20)

5.4 Conclusion

In this chapter a description of the measurement instruments chosen for the specific research study was given. In addition, the chapter presented details of the translation project, a new collaborative initiative between two academic departments, in an attempt to solve the methodological problems that could possibly occur during translation were provided.

The strength of the translation approach lay in the collaborative efforts between the Department of Linguistics and Language Practices at the University of the Free State and the Allied Health Professions, exploring new methods in an attempt to solve methodological problems that could occur during translation of questionnaires. During this process, professional as well as free-lance translators were used and the translation project was managed by a project manager, an accredited moderator for translations in South Africa. Despite using professional translators, the limitations of the translation process included a poor standard of translations, and in one instance the poor quality of the translation changed the intended plan of the project. Inaccurate translations, difficult wording, advanced and unfamiliar vocabulary choices and complex sentences and words were challenges that faced the translators.

Another limitation is the possible lack of generalisable use of the translations for more rural respondents. All the translators regarded themselves as fully bilingual in Sesotho and English, because their first language was Sesotho and they were working in an urban environment. The questionnaires were tested on Sesotho women living in a peri-urban community of Bloemfontein which meant that the Sesotho spoken by the women was a mix of IsiXhosa and Setswana due to the urbanisation that is taking place in South Africa. Although some women were IsiXhosa and Setswana speaking, they could all fluently speak and understand Sesotho due to urbanisation in the population being investigated in this study. However, the translated questionnaire might not be readily understood in a pure rural Sesotho environment or by unilingual Sesotho speaking individuals. Should the research study be duplicated in another population using the translated questionnaires, piloting would be advisable.

Despite these limitations, the researcher had confidence that the translation process resulted in versions that were culturally and linguistically equivalent to the source versions, and data collection was then initiated.

6 PREVALENCE, NATURE AND IMPACT OF MUSCULOSKELETAL CONDITIONS

6.1 Introduction

This study investigated the nature and prevalence of MSC in women between the ages of 40 and 64 years who attended a community clinic in the Free State for management of chronic diseases of life style (CDL) and/or musculoskeletal conditions (MSC). The outcome was to inform the development of the workbook and the intervention. In addition, the relationships between joint pain (musculoskeletal conditions) and other co-morbid conditions were examined. The research questions therefore included: How many of the clinic attendees eligible for inclusion experienced joint pain (musculoskeletal conditions)? What was the nature of their pain? Did the MSC occur co-morbidly with CD? If so, what clusters of co-morbidities were present which included MSC? Was substance use and obesity associated with joint pain? In those that did have joint pain (MSC), a further question was to establish whether the joint pain had a negative impact on their activities and participation.

The terminology “joint pain” (musculoskeletal conditions) was used during the formulation of the COPCORD questionnaire utilised for the survey. Therefore for the purpose of the epidemiological survey this terminology will be used when discussing the COPCORD questionnaire. The more generic terminology “joint pain” will be used in any other circumstances during the study.

6.1.1 Aims and objectives

The specific objectives of the epidemiological study were to examine joint pain (as defined by the COPCORD Phase I and II questionnaire), within women between the ages of 40 and 64 years, attending a community clinic in the Free State, in order to:

- determine the prevalence of joint pain;
- determine the nature of the joint pain;

- establish the most common clusters/patterns of co-morbidities in women experiencing joint pain;
- determine any co-morbid relationships between diabetes mellitus type II, hypertension and joint pain (musculoskeletal conditions); and
- to determine whether substance use and obesity were associated with joint pain in these women.

The second aim of the study was to determine the impact of joint pain on activity limitations and participation restrictions within the target population. The specific objectives were:

- to determine if those with joint pain (musculoskeletal conditions) had a lower quality of life as measured by the EQ-5D-3L compared to those without;
- to compare the functional limitations of those with joint pain (musculoskeletal conditions) to those without as measured by the WHODAS 2.0; and
- to establish the nature of dysfunction and/or participation restrictions in those participants with joint pain (musculoskeletal conditions).

6.2 Methods

6.2.1 Research design

The research design was a facility-based survey using a descriptive observational cross-sectional design.

6.2.2 Study population

The population consisted of all women between the ages of 40 and 64 years attending the community clinic in the Bloemfontein area, for CDL health-related issues.

6.2.3 Study sample

A sample of convenience was utilised in that all women between the ages of 40 and 64 years, who attended the community clinic, on the days of data collection, were included in the sampling frame. There was no randomisation or probability sampling and all women, within the age group, who agreed to participate, were included. This age group was recruited as joint pain and CDL increase with age and are more common in women (14). It was of interest to determine the prevalence of joint pain and co-morbidity within this targeted group as the Primary Health Care system needs to be able to provide their existing patients with appropriate and adequate care. Knowledge of the numbers of women who fit into this category would assist the Primary Health Care clinics with planning and aid in designing the intervention planned in the second phase. The planned intervention (Chapter 8) was intentionally aimed at those who perceived their health condition as being poor enough to warrant attendance at the clinic and who were living with the health conditions of interest.

6.2.3.1 Participation criteria

All women between the ages of 40 and 64 years, attending a community clinic, for personal health-related issues were included in the survey. The women had to give informed consent. As the questionnaires were only available in two of the three main languages spoken in the Free State Province, the women were required to understand English or Sesotho in order to participate in the study. The language proficiency of the participants was determined by asking the participants if they would be able to answer the questions asked by the researcher or the fieldworkers in any of the two languages. Women with neurological conditions such as adult cerebral palsy or stroke were excluded as they might have experienced joint pain due to abnormal biomechanics arising from contractures, increased spasticity or deformities. Women who had cognitive impairment, which might prevent understanding of the informed consent procedure and the questions asked, were also excluded.

Blinding was not applicable as all attendees at the clinic on the day of data collection fitting the criteria described were included and no intervention was performed.

6.2.3.2 Sample size

The sample size was calculated in Epi-info ™ 7 based on the prevalence estimates from a similar study in a primary health care clinic (PHCC) in Cape Town (32). It was expected that the population attending the PHCC would be 11 000 and that there would be only one clinic or cluster. The design effect was therefore set at one (519). The expected frequency of joint pain (musculoskeletal conditions) was entered as 10%, with a confidence limit of 1.5%. This implied that, if the true prevalence was 10%, the prevalence would range from 8.5-11.5% and that the researcher could be 95% sure that this was the true prevalence. One thousand three hundred and fifty three participants would be required, of which it was anticipated that approximately 135 would present with MSC.

6.3 Instrumentation

Chapter 5 described the translation and semantic validation of the instruments used in this part of the study. They included:

- a self-designed questionnaire to gather demographic and medical information; (Appendix 4)
- the COPCORD questionnaire to screen for joint pain; (Appendix 4)
- the EQ-5D-3L to monitor Health-Related Quality of Life (HRQOL) (Appendix 6) and
- functional ability was measured by the WHODAS 2.0. (Appendix 5a)

In addition, the following measurements were taken: body weight and height of participants, blood pressure measurements and random serum glucose levels using the finger prick tests.

- Body weight was determined by the fieldworkers on a calibrated electronic Safeway digital scale accurate to 0.05kg. The body weight was determined without shoes and excess clothing. The height of each participant was recorded to the nearest 0.1 cm using an adapted stadiometer, which consisted of a metal measuring tape, placed securely against a flat wall and a flat headboard at a right angle to the wall. Participants were instructed to stand with their backs, buttocks and heels as close to the wall as possible. The measurement was taken without shoes (123). All the measurements were taken in a separate room to protect the privacy of the patient

(520). The information obtained was documented on the data form, disclosed to the patient, but kept strictly confidential.

- Blood pressure was measured after a five-minute rest in the sitting position according to WHO guidelines. Two readings after three-minute intervals were obtained using an electronic table-model sphygmomanometer (Clever Chek TD-3250 – 2 in 1 blood pressure monitoring system). In each instance, the second reading of the participants was used as the baseline measurement (521). Blood pressure was classified as low: systolic blood pressure <120mmHg diastolic blood pressure < 80mmHg; normal : systolic blood pressure 120 – 129mmHg diastolic blood pressure 80 – 90mmHg; high normal/pre-hypertension: systolic blood pressure 130 – 139mmHg diastolic blood pressure 80 – 90-mmHg; stage I hypertension: systolic blood pressure 140 – 159mmHg diastolic blood pressure 90 – 99mmHg; stage 2 hypertension: systolic blood pressure 160-179mmHg diastolic blood pressure 100 – 109mmHg and stage 3 hypertension: systolic blood pressure ≥ 180 diastolic blood pressure ≥ 110mmHg (522).
- Random serum glucose levels were determined by the finger prick test performed by the trained fieldworkers. For safety purposes, Medlance extra plus 21 G sterile, needle lancets with a 2.4 mm penetration depth was used. All the lancets are protected by a safety cap to ensure first time use and after usage; the lancet retracts as a safety feature of the Medlance products. All the used lancets were discarded into a red sharps container at the community clinic in accordance with the facility's guidelines and national regulations. The Gluco Check classic blood glucose monitoring unit TD 4255, and glucose test strips were used for the test. Fieldworkers were instructed to wear sterile latex gloves at all times during the testing of the random serum glucose levels of the participants. The first drop of blood from the fingertip of participants was discarded in accordance with the manufacturer's recommendations as the first drop usually contains tissue fluid and serum, which may influence the test results. Plasma glucose levels range (mmol/L) before meals should be between 3.9 – 7.2 mmol/L and, two hours after meals, less than 10 mmol/L (523). As the survey was conducted mostly in the mornings and women travelled early to reach the clinic in time, most of the glucose levels were taken before meals, but not all of them . Unfortunately the researcher could not standardise the time of assessment of glucose levels. Therefore a non-fasting blood glucose level of more than 7.8mmol/L, were used as cut-off point for the classified as having diabetes mellitus type II. A TaiDoc Glucose Control Solution test was performed with each testing device to ensure that the device was reading the test strips correctly.

6.4 Fieldworkers

Five trained health care workers were recruited and appointed by the researcher to conduct the survey at a community clinic. The health care workers had recently completed their training, but still needed practical time in the field before receiving their training certificates. Their practical hours involved working under supervision in different clinical settings as decided upon by their training institution. The hours spent at the community clinic would count for their clinical hours and therefore the health care workers were recruited as fieldworkers for the purpose of the survey. Before commencement of the pilot study, the recruited health care workers were tested by their instructor in determining the body weight and height of participants and in the use of the blood pressure monitor and serum blood glucose testing device. After ensuring that they were all proficient in performing the necessary tests, the researcher explained the aim and objectives of the questionnaires and how to administer them. It was emphasised that informed consent and voluntary participation were both essential. Clear instructions were given regarding the time and dates for the survey as well as the procedure to be followed.

6.5 Pilot study

In the proposal, it was calculated that a pilot study needed to be conducted on 40 participants at the community clinic and if the sample did not yield at least four people (10%) with MSC, it would have to be extended until this number was reached. The pilot study was to inform the final sample size and determine whether the estimated number was grossly over- or underestimated. The pilot study was conducted between the 9th and 10th of June 2014, using the same procedure as planned for the full study and assessed the feasibility in terms of patient commitment, time to fill in questionnaires and to establish whether changes needed to be made. The pilot study was conducted on 53 participants who consented to participation. Unfortunately, one participant had to be excluded due to age. Of the 52 participants, 19 (36%) indicated that they had experienced joint pain in the last seven days. The sample size therefore did not change.

6.6 Changes made after the pilot study

Data collection was initially slow as the fieldworkers were unfamiliar with the setting at the community clinic and the women attending the community clinic were reluctant to participate in the study. A decision was made by the fieldworkers in consultation with the researcher to wear their caregivers' uniforms with name tags so that the women at the clinic would become familiar with the study. This strategy increased the response rate within the first week and, the more familiar the women became with the fieldworkers; the more they were willing to participate in the survey. The participants were not confident enough to complete the questionnaires by themselves in the presence of a fieldworker. Therefore, after the first day in the field, the decision was made that the questionnaires would be completed through structured interview where the fieldworkers read out the question to the participant and ticked their answer in the appropriate box as indicated. No other changes were made after completion of the pilot study. It was acknowledged that a structured interview might result in participant bias and the provision of socially more acceptable answers. In addition, the order and method of interview might influence the results. The researcher attempted to minimise these risks by ensuring that the fieldworkers were trained in a standardised method of administering the questionnaires. The project manager of the translation process observed and audio-taped a structured interview of each fieldworker with no prior warning. The project leader indicated to the researcher that the interviews were conducted as planned and that no discrepancies were noted.

6.7 Testing procedure

Ethical approval was obtained from the Human Research Ethics Committee, of the Faculty of Health Sciences, at the University of Cape Town (HREC reference number: 605/2013 (Appendix 21) and the Ethics Committee of the Faculty of Health Sciences, at the University of the Free State (ECUFS number: 185/2013) (Appendix 22). Approval was also obtained from the head of the Department of Health in the Free State and the head of the community clinic before commencement of the pilot study and execution of the study (Appendices 22 and 23). A copy of the permission letter for the execution of the survey at the community clinic was given to the sister in charge of the clinic well in advance. Permission was obtained from the sister in charge at the clinic and she was given an information leaflet regarding the survey and a calendar indicating the days on which the survey was to be conducted at the clinic. The

clinic is open on weekdays between 08:00 – 16:00. Most of the visits to the clinics take place during the mornings. Data was collected during the period from 11 June 2014 to 19 August 2014.

On the day of data collection, the fieldworkers approached women in the waiting room/reception area of the community clinic awaiting either treatment or the dispensing of their chronic medication for CDL. The age of the women as well as the presence of CDL was established by the fieldworkers, to ascertain their eligibility in the survey before explaining the aim of the research and obtaining informed consent. Participants were made aware that their participation in the study was voluntary, that non-participation would not affect their scheduled visit or services at the community clinic and they would not forfeit their place in the queue (Appendix 25).

Those women who consented to participate were taken to a screened-off area at the community clinic after ensuring that their place in the queue would not be forfeited. An information leaflet was then handed to the participant in her preferred language – English or Sesotho. An informed consent form complying with the elements as required by the Ethics Committees was read by or read to the participants and signed before completing the questionnaire (Appendix 26). If a participant was unwilling or unable to sign her name, she would have been asked to provide a fingerprint in the presence of a witness or the sister/nurse on duty at the clinic, who then signed the consent form as a witness. However, in no instance during the survey was this required.

The completion of the questionnaires was done in the format of a structured interview, as mentioned above. The questionnaires were made available in an English A5 bounded booklet or a Sesotho A5 bounded booklet. The first section of the booklet was the COPCORD Phase I questionnaire. The body weight and height of participants, blood pressure measurements and random serum glucose levels using the finger prick tests were then determined by the fieldworkers as described under measurements instruments/outcomes (Sections 5.2.1 and 6.3) and were entered on the first page of the Phase I document. If a participant indicated that they were living with joint pain (musculoskeletal conditions) during Phase I of the questionnaire they then went on to complete Phase II of the questionnaire in the booklet. If they indicated that they did not live with joint pain (musculoskeletal conditions) the fieldworkers proceeded by completing the WHODAS 2.0 questionnaire, followed by the EQ-5D-3L questionnaire which was the last questionnaire to be completed in the booklet. Once the fieldworker ensured that all the applicable questionnaires in the booklet were completed during the structured

interview, the booklet was placed in a sealed box provided by the researcher. Most of the participants preferred the fieldworkers to speak Sesotho to them and only a handful of participants preferred English.

Women who were presenting at the community clinic for the first time, and who had given informed consent and completed the questionnaire, but who did not have knowledge regarding their health status, were asked by the fieldworkers to return to the fieldworker after the consultation at the clinic to complete the data as required. Unfortunately, in some instances this did not happen and consequently some questionnaires had incomplete medical data.

In order to avoid duplicate responses from study participants, their identity numbers were checked by the researcher before data entry. No duplicate questionnaires were found by the researcher.

6.8 Statistical analysis

The overall score of the WHODAS 2.0 was calculated as per the manual (455, 524). (Appendix 5b)

The EQ-5D-5D-3L Index or utility score was calculated using the York Tariff (470).

Descriptive statistics, namely frequencies and percentages, were calculated for categorical data. Non-parametric tests were used for ordinal data. As the sample size was large, the central limits theorem applied (525) and parametric statistics, such as the t-test were used to compare numeric data, provided that the distributions were not grossly abnormal (Shapiro Wilk $p<.001$).

Analytical statistics, namely the Chi-Square test or Fisher's Exact test were used to compare proportions in different groups. The Mann Whitney U test was used to compare median values in different groups. A significance level (α) of 0.05 was used throughout the study.

6.9 Results

6.9.1 Description of sample

Altogether 1774 women were approached of whom 398 women declined consent, but did report whether or not they had joint pain. The reasons for declining to participate included that they did not want to answer questions that they did not have time, or no reasons were given. Of those who gave consent, two were excluded as they were too old. A total of 1376 participants were thus enrolled. Figure 7 shows a flow diagram of participation throughout the survey.

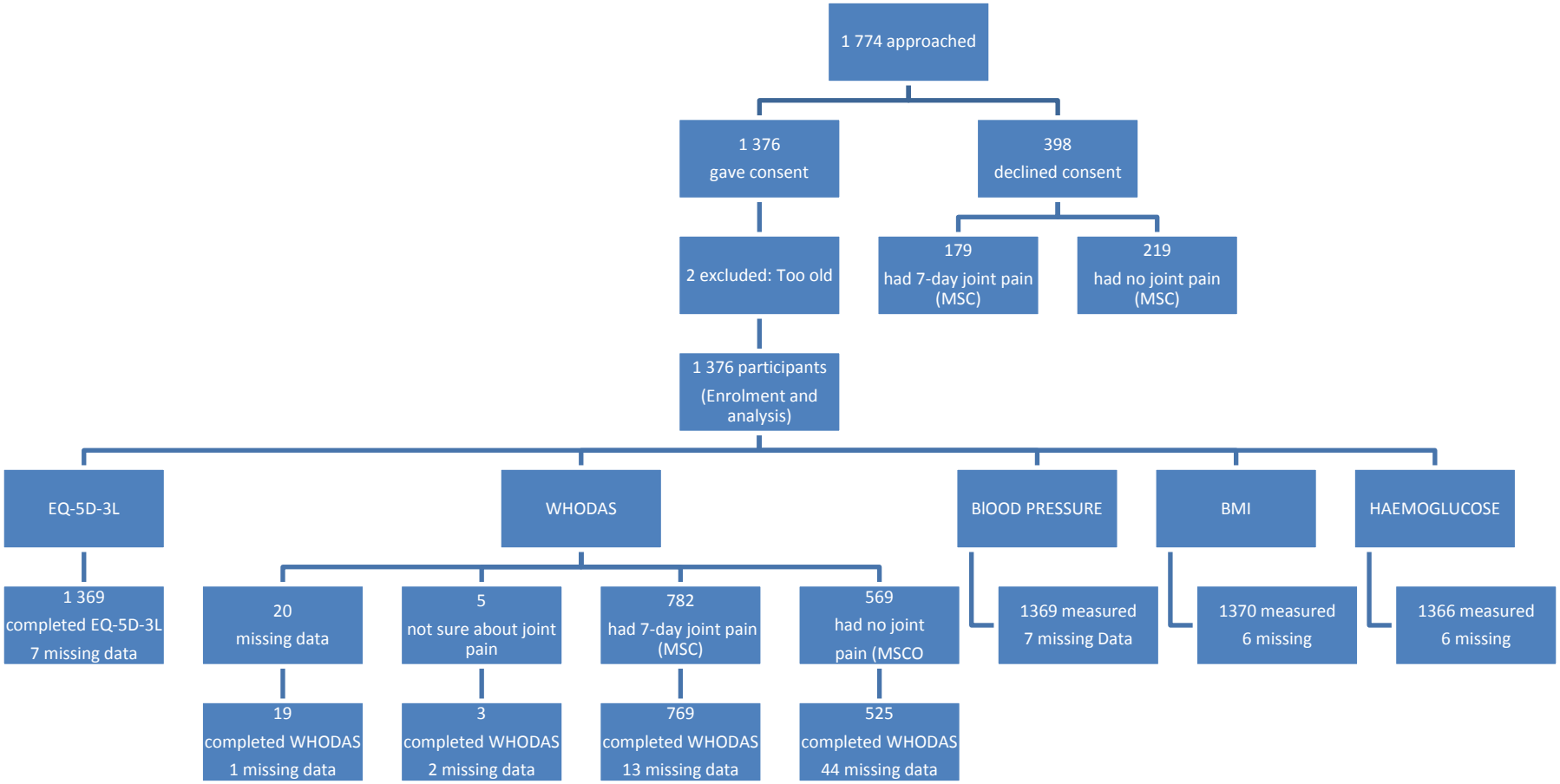
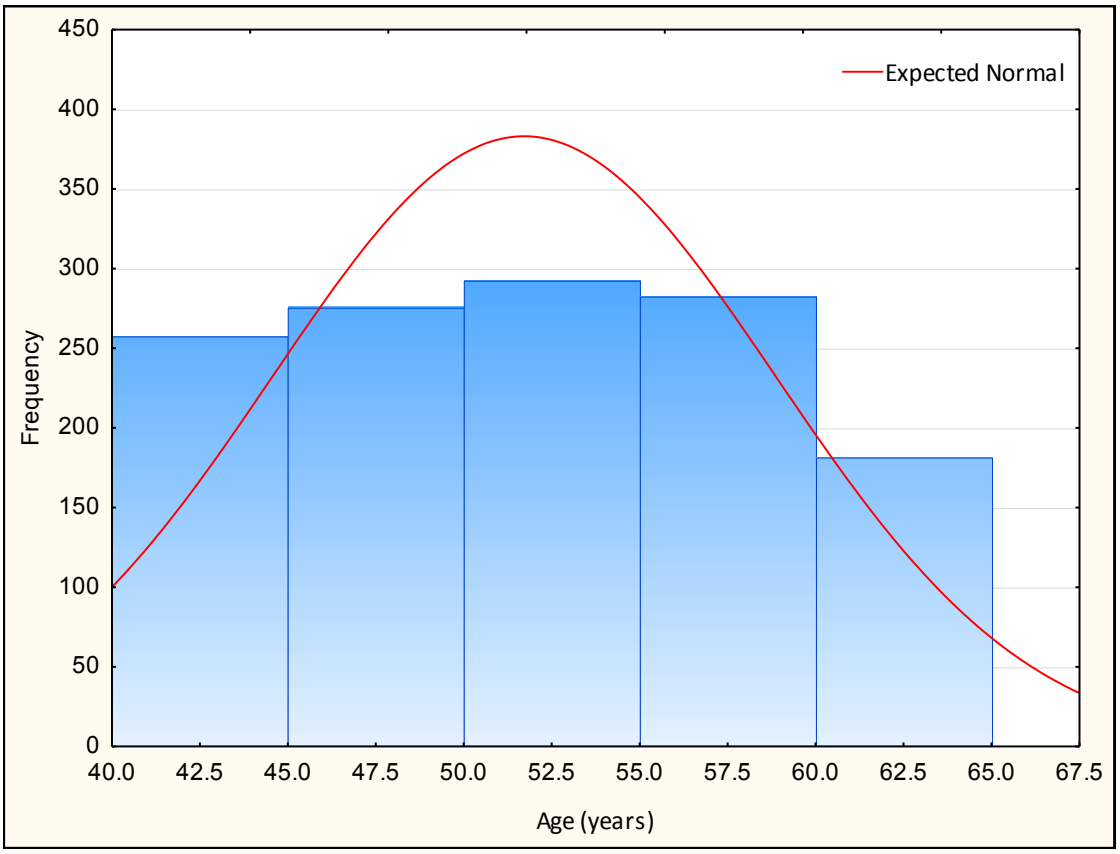


Figure 7: Flow diagram of participation

6.9.2 Demographic information of survey participants

The age distribution was not normal (W = 0.956 and p < 0.001) (Figure 8). The median age of the participants was 52y (inter-quartile range (IQR): 46-58y, and range of 40-64y). The mean age of the participants was 52y (SD 7.2).



(n=1373, missing 3)

Figure 8: Distribution of the age of the participants

The participants' demographic and dwelling details are given in Table 33 below. The home language of approximately two thirds of the participants was Sesotho, with Isixhosa (18%) and Setswana (13%) being the next most common home languages. Less than half of the participants were married (46%), followed by those who had never married (36%).

Almost 75% of the participants owned their own home, with the rest living with family or friends. Over 80% lived in brick houses. The median number of residents per household was five people (IQR: 4-6 people).

Table 33: Demographic and living conditions of the participants

Variable	Categories	Frequency (n)	Percentage of total
Language*	Sesotho	935	67.95%
	Isixhosa	246	17.87%
	Setswana	176	12.79%
	English	11	0.8%
	Afrikaans	2	0.15%
	Zulu	4	0.29%
	Missing	2	0.15%
Race	African	1371	99.64%
	Coloured	3	0.22%
	White	1	0.07%
	Missing	1	0.07%
Marital Status	Married	638	46.37%
	Never married	494	35.89%
	Widowed	171	12.43%
	Separated/divorced	71	5.16%
	Missing	2	0.15%
House ownership	Own	1024	74.42%
	Friend/family	340	24.71%
	Other	7	0.51%
	Missing	5	0.36%
Type of dwelling	Brick	1145	83.21%
	Informal	225	16.35%
	Missing	6	0.44%

Variable	Categories	Frequency (n)	Percentage of total
Number of residents per household	1	59	4.29%
	2	22	1.59%
	3	202	14.68%
	4	388	28.20%
	5	296	21.51%
	6	406	29.51%
	Missing	3	0.22%

**This question was only based on their home language and not the number of languages spoken.*

(n=1376)

Details of the level of education and employment status of the participants are given in Table 34. About 15% of the participants were either illiterate or could only read in their home language. The majority of participants (90%) had some education, which included primary, secondary or tertiary education. Only 14% of the participants had full-time employment, while 49% were currently unemployed. Sixty three per cent indicated the reason for unemployment as not being able to find a job, followed by health problems (31%). Twenty five per cent of the participants received a grant.

Table 34: Level of education and employment status of the participants

Variable	Categories	Frequency (n)	Percentage
Literacy	Unable to read/write	164	11.92%
	Read only	38	2.76%
	Read/write	1171	85.10%
	Missing	3	0.22%
Education	None	138	10.03%
	Primary	496	36.05%
	Secondary	692	50.29%
	Tertiary	49	3.56%
	Missing	1	0.07%
Current employment status	Unemployed	675	49.06%
	Pensioner	245	17.81%
	Housewife	150	10.90%
	*Worker - Full time	112	8.14%
	*White collar - Full time	82	5.95%
	Worker - Part time	81	5.89%
	White collar - Part time	21	1.53%
	Missing	10	0.72%
Reason for unemployment (n = 675 unemployed)	Cannot find work	425	62.96%
	Health problems	209	30.96%
	Family care	22	3.26%
	Disabled	6	0.89%
	Husband prevents	4	0.59%
	Missing	9	1.34%
Receive grant benefits	No	1025	74.49%
	Yes	349	25.36%
	Missing	2	0.15%
Type of grant benefits (n = 349 receiving grants)	Disability	123	35.24%
	Pension	202	57.88%
	Disability and pension	17	4.87%
	Not known	7	2.01%

(n=1376)

* White-collar work is performed in an office, cubicle, or other administrative setting, while a worker's job requires manual labour or service-orientated work.

6.9.3 Health-related information

6.9.3.1 Reason for clinic visit

The most frequently reported reasons for visits to the clinic were to collect medication (53%) and for a doctor's consultation (45%). (Table 35)

Table 35: Reasons for participants visiting the clinic

Reason	Frequency (n)	Percentage*
Collect medication	729	53%
Doctor consultation	619	45%
Consultation with nurse and medication collection	234	17%
Attending on behalf of others	41	3%
Nurse consultation	41	3%
Consultation for joint pain	28	2%
Consult dentist	28	2%
Consult physiotherapist	14	1%
Work or training at clinic	0	0%
Unknown	14	1%

**Note that some participants attended for more than one reason. (n=1376)*

6.9.3.2 Health conditions of participants

Information was obtained regarding the participants' health over the previous three months. Participants were asked to indicate all applicable co-morbidities at the beginning of the questionnaire and later to indicate whether they had been diagnosed with a specific health condition and, in a separate question, they were asked to indicate the health condition (s) they suffered from in the last three months (Questions Q7, Q25 and Q27, respectively in Appendix 4). Diagnosed implied that the nature of the health condition was determined by examination of the symptoms presented by the patient, while self-reported related to the experience or feeling of the specific health condition (526).

Hypertension was the most commonly self-reported health condition (62%), followed by joint pain (23%) and diabetes mellitus (12%). The majority of the participants (64%) were also diagnosed with hypertension, 25% with joint pain and 13% with diabetes mellitus. One percent of the participants indicated that they had high cholesterol. It is interesting to note that 45% of the respondent reported living with depression.

Table 36: Health conditions reported by the participants

Health condition	**Medically diagnosed health condition self-reported**
	Frequency n* (%)
Hypertension	873 (64%)
Diabetes mellitus	179 (13%)
Heart condition (cardio-vascular)	Not reported
Infection	Not reported
Stomach condition	Not reported
Cancer	Not reported
Paralysis	Not reported
Obesity	6 (0.4%)
Injury	Not reported
Genitourinary tract infection	Not reported
Joint pain	341 (25%)
Cholesterol	7 (0.5%)
Depression	Not reported
Stroke	47 (3.4%)
Respiratory	Not reported

**Note that some participants had more than one condition. Not reported implied that no-one was aware of having this condition.*
(n=1376)

As can be seen from Table 37, the median value for the haemoglucose was 5.5 mmol/l as determined by the fieldworkers, but 20% of the participants had a non-fasting blood glucose level of more than 7.8mmol/L, which meant that they were classified as having diabetes mellitus type II. The participants were classified as having diabetes mellitus type after testing by the fieldworkers, using the method as described in the instrumentation (section 6.3).

Table 37: Health variables of the participants as determined by the researcher and fieldworkers

Variable	n	Median	Inter-quartile range
Haemoglucose (mmol/l)	1370	5.5	4.6 – 7.2
Systolic BP (mmHg)	1371	147	132 – 159
Diastolic BP (mmHg)	1371	91	84 - 99

Table 38: Diagnosed DM II versus DM II as determined by the fieldworkers

DM II	Clinic DM II Positive Frequency (n)	Clinic DM II Positive Percentage	Clinic DM II Negative Frequency (n)	Clinic DM II Negative Percentage	Row	Percentage
Test Positive	130	9.5%	143	10.5%	273	20%
Test Negative	50	3.7%	1045	76.4%	1095	80%
All Groups	180	13.2%	1188	86.8%	1368	100%

As can be seen in Table 38 above, 9.5% of the participants tested positive on the days of data collection and had been previously managed, 10.5% of the total tested positive for diabetes mellitus type II on the days of data collection and had not been previously diagnosed by the clinic staff. A further 3.7% had been diagnosed previously by the clinic staff, but were not positive on testing by the fieldworkers on the day of data collection. The total number with diabetes mellitus type II was 323 (273+50), which represented 24% of the total sample.

The majority of the participants (66%) were classified as being hypertensive after testing by the fieldworkers, using the method as described in the instrumentation (section 6.3). It was unclear how many participants were taking anti-hypertensive medication due to missing data (Table 39)(527).

Table 39: Prevalence of hypertension as determined by objective measurement

Classification*	Frequency	Percentage
Normal	458	33%
Stage I	501	37%
Stage II	232	17%
Stage III	180	13%
Total	1371	100%

**Normal: Systolic blood pressure 120-139mmHg Diastolic blood pressure 80-90mmHg*
Stage I hypertension: Systolic blood pressure 140-159 mmHg Diastolic blood pressure 90-99mmHg
Stage 2 hypertension: Systolic blood pressure 160-179 mmHg Diastolic blood pressure 100-109mmHg
Stage 3 hypertension: Systolic blood pressure ≥ 180mmHg Diastolic blood pressure ≥110mmHg

(n=1371)

From Table 40, it can be seen that 918 (66.8%) blood pressure measurements as determined by the fieldworkers were classified as being hypertensive, compared to 875 (63.6%) diagnosed by the health staff. Of the total, 18%, who had not been identified by the clinic staff were diagnosed by the researcher. Conversely, 15% had been diagnosed by the clinic staff and were not identified by the researcher's screening. Approximately one half were diagnosed by both the researcher and clinic staff as having hypertension. The total number with controlled or uncontrolled hypertension was thus 1 125 (918+207), or about 80% of the respondents.

Table 40: Diagnosed hypertension versus hypertension as determined by the researcher

BP classification	Diagnosis Positive Frequency (n)	Diagnosis Positive Percentage	Diagnosis Negative Frequency (n)	Diagnosis Negative Percentage	Row	%
Test Positive	668	48.6%	250	18.2%	918	66.8%
Test Negative	207	15.1%	250	18.2%	457	33.2%
All Groups	875	63.6%	500	36.4%	1375	100%

%= % of total respondents (n=1375)

6.9.4 Prevalence of joint pain (musculoskeletal conditions)

Participants were asked whether they experienced pain, aching, swelling, stiffness (tightness) in or around their joints or back which was not related to an injury/accident in two separate questions. In Sesotho the word stiffness has a sexual connection and that is why the wording (tightness was included) to provide a clearer description. The first question enquired regarding the above mentioned symptoms during the time frame of the last three months and the second question during the last seven days. The three months was viewed as long term and the seven days as short term. These were the denominators from which the prevalence of joint pain (musculoskeletal conditions) was calculated. The prevalence of joint pain (musculoskeletal conditions), experienced in either the short or long term (within the previous three months) was 62.1% (CIs 59.5-64.6%). (Table 42) Only 25% of participants had been diagnosed with joint pathology by the clinic staff. Those with joint pain (musculoskeletal conditions) were twice as likely to consent to participation (Table 41).

Table 41: Prevalence of joint pain (musculoskeletal conditions) in consenters and non-consenters

	Joint pain (musculoskeletal conditions)	**No joint pain (musculoskeletal conditions) or unsure**	**Total**
Consent	854 (62.1% RT, 82.7% CT)	522 (38.0% RT, 70.5% CT)	1376 (77.6% CT)
No consent	179 (45.0% RT, 17.3% CT)	219 (55.0% RT, 29.5% CT)	398 (22.4 CT)
All approached	1033 (58.3% RT)	741 (41.8% RT)	1774

RT=Row total, CT = Column total
Chi square = 37.07, p<0.001 Odds ratio = 2.00 (95% CI: 1.60 - 2.51)

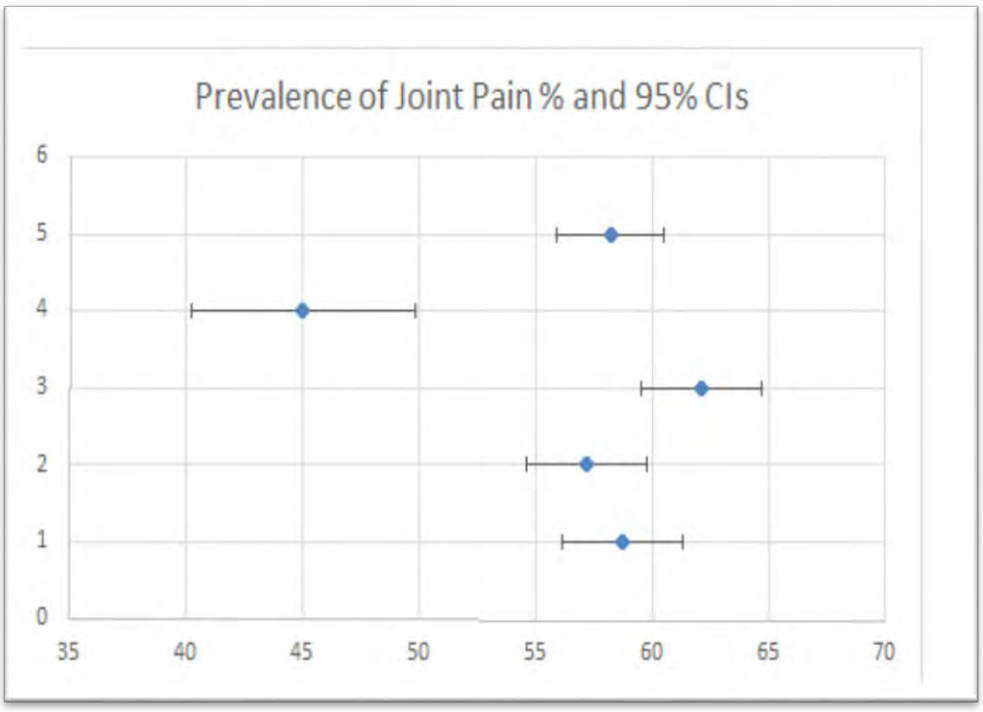
Table 42: Prevalence of joint pain over short and long term

Period experiencing joint pain	Count	Total number of participants	Percentage with joint pain	95% Confidence Intervals
Long-term joint pain (3 months)	808	1376	58.7%	56.1-61.3
Short-term joint pain (7 days)	787	1376	57.2%	54.6-60.0
Long- or short-term joint pain	854	1376	62.1%	59.5-64.6
Non-consenters with joint pain	179	398	45.0%	40.2-50.0
All those approached	1033	1774	58.2%	55.9-60.5

(n=1376)

* The terminology for short-term or long-term joint pain is standardised according to COPCORD terminology and has been validated. Short-term joint pain refers to joint pain experienced during the last seven days and long-term joint pain to joint pain experienced during the last three months.

As can be seen in Table 42 and Figure 9, the combined seven day/three month joint pain, had the highest prevalence but that the CIs overlapped with the other groups. The prevalence was much lower in the non-consenting joint pain group, but as the numbers of participants in the non-consenting joint pain group were relatively small, their inclusion in the prevalence rate of all those individuals approached, did not result in a prevalence rate in which the CIs overlapped with the combined long- or short-term joint pain prevalence (Number 5 in the forest plot).



Key: Study number
5= All those approached 1033/1774

4=Non-consenters joint pain 179/398

3=short-term or long-term joint pain 787/1376

2=short-term joint pain 787/1376

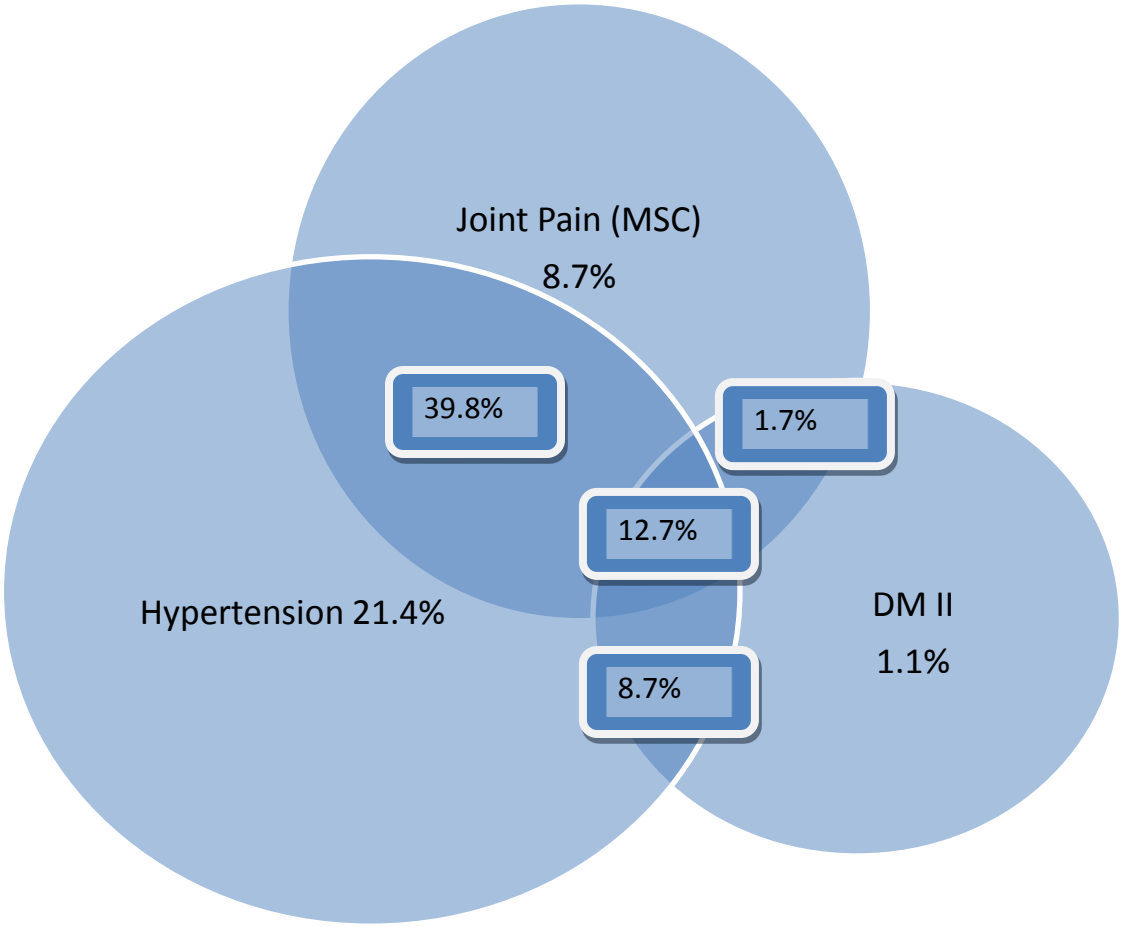
1 = long-term joint pain (3 months) 808/1376

Figure 9: Forest plot of prevalence rates and 95% CI's of joint pain

The mean age of those with joint pain was 52.6y (SD=6.8) which was significantly higher than those without joint pain (50.3y, SD 7.43; t separate variances =5.73, p<.001).

6.9.5 Prevalence of co-morbidity

In each case the denominator used was the combined positive on testing and positive on clinic diagnosis. In summary, the total number of participants with joint pain was 854; with hypertension was 1125; and 323 with diabetes mellitus type II, below indicates the interaction between these conditions.



Note that the rounded up percentage refers to the total number of respondents (n=1348) 6.4% had none of the above health conditions. Missing responses = 28

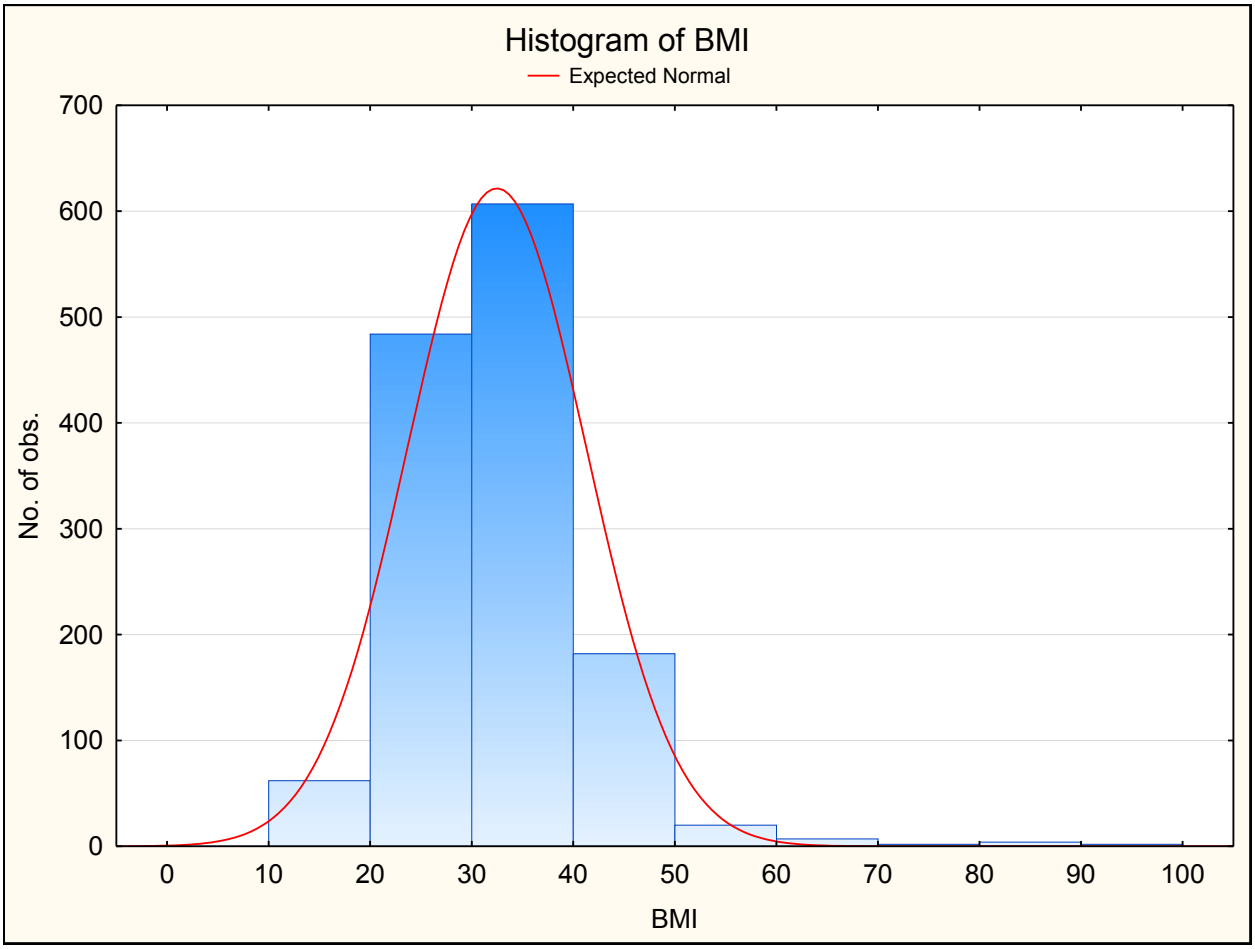
Figure 10: Interaction between the prevalence of joint pain, hypertension and diabetes mellitus type II

Over two thirds (67%) reported two or more health conditions. The greatest co-morbidity was between hypertension and joint pain, with 53% reporting both. No difference in proportions was found between DM II and joint pain (Chi-Square=.864, p=.352), while the difference between joint pain and hypertension approached significance (Chi-square=3.0, p=.085).

6.9.6 Risk factors

The risk factors for chronic diseases that were examined, included BMI and substance use/abuse.

The BMI values were not normally distributed (K-S d = 0.90471, p < 0.001), with a mean of 32.5 (SD=8.8, range =15.8-94.1)



(n=1372)

Figure 11: Histogram of BMI of participants

The median BMI was 31.6 (range 15.8-94.1) (Table 43) and 81% of the participants in the study were classified as being overweight or obese (Table 44). The body weight and height of the participants were determined by the fieldworkers as discussed in the instrumentation (section 6.3) while the researcher calculated the BMI values.

Table 43: Weight, height and BMI of participants

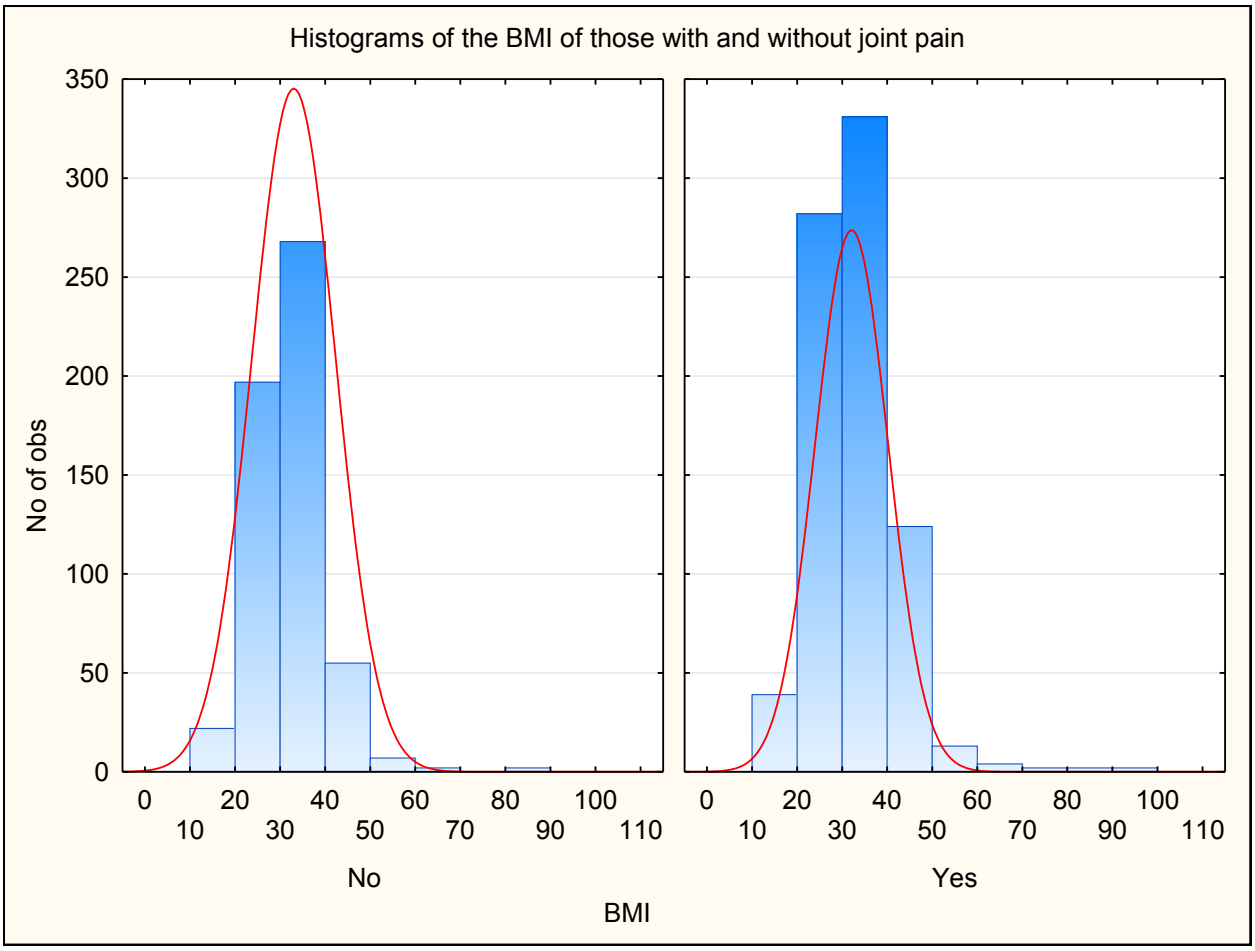
Variable	n	Median	Inter-quartile range	Range	Mean	Standard Deviation
Weight (kg)	1372	80.0	65.0 – 92.7	35.0 – 190.0	80	19.9
Height (cm)	1370	158	154 – 163	101.0 – 180.0	158	8.2
BMI (kg/m^2)	1370	31.6	26.8 – 37.0	15.8 – 94.1	33	8.8

(n=1372)

Table 44: Prevalence of obesity

Classification*	Frequency (n)	%
Underweight	23	2%
Normal	228	17%
Overweight	294	21%
Obese	825	60%

**Underweight: BMI < 18.5; Normal weight: BMI 18.5-24.9; Overweight: BMI 25-30; Obese: BMI > 30 – (n=1370)*



Joint pain n=850, without n=500, 26 missing responses

Figure 12: Histograms of BMI of those with and without joint pain in the last three months

The difference between the BMI of those with and without joint pain was 1.1 which was significantly higher (p = 0.023) when tested with separate variances. The mean BMI for those with joint pain was 32.9 and for those without joint pain 31.8. The standard deviation for those with joint pain was 9.15 and those without joint pain 8.10. The T value*t. was 2.28.

The substance use listed by participants indicated that 86% of participants never smoked, 80% never used snuff and 80% never used alcohol. (Table 45)

Table 45: Participants' history of substance use

	Smoking (n = 1369)	Snuff (n = 1359)	Alcohol (n = 1366)
Currently	11%	17%	17%
Formerly	3%	3%	3%
Never	85%	80%	80%

(n=1369)

There was no difference in proportions found between snuff and alcohol use and having joint pain, with fewer respondents with joint pain having never used snuff or alcohol (p=0.001 and p<.001 respectively. (Table 46)

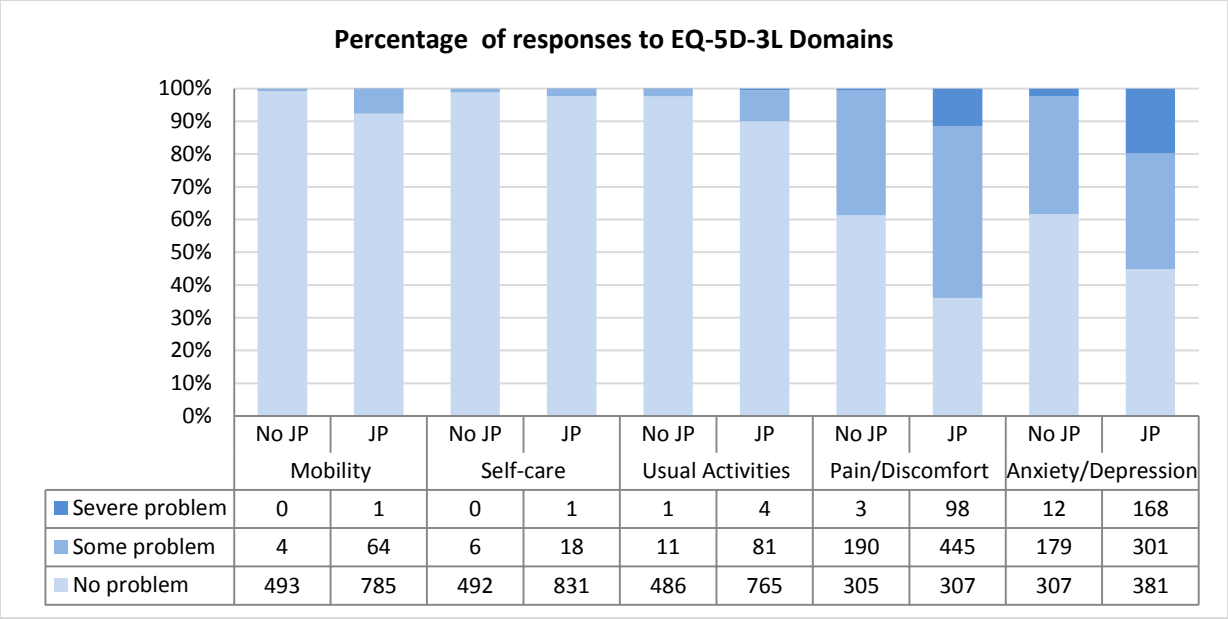
Table 46: Participants without and with joint pain and substance use

	Without joint pain n (%)	Joint pain n (%)	p-value
Never smoked	438 (83.9%)	720 (84.3%)	
Currently smoking	51 (9.8%)	99 (11.6%)	p=0.418
Formerly smoked	13 (2.5%)	30 (3.5%)	(Chi-square = 1.744
Missing data	20 (3.8%)	5 (0.6%)	
Never used snuff	412 (78.8%)	655 (76.6%)	p=0.001
Currently using snuff	61 (11.5%)	164 (19.2%)	(Chi-square =14.729
Formerly used snuff	25 (5.0%)	24 (2.9%)	
Missing data	24 (4.7%)	11 (1.3%)	
Never used alcohol	430 (82.3%)	648 (75.9%)	P<.001
Currently using alcohol	57 (10.9%)	176 (20.6%)	(Chi-square = 19.896)
Formerly used alcohol	12 (2.4%)	25 (2.9%)	
Missing data	23 (4.4)	5 (0.6)	

n = 522 no joint pain n = 854 joint pain

6.9.7 Impact of joint pain (musculoskeletal conditions) on quality of life

The quality of life of the participants was assessed using the EQ-5D-3L measurement instrument that consists of five dimensions, namely: mobility (M), self-care (SC), usual activities (UA) (work, study, housework and family), pain or discomfort (PD) and anxiety or depression (AD). Almost half of the participants in both groups experienced some problems with pain or discomfort and anxiety or depression, while a minority of participants experienced severe problems with anxiety or depression and pain or discomfort.

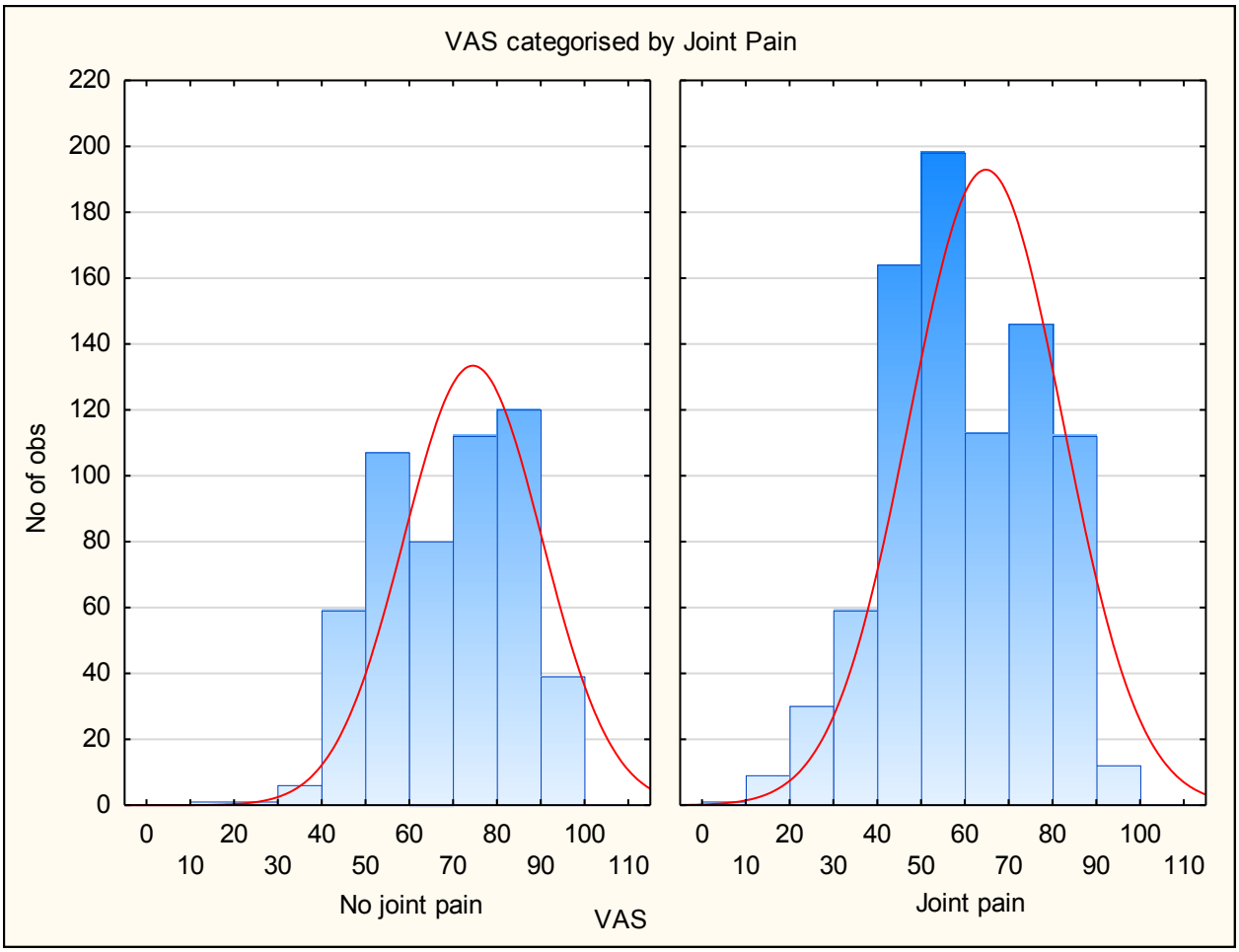


	No JP	JP	No JP	JP	No JP	JP	No JP	JP	No JP	JP
	Mobility		Self-care		Usual Activities		Pain/Discomfort		Anxiety/Depression	
Severe problem	0	1	0	1	1	4	3	98	12	168
Some problem	4	64	6	18	11	81	190	445	179	301
No problem	493	785	492	831	486	765	305	307	307	381

** JP=Joint Pain Joint Pain N=850, without Joint pain N=498 (some missing responses in some domains).*

Figure 13: Dimension for the quality of life experienced by participants without or with joint pain (musculoskeletal conditions)

Those with joint pain (musculoskeletal conditions) reported significantly more problems ($p<0.001$) in all domains apart from self-care ($p=0.176$) than those without joint pain (musculoskeletal conditions).



Without joint pain (MSC) n=497, 25 missing; with joint pain (MSC) n=850 (8 missing)

Figure 14: Visual analogue scale of EQ-5D-3L compared between the two groups

The EQ-5D-3L index score was calculated using the York tariff based on the domain scores, and this and the VAS, were significantly different between the two groups, with those reporting joint pain (musculoskeletal conditions) having a worse quality of life. Those with joint pain (musculoskeletal conditions) had a utility value of 0.13 of a year less than those without ($t=-14.1$; $p<0.001$) and their perceived health was 8% less ($t=-11.1$; $p<0.001$) (Table 47).

Table 47: Comparison of the EQ-5D VAS and Index scores between those with joint pain (musculoskeletal conditions) and those without.

	Joint Pain (MSC) Mean	Std Dev.	No Joint Pain (MSC) Mean	Std Dev	t tested with separate variances.	df	p 2-sided	Joint Pain (MSC) N	No Joint Pain (MSC) Mean
Index	0.70	0.23	0.83	0.11	-14.1	1320	<.001	853	500
VAS	64.48	17.45	74.65	15.37	-11.1	1146	<.001	850	497

6.9.8 Comparison of Functioning in those with and without joint pain (musculoskeletal conditions)

6.9.8.1 The WHODAS 2.0

Participants' level of functioning was measured using the WHODAS 2.0 instrument consisting of 12 items representing possible limitations in functioning. Each item is scored according to five levels - none, mild, moderate, severe and extreme/cannot do as seen below.

Participants experienced mild problems with washing, getting dressed, managing unknown people and doing household activities. The functional limitation with the highest proportion of participants experiencing no problems was community activities (approximately 40% for both groups). The largest overall proportion was those with moderate or severe problems with emotions (54% in those without joint pain (musculoskeletal conditions).

Table 48: Level of functioning of participants without or with joint pain (musculoskeletal conditions)

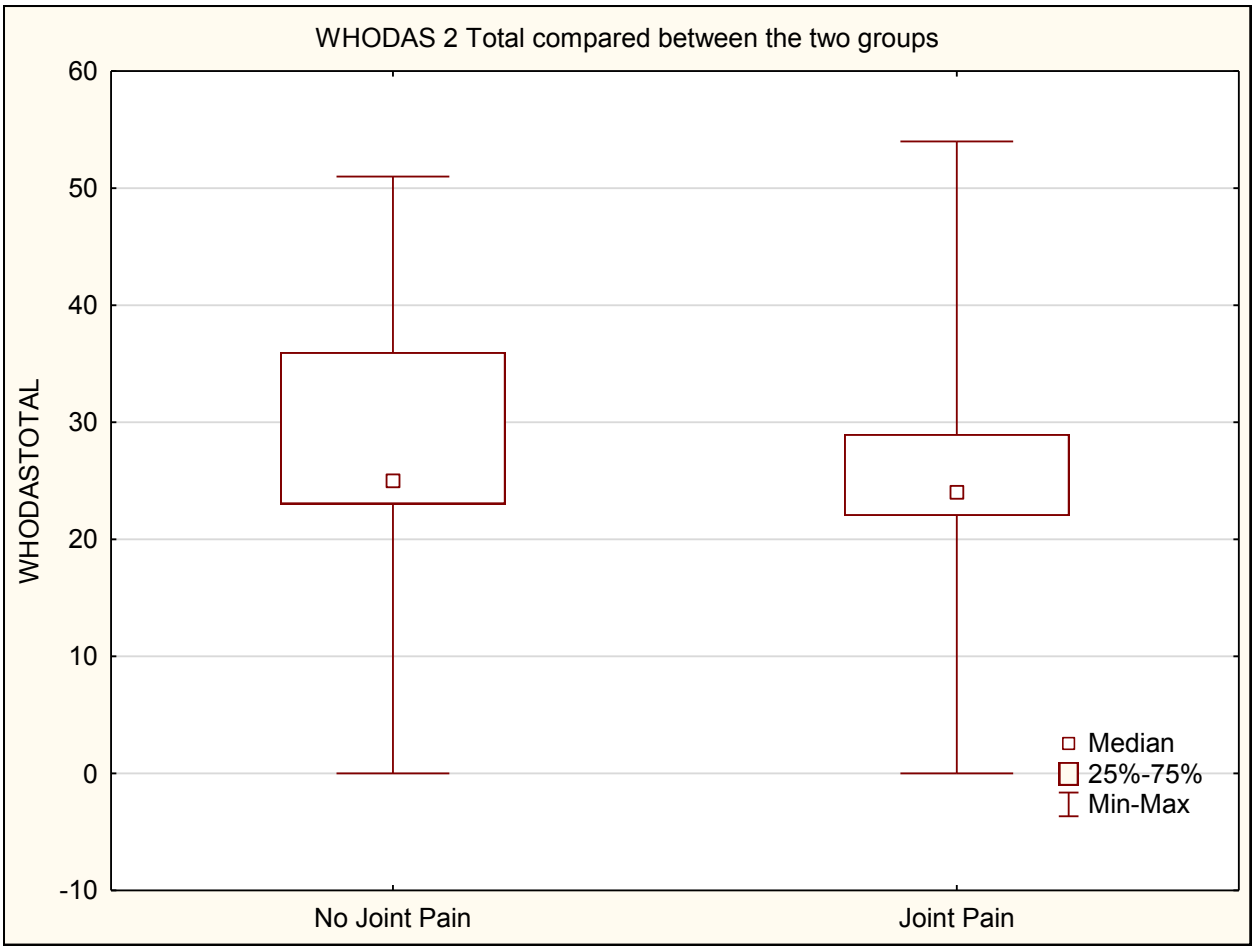
Item	Group	None		Mild		Moderate		Severe		Extreme		
		Frequency (n)	%	Frequency (n)	%	Frequency (n)	%	Frequency (n)	%	Frequency (n)	%	Total
Standing long	Without joint pain (MSC)	76	15.3%	200	40.2%	189	38.0%	18	3.6%	14	2.8%	497
	With joint pain (MSC)	215	25.3%	418	49.1%	149	17.5%	52	6.1%	17	2.0%	851
Household	Without joint pain (MSC)	55	11.1%	239	48.1%	184	37.0%	17	3.4%	2	0.4%	497
	With joint pain (MSC)	60	7.1%	578	67.9%	166	19.5%	45	5.3%	2	0.2%	851
New task	Without joint pain (MSC)	56	11.3%	213	42.9%	195	39.2%	19	3.8%	14	2.8%	497
	With joint pain (MSC)	122	14.3%	434	51.0%	245	28.8%	45	5.3%	5	0.6%	851
Community activities	Without joint pain (MSC)	187	37.6%	94	18.9%	145	29.2%	25	5.0%	46	9.3%	497
	With joint pain (MSC)	400	47.0%	240	28.2%	145	17.0%	50	5.9%	16	1.9%	851
Emotion	Without joint pain (MSC)	58	11.7%	98	19.7%	270	54.3%	64	12.9%	7	1.4%	497
	With joint pain (MSC)	225	26.4%	155	18.2%	320	37.6%	107	12.6%	44	5.2%	851
Concentration	Without joint pain (MSC)	56	11.2%	215	43.2%	212	42.6%	14	2.8%	1	0.2%	498
	With joint pain (MSC)	106	12.5%	480	56.5%	193	22.7%	65	7.6%	6	0.7%	850
Walking long distances	Without joint pain (MSC)	155	31.1%	113	22.7%	201	40.4%	15	3.0%	14	2.8%	498
	With joint pain (MSC)	247	29.0%	374	43.9%	168	19.7%	45	5.3%	17	2.0%	851
Washing	Without joint pain (MSC)	44	8.8%	236	47.4%	203	40.8%	15	3.0%	0	0.0%	498
	With joint pain(MSC)	45	5.3%	596	70.0%	153	18.0%	51	6.0%	6	0.7%	851

Item	Group	None		Mild		Moderate		Severe		Extreme		
		Frequency (n)	%	Frequency (n)	%	Frequency (n)	%	Frequency (n)	%	Frequency (n)	%	Total
Dressing	Without joint pain (MSC)	46	9.2%	224	45.0%	212	42.6%	15	3.0%	1	0.2%	498
	With joint pain (MSC)	45	5.3%	596	70.0%	158	18.6%	51	6.0%	1	0.1%	851
Dealing with unknown people	Without joint pain (MSC)	47	9.4%	218	43.8%	187	37.6%	17	3.4%	29	5.8%	498
	With joint pain (MSC)	66	7.8%	558	65.6%	166	19.5%	51	6.0%	10	1.2%	851
Friends	Without joint pain (MSC)	48	9.6%	223	44.8%	177	35.5%	25	5.0%	25	5.0%	498
	With joint pain (MSC)	169	19.9%	434	51.0%	189	22.2%	51	6.0%	8	0.9%	851
Work	Without joint pain (MSC)	77	15.6%	147	29.7%	250	50.5%	21	4.2%	0	0.0%	495
	With joint pain (MSC)	180	21.2%	373	43.8%	235	27.6%	57	6.7%	6	0.7%	851

(n=1364)

Joint pain (MSC) n=851, without joint pain (MSC) n=498 (24 missing from total); (3 missing from total), Shaded blocks indicate modal responses.

The median value for the summed WHODAS score for those without joint pain (musculoskeletal conditions) (n=498) is 13.0 and IQR 11.0 – 20.0 and for those with joint pain (n=851) the median value is 13 and the IQR 10.0 – 24.0 When comparing the summed WHODAS 2.0 scores, it became apparent that the results were counterintuitive, in that those without joint pain (musculoskeletal conditions) reported significantly poorer functioning than those with joint pain (musculoskeletal conditions) (Adj Z= -5.51, p<0.001) (Figure 15), thus casting doubt on the discriminate validity of the WHODAS 2.0.



No joint pain (MSC) N=498, 25 missing Joint Pain (MSC) 851, 3 missing. Note that a higher score indicates a poorer level of functioning.

Figure 15: Comparison of WHODAS 2.0 scores between those with and those without joint pain (musculoskeletal conditions)

Table 49: Comparative summed WHODAS 2.0 scores

	Valid N	Median	Minimum	Maximum
Joint pain (musculoskeletal conditions)	854	23.5	12	54
No Joint pain (musculoskeletal conditions)	502	26.4	12	51

In addition, there was a significant, although very low, *positive* correlation between the EQ-5D-3L Index score and the WHODAS 2.0, ($r = 0.069$, $p = 0.010$). As a higher Index score indicates better health and a higher WHODAS 2.0 score should indicate poorer functioning, the WHODAS 2.0 did not demonstrate concurrent validity. The data entering process was revisited and it appeared as if the results had all been entered correctly.

The possibility was explored that the respondents were unable to differentiate between "mild " and "moderate" problems and between "severe" and "extreme" problems and we collapsed the items into a three-point instead of a five-point scale. The "collapsed" scoring system did not perform better. Those who had had a stroke still scored lower (better functioning), (Adj $Z=-3.34$, $p<o.001$), as did those who reported joint pain (musculoskeletal conditions) (Adj $Z= -3.64$, $p<0.001$). The concurrent validity was also not improved as evidenced by a lack of correlation between the EQ-5D-3L Index score and the WHODAS 2.0 ($r=0.040$, $p=0.136$).

It was concluded that the WHODAS 2.0 demonstrated no evidence of validity in this population and the results were not subjected to further statistical analysis.

6.9.9 Characteristics of those with three months of joint pain (musculoskeletal conditions)

In this section the nature of the joint pain of the respondents who had experienced joint pain within the previous three months will be discussed.

6.9.9.1 Medical management

This section refers to the second section of the questionnaire where questions were specifically posed to participants who indicated that they live with joint pain (musculoskeletal conditions). It is interesting to note that there is a discrepancy regarding those who indicated in the first section of the questionnaire that they had been diagnosed with joint pain (musculoskeletal conditions) and those who completed the second section of the questionnaire. The reason for this discrepancy is not clear.

Of the 854 respondents experiencing pain or stiffness, 299 (35%) reported that a formal diagnosis of joint disease had been made and 177 (21%) indicated that they had been diagnosed or have been told by someone that they have arthritis or another joint disease like rheumatism. None of the participants indicated that they were specifically diagnosed with OA. Of the 299 participants formally diagnosed with some type of joint disease, the diagnosis was primarily made at a clinic (86%) with 48% having been diagnosed by a doctor.

More than half (53%) of the 854 participants indicated that they used medication to relieve their joint pain of which 56% used over the counter medication and 40% used prescribed medication. Ointment was used by 5% of participants as an alternative method to relieve their pain.

6.9.9.2 Nature of joint pain

The majority of the 854 participants (63%) had been experiencing joint pain for over a year and the pain of 18% of participants had started three months ago. The same proportion of participants experienced severe joint pain during the previous seven days as during the last three months, while more participants (29%) had experienced very severe joint pain during the previous seven days than during the previous three months (22%). (Figure 16)

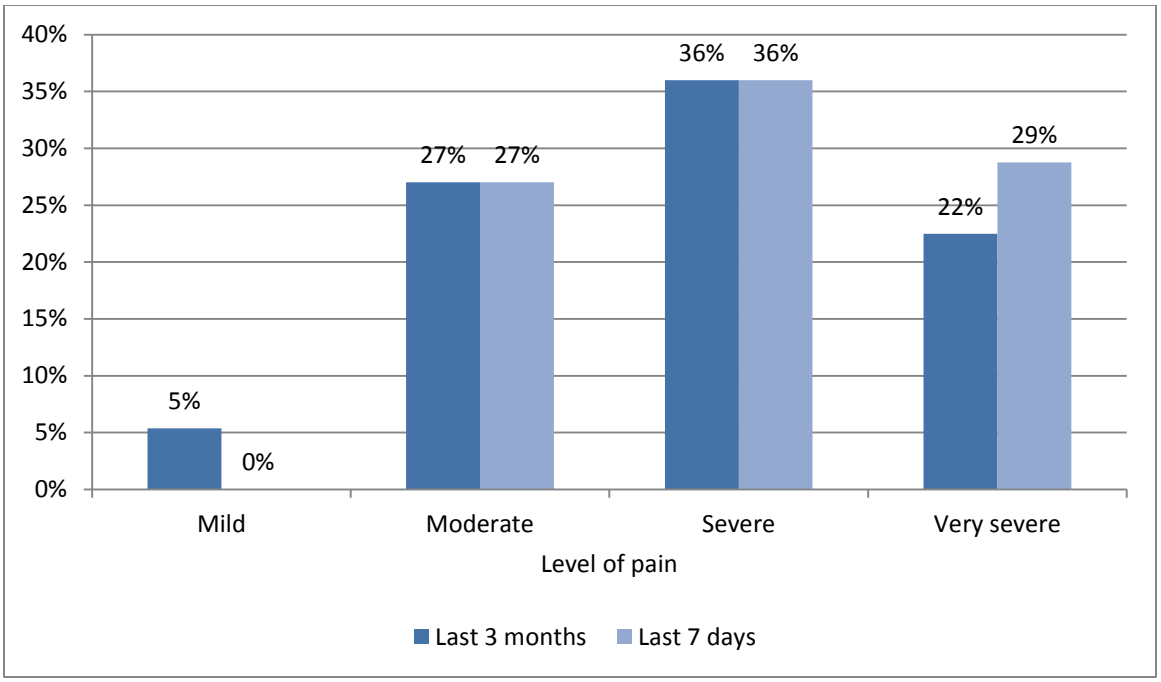


Figure 16: Joint pain intensity of participants reporting pain over the short and long term

(n=859)

Short- and long-term joint pain will now be generalised for the purpose of the study as simply joint pain. Eight hundred and fifty four participants reported recurrent joint pain and 43% reported that the joint pain had lasted a few days while 30% indicated that their recurring joint pain had lasted more than three months. The most intense joint pain was felt after activities (31%), followed by after resting or sleeping (29%). More than two thirds had experienced joint tightness/stiffness in the morning during the last year (71%) and in 50% of the cases that reported tightness/stiffness, the stiffness lasted more than 30 minutes. The majority of participants experiencing tightness/stiffness (53%) indicated that the tightness/stiffness had gone away after exercise or during movement of the joint.

Table 50: Time of day of the activity when joint pain of participants is most intense

Category	Valid N	Percent
After activity	266	31%
All the time	168	20%
Mornings	146	17%
Resting / Sleeping	250	29%
Walking a distance	2	0.2%
When cold	5	0.6%
Missing	22	3%

(n= 859)

6.9.10 Results summary

Based on the information above, the 'typical' respondent in the survey spoke Sesotho, was married, owned their own brick home and lived in a household with about five other people. They could read and write and had attended secondary school. As they were unable to find work, they were unemployed. They did not receive any benefit grants. They were visiting the clinic either to collect medication or to consult with a health professional. They had hypertension of various stages and almost half reported some or severe anxiety/depression and some or severe pain and discomfort. They were obese, but were not using any harmful substances.

The prevalence of joint pain was 62%, and 53% had joint pain in conjunction with either hypertension and/or diabetes mellitus type II. There was a weak association between hypertension and joint pain. Those who had joint pain (musculoskeletal conditions) had a BMI which was significantly higher than those without any joint pain.

Those with joint pain (musculoskeletal conditions) reported a poorer quality of life, both with regard to the EQ-5D-3L index score and the more global VAS score. The dimensions affected include mobility, usual activities, pain/discomfort and anxiety/depression.

For those who reported joint pain (musculoskeletal conditions), the joint pain had typically been present for over a year and was most intense after activity or after sleeping or resting. They had experienced

joint pain within the previous three months at severe to very severe levels and experienced joint stiffness in the mornings that diminished with activity. They used over the counter medications to manage their joint pain. The WHODAS 2 demonstrated a lack of construct validity and was not analysed in depth.

6.10 Discussion

This discussion will draw on the above summary and will explore whether the sample was representative of the target population by comparing it to the demographics of the population. The health conditions will be discussed, with particular reference to the interaction of co-morbidities. The prevalence of joint pain (musculoskeletal conditions) will be compared to that in the published literature and the nature and effect of joint pain (musculoskeletal conditions) on function and HRQOL will be discussed. Finally, the implications of the findings for the development of a context specific intervention will be presented.

6.10.1 Demographic and living conditions of participants

The sample of respondents was likely to be representative of the target population, with three quarters of those approached agreeing to take part. The final sample was 1376 and thus the target sample size of 1353 was achieved. The language of two thirds of the participants was Sesotho which is to be expected as the languages most spoken in the Free State are Sesotho (64.2%), Afrikaans (12.7%) and Isixhosa (7.5%) [560]. Similar to the respondents in the 2015 Mangaung statistics of the area and 2011 census, the majority of the participants were married and almost three quarters of the participants owned their own homes while the rest lived with either family or friends (528, 529). More than 80% of the participants indicated that they stayed in brick houses which included Reconstruction and Development Programme (RDP) houses (a government initiative for impoverished communities) [561]. The median number of residents per household was five and the number varied between 4-6 people. In terms of race, only three respondents did not fall within the ethnically Black population (26, 371). The majority of the participants (90%) had some level of education, which included primary, secondary or tertiary education. These findings are similar to the findings of Copley et al., in 2013 who found that

89% of the population were literate and could read and write while only 20.41% had obtained Grade 12 level of education. According to Woolard (2002) about 15% of adults in South Africa are illiterate [562] despite government policies stipulating that education is compulsory for every South African child between the ages of 7 and 15 years. The study of Copley et al., included both male and female participants over the age of 18 years attending a community clinic [326] and reported that 14% of the participants had full time employment while nearly half of the participants (49%) were unemployed. The results of the study are similar to the results of the present study. The unemployment rate in 2014 in South Africa is stated to be 25.5% at the time of the epidemiological survey, with the unemployment rate for women being slightly higher compared to that of their male counterparts [565]. The official unemployment rate of people in the Free State was given as 34.7% during this time [565].

Unfortunately, the percentage of unemployment stated did not distinguish between male and female unemployment and therefore, it is difficult to compare the unemployment rate of the participants with that of the rest of the Free State province. A likely explanation for the study participants' low income and high unemployment rate could be that services at the community clinic are free of charge and specifically cater for the low-income population, although more affluent patients also utilise services at the community clinic [26].

The situation reported in 1995 by Ardington and Lund (1995) appears to be the same, with the pension system in South Africa reaching rural areas, effectively targeting women in the community and keeping a number of households in South Africa out of poverty [561]. This was borne out by this study where 25% of all participants indicated that they received a grant or state pension. In South Africa people can apply for pension above the age of 60 for women and above the age of 65 for men [566]. As mentioned previously the median number of participants per household of the survey was five individuals, which would substantiate the statement made by Posel et al., (2006) regarding living arrangements of pensioners in South Africa especially in three-generation African households in rural areas.

It would thus appear that the sample was representative of the target population. With regards to socio-economic situation, the respondents were generally financially stressed but not destitute, with most receiving grants and living in permanent shared accommodation. Fewer than half were currently married. These findings imply that if the intervention were to be tailored to meet the needs of this group, it could be applied with confidence to other women attending the clinic with similar problems. In

addition, individuals with lower educational levels are less likely to have access to health education and more often act in ways that would harm their health, as they find it difficult to cover their basic every day needs they are unlikely to benefit from medical interventions (530) (531, 532). In contrast, this group of women did have access to income and permanent housing and would be more likely to actively engage in improving their health.

6.10.2 Health conditions and risk factors

The majority of the participants visited the clinic to collect medication (53%) or for a doctor's consultation (45%). The reasons for the visits by participants would therefore be in line with the purpose of the community clinic as described by Prinsloo et al., (2011) as being a "centre for follow-up of down-referrals of stabilised secondary patients" (43). Approximately 64% of the participants were diagnosed with hypertension, but there was a discrepancy of 3% between the frequency of hypertension as detected by the fieldworkers and the frequency of those reporting being diagnosed with hypertension. This discrepancy needs to be researched in the future; it is not clear if it was due to participants awaiting a first time diagnosis of hypertension (e.g. first clinic visit), or if the hypertension had not been diagnosed on previous clinic visits. About 13% were aware of being diabetic and had been diagnosed as such. This was slightly more than the 10.5% who tested positive with a non-fasting blood glucose level of more than 7.8 mmol/L, which is indicative of diabetes mellitus type II, and had not been diagnosed previously. The discrepancy in percentages could be attributed to the fact that the fieldworkers were taking blood glucose levels as participants were approached by the fieldworkers whilst waiting at the clinic for services and the time frames of the measurements could differ from the standardised testing procedures of the clinic. To be noted is that the fieldworkers were not able to diagnose conditions and that the participants received standard care at the clinic.

Although 60% of participants were classified as obese, very few participants indicated that they had been diagnosed with or that they were living with obesity. This high prevalence of obesity was not unexpected, in the light of the published literature. In June 2007 the prevalence of obesity in women attending the same community clinic, was reported to be 44.1%, but the mean age of the obese group was 30.6 years which is lower than the mean age of survey group of the present study (43). According to Health 24, South Africa has the highest rates of overweight and obesity in sub-Saharan Africa and

also ranks high on the world list of regions in the world for overweight and obese women (533). According to the same article nearly 30% of people worldwide are overweight or obese and 69.3% of South African women fall into this category, which is almost double the global average. An ObeCity Index was created by Discovery Vitality (a private medical scheme in South Africa) along with experts in the field of obesity to determine how healthy South Africans were. Discovery collected information about the health status and health habits of their members. The ObeCity Index revealed that Bloemfontein as a community has the least healthy weight status, has the lowest scores for fruit and vegetable intake and the highest consumption of salty foods and sugary drinks. Bloemfontein also ranked as the second lowest city for physical activity. The ObeCity Index ranking is scored on the relative weight status of members as well as associated risk factors. Bloemfontein was ranked lowest in three categories, weight status of members, food and beverage choices and finally psychological well-being and is ranked third in physical activity, rating the city first in the overall ObeCity Index and therefore making the city the unhealthiest city in South Africa (534, 535).

Of concern was the fact that no participant identified herself as obese. Cultural beliefs and perceptions in the black community may contribute to the obesity epidemic in South Africa. The conclusions of Puoane et al., (2005) that being overweight is associated with happiness, respect, health, wealth and being treated well, while being thin is stigmatised in black communities due to the belief that many thin people are HIV-positive (40, 43), may well apply to this population.

The implication for the design of the intervention is that a strong educational component should be included relating to the dangers and causes of obesity. It is evident from the literature that obese and overweight individuals appear to be in a chronic low grade inflammatory state which contributes to chronic pain, while the increased load on the joints and the spine due to the individual's weight is the most discussed link between obesity and pain in the literature. Altered body mechanics and postures often observed in obese individuals may also be involved in the link between obesity and pain (536). The BMI of those with joint pain (musculoskeletal conditions) was higher than those without joint pain (musculoskeletal conditions) and an exercise programme targeting weight loss would also need to be included. In addition, as exercise and physical activity are considered important management strategies in the primary and secondary prevention of chronic diseases including diabetes mellitus type II, hypertension and obesity, this would be an important component. Appropriate exercises would include

30 to 45 minutes of cardio-vascular exercises of moderate intensity, performed at least three to five days per week. The exercise programme could also include weight resistance modalities (294, 537, 538).

6.10.3 Prevalence of joint pain (musculoskeletal conditions) and co-morbidities

The prevalence of joint pain (musculoskeletal conditions) in non-consenters was 45% in the study, while the prevalence of consenters was 62.1%. Taking into consideration both the consenters, and the non-consenters the prevalence of joint pain (musculoskeletal conditions) for all women in the target population was 58.2% (Table 41). Therefore, the prevalence of joint pain (musculoskeletal conditions) in this sample was high, with nearly two out of three participants reporting pain. This is more than double that of the general population as reported in other studies. For example, the rates of joint pain range from 20-25% of the adult population in European Countries and Australia and 11 % of adults in Spain (3, 9, 217, 218). However these rates are not comparable as this population (middle-aged women attending community clinics) was purposively chosen because it was expected that they would exhibit a high prevalence of joint pain which was indeed the case.

The rate was also higher than in other South African studies, which indicated that 30-36% of women attending Primary Health Care Clinics had musculoskeletal conditions (30%) (539) or joint pain (36%)(32). In 2013 a study was conducted at a community clinic in Cape Town to determine the prevalence and impact of musculoskeletal conditions amongst people attending a community clinic. The prevalence was found to be 45.82% (31). A major difference between the present survey and the two studies undertaken in South Africa was that the population of the present study was only female, whilst the other two studies included both sexes. The ages of the participants also differed in that in the present study, the ages ranged from 40 to 64 years and the other two studies included all attendees to the health centres above the ages of 18. As previously mentioned, the current study specifically targeted those who were predicted to have a high prevalence of joint pain (musculoskeletal conditions), which is higher in women and increases with age (6, 14, 540, 541). The high reported prevalence in this sample supported the development of an intervention programme specifically targeted at older women.

It was postulated in the Introduction to this thesis that there might be a relationship between CDL, obesity and joint pain and a lack of physical activity. However, a statistical association between CDL and joint pain was not established and CDL were not associated with joint pain. Nevertheless, the BMI of those with joint pain was higher than that of those without joint pain.

As previously mentioned in Chapter 2, musculoskeletal pain in diabetes mellitus type II patients may be caused by various factors and only suggestions can be made regarding the underlying aetiology. The exact patho-physiology of these musculoskeletal conditions remains unanswered; however, advanced glycation end products that accumulate in the joints and connective tissue, micro-vascular abnormalities with damage to blood vessels and nerves, neuropathy or vasculopathy may have a synergistic effect on the increased incidence of musculoskeletal conditions in individuals living with diabetes mellitus type II (542-544).

It was surprising that no association was found between diabetes mellitus and joint pain. In a large scale population-based cross-sectional study in Norway, multivariate analysis indicated that chronic widespread musculoskeletal conditions were 1.6 times more likely to be found among subjects younger than 60 years of age with diabetes mellitus than those individuals without it. The authors raised the question whether diabetes mellitus type II in some way worsened musculoskeletal conditions or the other way around (251). Similarly, Molsted (2012) reported that individuals with diabetes mellitus type II had a significantly higher prevalence and increased risk of developing rheumatic disorders and experiencing musculoskeletal pain compared to a matched sample (age and gender) of the general population in the same geographical region in a Danish population (256, 545).

As previously mentioned in Chapter 2 one of the factors associated with musculoskeletal pain is obesity, and reduction in weight has been demonstrated to reduce the functional limitations related to OA of the knee by not only reducing the pain of the individual, but also improving mobility (6). The prevalence of chronic musculoskeletal conditions increases with Body Mass Index (BMI) with a peak among those individuals with a BMI of more than 30kg/m^2 (251, 256). In the present study 60% of the participants had a BMI of more than 30kg/m^2, had joint pain (musculoskeletal conditions) and their BMI was significantly higher, which supports the published findings.

The majority of respondents with joint pain (musculoskeletal conditions) reported co-morbidities, with over half having joint pain (musculoskeletal conditions) and/or hypertension and diabetes mellitus type II. It thus emerged that, whereas there was no evidence of a causative link between the conditions, it would make sense to include aspects of the management of obesity, hypertension and diabetes mellitus type II in the intervention programme.

6.10.4 Impact of joint pain (musculoskeletal conditions) on quality of life

The quality of life of the participants, as assessed using the EQ-5D-3L measurement instrument, indicated that the majority of participants without and with joint pain (musculoskeletal conditions) experienced no problems in mobility, self-care and usual activities, whereas problems in the pain/discomfort and anxiety/depression domains were far more frequent. This distribution of findings is commonly reported, with the prevalence of problems in the pain/discomfort and anxiety/depression domains being higher than in the community-based surveys in Zimbabwe (546), the United Kingdom (547) and Latin America (548), all of which reported few problems in the functional domains and a higher prevalence of moderate to severe problems in the other two. It is evident that many of the health problems in South Africa are socially and culturally rooted and compounded by poverty, crime and violence, especially for people in the lower income brackets. South Africa has a relatively high 12-month prevalence of anxiety and mood disorders when compared to several other high- and middle-income countries (549, 550). Therefore, it is not surprising that the anxiety/depression domain is higher. It is well recognised that anxiety/depression and pain/discomfort are interrelated and as mentioned previously, the anxiety/depression of South Africans are worse, then it is also not surprising that pain/discomfort is higher. Therefore, the interrelationship between anxiety/depression and pain/discomfort should be acknowledged in treatments rather than just treating one or the other. The approach in the management of individuals should consequently be according to the bio-psychosocial ICF model as discussed in Chapter 2 (551).

Pain on that day (as stipulated by the EQ-5D-3L questionnaire) was reported in nearly three quarters of the participants. Weir et al., (1996) looked into gender differences in psycho-social adjustment to chronic pain and found no differences between males and females in a heterogeneous sample, but they found that the predictors for psycho-social adjustment varied between the sexes. The female

participants adjusted to chronic pain primarily through cognitive factors such as the meaning they attributed to the pain they experienced, while social support was the strongest predictor of adjustment in the male participants (552). Thus the educational component of the intervention as well as goal-setting and self-efficacy were deemed to be important in the intervention to ensure that the participants understood the pain they experienced as well as the management of the pain.

The high number of those reporting some or severe anxiety/depression corroborates the high prevalence of self-reported depression which was not clinically diagnosed. It would appear that, although the proportion with severe or extreme problems was significantly greater in those with joint pain (musculoskeletal conditions), many of those attending the clinics are in need of support to manage their anxiety and depression. In 2008 Kagee found in the Western Cape, South Africa, that 45.9% of individuals living with hypertension and diabetes mellitus experienced clinically significant symptoms of depression (553) which substantiates the findings of the present study. It is interesting to note that results of a study by Herman et al., (2009) indicated that the lifetime prevalence for all mental disorders in the Free State was 37.5% and for anxiety 21.5% (549). In 2012 Peltzer et al., found that 19.4% of women attending an urban outpatient department in a Limpopo, hospital in South Africa experienced psychological distress which was associated with chronic disease, poor self-rated health status and pain (554). A research study conducted by Novy et al., (1996) on a heterogeneous chronic pain population found that there were no sex differences between the total depression scores of participants, but that certain depressive symptoms were more common amongst females, especially fatigue and body image distortion (555). In addition, one in five respondents with joint pain (musculoskeletal conditions) reported feeling severe anxiety/depression, and a comprehensive intervention programme for this group should address this aspect of HRQOL. The EQ-5D-3L Index did discriminate between those with and those without joint pain (musculoskeletal conditions) and the Index emerged as a good candidate outcome measure for the intervention study.

The median of the measure of global health, the VAS score for those without joint pain (musculoskeletal conditions) was 80 and those with joint pain (musculoskeletal conditions) 60 out of a possible 100. Those without joint pain (musculoskeletal conditions)are similar to the mean score on the Visual Analogue Scale (VAS) reported in a community-based Zimbabwean sample (mean 79.8), a United Kingdom sample (mean 82.5) (546) and a Cape Town sample of Isixhosa speaking respondents (80). Those with joint pain (musculoskeletal conditions) had a mean score of 64.5. This is not surprising as this

was a facility based sample, similar to those receiving treatment for HIV in a Cape Town study which recorded a mean VAS of 62 prior to the initiation of anti-retroviral therapy, and 70 after four weeks on treatment (556). The participants of this study perceived their health to be worse than that of other groups, and it seems as if CDL resulted in a decrease and the presence of joint pain (musculoskeletal conditions) further decreased the perceived HRQOL.

The results of the EQ-5D-3L indicated that an effective intervention programme is needed to address the impact of joint pain (musculoskeletal conditions) on performance of day-to-day activities, pain perception and on mood.

6.10.5 Impact of joint pain (musculoskeletal conditions) on functioning

The WHODAS 2.0 has previously displayed good clinimetric properties, thereby supporting the use of the questionnaire as an international instrument for measuring disability based on the ICT model (458, 461). Participants experienced mild problems with washing, getting dressed, managing unknown people and doing household activities. The functional limitation with the highest proportion of participants experiencing extreme problems was community activities, while moderate or severe problems were emotions being affected. The discriminate validity of the questionnaire was found to be poor in the present study and the above results cannot be accepted with confidence.

However, there was some agreement between the questionnaires, in that emotion emerged as the domain with the highest number of problems, similar to the EQ-5D-3L domain of anxiety/depression. In contrast, the usual activities domain of the EQ-5D-3L indicated that those with joint pain (musculoskeletal conditions) had the most problems, whereas the WHODAS 2 responses showed that those without joint pain (musculoskeletal conditions) had more problems.

It is difficult to explain why this instrument does not seem to be a valid instrument to describe the activity limitations and participation restrictions with this study. It had performed well in similar studies in South Africa, when the isiXhosa version had been utilised It was subjected to a rigorous translation process, as described in Chapter 5 by the Linguistic Department of the University of the Free State and had performed well in other community-based surveys in South Africa (466). The translation was

rechecked to ensure that no inversion of levels had inadvertently taken place. Data entry was rechecked. Collapsing of the different levels (e.g. mild with moderate and severe with extreme or other combinations) did not improve the performance. The counterintuitive results are therefore surprising and further research should be undertaken to identify whether the translation was inadequate (although done rigorously), or the choice of the five Likert scale responses was too demanding for older rural women with relatively low levels of education. According to Dowse (2016), it is troublesome that health-literacy in developing countries is under-researched despite the likelihood of inadequate health literacy being prevalent in South Africa (557). It is well known to researchers that low literacy and culturally diverse populations struggle with response formats that require more than just a concrete "yes" or "no" answer, such as the Likert scale, which is unfamiliar and poorly understood by these populations. The concept of choosing a number on a scale proves to be too abstract and choices are often made randomly (557, 558).

6.10.6 Nature of joint pain

A common symptom of osteoarthritis is morning stiffness lasting for less than 30 minutes for knee OA and less than 60 minutes for hip OA (559) and difficulty with moving when experienced in the lower limbs (560). Specific features of OA include pain during movement, pain during the night when sleeping, or constant pain, stiffness and a limited range of movement as well as impairment in everyday activities (561). Although no medical tests or X-rays were taken, nearly two thirds of the participants demonstrated symptoms consistent with a diagnosis of OA or at least early degeneration if not the stabilisation phase of OA. During the initial phases of OA there is pain due to a chronic inflammatory responses in the synovium, and during the last phase of OA, the stabilisation phase, the individual complains of pain as well as stiffness as the compensatory bone overgrowth that occurs attempts to stabilise the joint (562).

The study conducted in Cape Town by Parker et al., (2010) in a sample of middle-aged women attending a primary health care clinic, reported that those respondents reporting joint pain experienced pain and stiffness (80%) most commonly after awakening or a long period of rest. Most of the participants (85%) indicated that they experienced improvement of their symptoms with movement or exercise. The stiffness reported by the participants (51%) in the Parker et al., study lasted for more than 30 minutes, very similar to the 50% in the present survey (32). Similarly, Copley et al., (2013) reported 84% of their

participants experienced stiffness in their joints in the morning, which lasted for more than 30 minutes (31). When analysing the findings of the present survey and the findings of Parker et al., (2010) and Copley et al., (2013) it seems that the differences in the findings could be attributed to the different populations of the studies and more specifically whether males were included. In a longitudinal study reporting pain from middle to old age by Brattberg et al., (1997) the researchers found that women reported musculoskeletal pain in more locations and more often than males (563). The statement of Brattberg et al., (1997) is supported by various epidemiological surveys and research which demonstrated that females report more pain-related symptoms that males in the general population and could therefore not be attributed to the greater tendency among females to seek medical attention for pain (564-569).

After reviewing the available literature it thus appears that females have an increased risk of experiencing pain-related symptoms and that women may also differ in their response and adjustment to pain. In both clinical and experimental pain, several mechanisms have been proposed to explain the possible sex differences of experiencing pain, and as characterised as biological versus psychosocial mechanisms (570-574). It is, however, essential to take note of the artificial nature of the distinction due to the fact that the classification of biological and psychosocial mechanisms, are based on the level of analysis of the studies and not the actual mechanisms. A commonly cited "psychosocial" mechanism in pain perception is that the female role in society permits a female to acknowledge pain, while society discourages the expression of pain in males. Despite the appeal of this explanation, there is little evidence to support this statement, and the evidence found was primarily in the context of experimental rather than clinical pain (570-573).

At a biological level of analysis, environmental and biological factors that influence perceptual and behavioural responses associated with female roles also influence nociceptive processing of pain. These factors could include ovarian hormones, endogenous pain regulatory systems and expectancies, all of which have been established as altering the neurophysiology of pain. It is therefore important when considering the possible mechanisms underlying male-female differences in pain responses that psychosocial and biological explanations may refer to the same underlying processes, as mentioned earlier (570-574). It is also possible that cognitive-affective factors such as pain coping strategies of the individual, and emotional distress experienced at the time as well as pain-related expectancies may contribute to the sex differences in pain. These psychological factors have been noted in both

experimental as well as clinical pain (570-574). An example of psychological factors that play a role in pain perception is depression and anxiety. Both have been found to be more prevalent amongst females and depression is associated with increased pain and other physical symptoms (565, 575, 576).

In addition to affective variables, cognitive factors including coping and self-efficacy may also be determinants of differences in pain perception by males and females. Catastrophising has been associated with females and is a predictor of poorer adjustment to clinical pain, whereas higher levels of self-efficacy to decrease or control pain have been associated with better adjustment to chronic pain in females, but not in males (570, 571, 577-579).

Only 35% of the participants in the survey experiencing either pain or stiffness had been medically diagnosed with some type of joint disease and only 21% had been specifically diagnosed with arthritis. When the participants were asked what diagnosis was given to them, they used the colloquial term for arthritis and joint pain, “rumatiki”. None of the participants were diagnosed with RA. In the study done by Parker et al., (2010), only 15% of the participants had previously been diagnosed and the majority (60%) were diagnosed with joint pathology on examination by a physiotherapist. The common diagnosis was arthritis with a rate of 76% (32). In the Copley et al., study (2013) 46% of the participants were diagnosed with arthritis (31). It is clear that joint pathology was prevalent in the current study sample and that in the majority of cases it had not been diagnosed or treated by the medical personnel at the clinic which was expected, but this should be addressed as soon as possible as this has an impact on the quality of life of individuals living with MSC.

More than half (53%) of the participants indicated that they used medication to relieve their joint pain (musculoskeletal conditions). The medication mentioned by the patients most frequently was panado-co tablets. Each tablet contains paracetamol 500 mg, codeine phosphate 8 mg and 0.1% m/m potassium sorbate as preservative and is sugar free. In some instance the doctor prescribed anti-inflammatory medicine and specifically Brufen. No participants indicated that they were ever told by a doctor or sister/nurse to follow an exercise program, nor did anyone indicate that they received any type of treatment other than medication, for pain. Therefore the aim of the intervention should be to relieve the joint pain (musculoskeletal conditions) experienced by participants and improve their quality of life. In the long run an intervention also has the potential to reduce the financial burden placed on individuals to buy over the counter medication in an attempt to relieve their joint pain.

6.10.7 Strengths and limitations of the study

The STROBE statement checklist (580) of items that should be addressed during observational studies will be discussed to validate the reporting of the epidemiological study.

Table 51: Checklist of items discussed and included in the present study

Included in the present study
A facility-based survey using a descriptive observational cross-sectional design was identified as being the most appropriate design for the study.
Scientific background and rationale for the study are presented.
Aims and objectives for the study are specified.
Setting, location, relevant dates including the period of recruitment and data collection are discussed.
Eligibility criteria, source and methods of selection of participants are discussed.
Possible variables and confounders are discussed.
Details of the methods of measurement are discussed in detail.
Calculation of the study size is discussed.
Statistical methods used, methods used to examine subgroups and interactions and missing data are described in detail.
The results of the study regarding reasons for non-participation as well as a flow diagram of participation are provided.
Detailed descriptive data is provided regarding the characteristics of the study participants as well as the number of participants with missing data.
Outcome data and main results of the study are provided.
A comprehensive discussion is presented including the summary of the key results, the limitations of the study, and the overall interpretation of the results.

It was surprising that many of the more common conditions that were to be expected in this specific population were not stated when asked whether they suffered from heart conditions etc during the last three months. The main reason why participants visited the primary health care clinic was to either collect medication or consult with a doctor for health related reasons, as this is a general clinic. The more specialised clinics are run from the National District Hospital and the Tertiary Hospital in the vicinity, and patient attendance at these clinics rather than the local clinic might account for the lack of reporting of these conditions.

The results of the study are generalisable regarding the prevalence of joint pain (musculoskeletal conditions) in middle-aged women attending a community clinic. However, these rates are not comparable to the general population because middle-aged women attending community clinics were purposively chosen as it was expected that they would exhibit a high prevalence of joint pain (musculoskeletal conditions), which was indeed the case. When comparing the results of the epidemiological survey with those of the intervention study regarding demographic information as well as health-related information it is clear that the groups were similar. Sources of funding and role of the funders are mentioned under acknowledgements. The full STROBE statement checklist is attached as Appendix 27.

The use of structured interviews might have resulted in respondent bias and this is acknowledged as a weakness of the study. It was hoped that rigorous training and monitoring of the research assistants would minimise this affect.

The disappointing performance of the WHODAS 2, limited the information gathered with regard to functional restrictions. However, the EQ-5D-3L did give some guidance as to the areas in which participants experienced the greatest number of problems.

The lack of information relating to the levels of physical activity is acknowledged as a weakness in the study. However, those with joint pain (musculoskeletal conditions) did report more problems with mobility and about 30% of the entire sample reported moderate to severe difficulty in walking long distances on the WHODAS 2. So it would appear that physical activity is generally curtailed (although not necessarily only in the group with joint pain (musculoskeletal conditions) and it would have been useful to have an objective measure of the extent of this.

6.10.8 Conclusion

The results of the epidemiological survey were used in conjunction with the results of the systematic reviews to develop the six-week intervention programme and to modify and adapt existing workbooks. The 'typical' participant in the survey spoke Sesotho, was married, owned their own brick home and lived in a household with about five other people. Therefore, the workbook was developed in English

and translated into Sesotho to make it more user friendly for the participants as the workbook contained sections on self-efficacy and goal setting that the participants in the intervention phase of the study had to complete during the six-week intervention programme. It was also decided by the researcher to train and educate a fourth year Sesotho speaking physiotherapy student as a research assistant to facilitate the educational session during the intervention and to assist with the explanations during the exercise sessions if deemed necessary.

The ages ranged from 40 to 64 years with the median age of 52 years of the present study's population. During the development of the exercise component of the intervention programme, the appropriateness of the exercises for the age range of the participants was considered to ensure the safety of the participants during participation without compromising the effectiveness of the exercises. Participants could read and write and had some education which included primary, secondary or tertiary education. Therefore it was decided to compile the workbook on the level of Grade 4 (a scholar in their fourth year of primary school at approximately 10 years of age) to ensure that participants would be able to understand the health-related information in the workbook and that they would be able to complete the goal setting tasks set out in the workbook to increase self-efficacy. According to the Flesch Kincaid grade level of readability in Microsoft Word, the readability of the workbook was a Grade 2.5.

Most of the participants were unable to find work and they did not receive any benefit grants. They were visiting the clinic either to collect medication or to consult with a health professional. They had hypertension in various stages; some also had diabetes mellitus type II, and were depressed. They regarded their general health as being fair to poor. They were obese but did not take any harmful substances. Most of the respondents were unsure of what medication they were taking. The majority of the respondents mentioned having joint pain either short or long term and in conjunction with the joint pain (musculoskeletal condition) they either had hypertension and/or diabetes mellitus type II. The respondents with joint pain (musculoskeletal conditions) were less likely to have diabetes mellitus type II, but there was no association between hypertension and joint pain (musculoskeletal conditions). Those who had joint pain (musculoskeletal conditions) had a BMI which was significantly higher than those without joint pain (musculoskeletal conditions).

The exercises included in the intervention were selected after taking into consideration the appropriateness of the exercises for individuals with hypertension, diabetes mellitus type II, joint pain

(musculoskeletal conditions) and being obese. The safety of the exercises was also considered by the researcher for the target population before including the exercises in the programme. The workbook was designed in accordance with the health conditions of the survey participants and therefore had to include education regarding hypertension, diabetes mellitus type II, being overweight and joint pain (musculoskeletal conditions).

To exclude participants with an increased risk attached to participating in exercise during the intervention phase (as a number of participants had Stage II and Stage III hypertension), it was decided that all participants would be screened and a physical examination performed by a qualified medical practitioner with a special interest in Community Health before enrolment in the intervention programme. A trained ER 24 paramedic was also approached by the researcher to be present during each intervention sessions for any medical emergencies as the targeted group could be deemed to be a high risk group.

Those with joint pain (musculoskeletal conditions) reported a poorer quality of life, both with regard to the EQ-5D-3L index score and the more global VAS score. The dimensions affected included mobility, usual activities, pain/discomfort and anxiety/depression. With regard to the functional impact of the joint pain (musculoskeletal conditions), those with joint pain (musculoskeletal conditions) experienced a mild effect on participation such as family life, work and social life and a moderate effect on their financial position. They had had to stop working or alter their employment due to their joint pain (musculoskeletal conditions). They experienced fatigue and depression. They reported significantly more difficulty with concentration, walking long distances, washing and dressing and interacting with unknown people and friends than those without joint pain (musculoskeletal conditions). If possible, functional activities for strengthening and cardio-vascular exercise would be considered by the researcher for inclusion in the exercise component of the intervention to address the functional impact the joint pain (musculoskeletal conditions) has had on the participants' qualify of life.

It is accordingly clear from the results of the epidemiological sub-study and the epidemiological transition that is rapidly taking place in South Africa that primary health care systems should be developing an approach for the effective management and identification of CDL and MSC and should respond effectively to specific needs of communities and individuals alike. There is a definite need for improvement in services at the community health care clinics in the area, specifically to be able to

screen and identify accurately chronic health conditions within middle-aged women attending the clinics. Based on the above results there are many disadvantaged middle-aged women in the community with MSC and CDL and it is time for physiotherapists to participate actively in the development of appropriate methods of intervening at community level. Specifically, physiotherapists in primary health care clinics can address the negative impact of MSC and CDL on functioning and quality of life of individuals living with the disease. It is imperative that research should be conducted on individuals living with MSC and CDL in the community for the optimal planning of quality primary health care systems that need to address the growing health burden of CDL, especially to determine the risk factors of health problems, as well as the distribution of health problems in South Africa.

7 MODIFYING AND ADAPTING EXISTING PROGRAMMES INTO AN INTERVENTION PROGRAMME

7.1 Introduction

Based on the information reported in the literature which consistently reported that middle-aged women are the most likely to experience joint pain (musculoskeletal conditions) and that many experience functional limitations, an intervention was developed for this specific population. The aim of the intervention was to attempt to enhance self-management and increase physical activity for individuals living with joint pain (MSC), but to be mindful of common co-morbidities more specifically hypertension, diabetes mellitus type II and obesity. The programme was designed to educate, empower, maximise functional status and improve the quality of life of the women.

The purpose of this chapter is to describe the intervention programme that was developed and to justify and discuss the choices made regarding the structure, frequency and duration of the intervention, the length of the programme and also the content of each educational session.

7.2 Description of the intervention

The six-week intervention programme was developed utilising physical exercise in group format, health education, facilitating the development of self-management, problem-solving skills, decision-making skills and maintaining a balanced lifestyle utilising a workbook that was adapted and modified from previous workbooks successfully used in studies conducted in South Africa and elsewhere (see 7.2.6). The workbook and health education were developed taking into account adult learning principles. Dietary information as well as practical considerations and safety aspects were also considered during development. The justification for including each aspect of the intervention will be discussed in the following sections.

7.2.1 Specific population

The intervention was targeted at middle-aged women, aged 40 to 64 years with joint pain (musculoskeletal conditions) and co-morbidities. This population was targeted as the survey indicated the majority of women with joint pain (musculoskeletal conditions) in the survey were in this group and had at least one co-morbid condition, either hypertension, DM II or were obese. In addition, this group was chosen as they reported a worse HRQOL and more functional problems in the Anxiety/Depression and Pain/Discomfort domains. Finally, they regarded their general health as fair to poor.

7.2.2 Length of time of the intervention

Based on the published literature, the planned intervention was to be six weeks long. The literature included intervention programmes conducted in clothing/textile manufacturing companies in South Africa (22), on women with fibromyalgia syndrome (23); on patients with knee pain (397); women living with HIV/AIDS and experiencing pain in South Africa (364); women living with DM II (581, 582); individuals living with hypertension (583-585), and on chronic disease self-management programmes as well as chronic pain self-management programmes (338, 490, 491, 586-588). In the programmes reviewed, a time period of six weeks was used as this is regarded as the minimum time required to effect a change in behaviour while also being a period of time which is not regarded as excessively long by patients (589). In this time period, improvement was also demonstrated in the following aspects: health-related behaviours, self-efficacy, health-related quality of life and health status of individuals; large improvements in physical function; improvement not only in cardiovascular fitness but also flexibility; reduced pain severity and pain interference; better short- and long term glycaemic outcomes, (583) and decreases in blood pressure (583, 585).

7.2.3 Frequency and duration of the intervention

The frequency of once a week and the duration of two hour sessions (one hour education and one hour supervised exercises) were also based on the above literature (22, 23, 364, 583-585, 590-593). According to ACSM's guidelines, exercise training sessions should be approximately 60 minutes, but

could start with a shorter duration and then be increased by five to 10 minutes per session every one to two weeks over the first four to six weeks (594) to achieve health benefits including cardio-vascular fitness.

7.2.4 Type of intervention

The planned intervention was to be delivered in group format. The group approach has many advantages including learning from each other, sharing of goals and group members supporting each other, through interaction and feedback. The learning experience is enhanced in a safe and non-threatening environment which is enhanced through sharing experiences and challenges (333, 595).

It is generally recommended that a group size should be limited to a maximum of 12 people to ensure that a relationship between the group leader/physiotherapist and the participants can be established and to facilitate discussion during the educational sessions (428, 595). Due to the sample size calculation it was anticipated that the group would consist of more than 12 participants which would make it challenging to manage the interaction between the group members and the research assistant presenting the programme. Increasing the number of sessions was not feasible given the limited availability of the venue. It was therefore decided that two more research assistants in addition to the researcher would be on hand to assist with the facilitation of the exercises as well as the educational session if deemed necessary.

7.2.5 Importance of adult learning

An important factor that was considered during the adaptation and development of the workbook and the intervention was adult learning. An adult learner is seen as a learner who carries “adult responsibilities” which are translated through their family, community and financial commitments and who brings complex life experiences to the learning environment (596).

In adult learning there are specific basic principles that need to be followed in order to achieve the desired goals in this study of achieving increased self-efficacy regarding chronic conditions of lifestyle. According to Knowles, Holton, and Swanson (1998) as cited by Fidishun (2005), adult learning should be autonomous and self-directed (597). In the standard pedagogical model the students may simply learn what they are told, but adult learners need to know the reason why they are learning something and how the knowledge would benefit them (597).

This principle of self-directed adult learning would be achieved in the intervention programme by actively involving the participant in the learning process. The research assistant would serve as facilitator in order to obtain the participants' perspectives on the specific topics covered in the workbook and to guide the participants in gaining their own knowledge rather than supplying them with facts. Adult learners are viewed as goal-orientated and relevancy oriented. The goal setting sheets included in the workbook would also ensure that this goal would be achieved by the end of the six weeks and the research assistant would ask participants regarding their goal setting during follow-up educational sessions. Therefore, the aim of the researcher was to ensure that the education sessions and the workbook were organised in specific topics/chapters with specific goals. The goals and objectives would be made clear early in the education session to ensure that the goal-orientated component of adult learning was addressed as well as the relevance.

Adults become ready to learn when they experience a need to learn something in order to cope better with real-life tasks or problems (598). Therefore, one of the most important aspects of adult learning is that of practicality. All educational sessions of the intervention would aim to address aspects that would be useful to the participants in their daily lives. Respect is also seen as one of the key aspects of adult learning and, in order to achieve the objective, a female research assistant fluent in Sesotho was selected to be trained to present and facilitate the educational sessions of the intervention programme. The student would be familiar with the culture of the participants, due to her upbringing and own culture, and could therefore show the necessary respect for the wealth of life experience that the participants brought to the sessions; an essential part of adult learning (599).

Motivation is also seen as a key aspect of adult learning (599) and therefore it was made clear to all the research assistants involved in the intervention not only to motivate and encourage participants as a group, but also to motivate and assist individuals if deemed necessary. It was also planned by the

researcher that participants would receive something to drink and a healthy snack between the exercise and education session which would also serve as motivation as the participants would experience being cared for.

Three other critical elements of learning that would be addressed during the educational sessions and the workbook were reinforcement, retention and transference. Reinforcement forms an integral part of the learning process, and according to the literature, it is the facilitator's responsibility to encourage the correct mode of behaviour and performance in the adult learner (599). Thus participants in both the intervention and control group would be "rewarded" with a T-shirt with the logo "Exercise is Medicine", indicating their commitment and dedication to the research study, to ensure positive reinforcement.

Participants also needed to retain the information they received during the educational sessions. The amount of retention is directly affected by the degree of original learning. Simply stated this means that if the participant did not learn the material well in the beginning, she will not retain the information in the long run (599). It was decided that the research assistant would pose specific questions to the participants during the follow-up sessions to reinforce the previous week's information and to ensure some retention of information by the participants (599). It was made clear to the student that this should be done in a non-threatening manner so as not to discourage further participation.

The last aspect that needed to be addressed was transference. Positive transference would mean that the participants would use the information and behavioural changes taught in their daily lives. This would be achieved by giving participants time before the next educational session to reflect upon their exercise diary and their goal setting. According to Lieb (1991) transference would only occur with association, similarity, degree of original learning and critical attributing elements (599).

In summary, the modern concept of competence does not only consist of relevant knowledge and skills, but also of a range of personal qualities of the individual and the ability to perform both flexibility and adequately in known and unknown situations (600). Learning includes two different processes: the first being the external interaction between the participant and her cultural, social and environmental setting and the internal psychological process of acquisition of knew knowledge and elaboration of previous knowledge. The second process is that all learning includes three dimensions, a cognitive dimension of

knowledge and skills, the emotional dimension of feelings and motivation and lastly, the social dimension of communication and cooperation (600).

7.2.6 Workbook

A workbook titled "Balanced lifestyle" (Appendix 28) was adapted and modified from a workbook titled "Positive Living"[5] developed by Dr R Parker^{PhD}, based on chronic pain educational material and also on "Living with Osteoarthritis: patient workbook "[6] developed by Dr Romy Parker, Melissa Saw and Tina Kruger-Jenkins (601) which was found to be appropriate in a similar age group of participants living with a chronic disease; and on the findings of the survey. Both the workbooks aimed to facilitate the development of self-management, problem solving skills, decision-making skills and finding and utilising resources to assist with managing the chronic disease (586). Both the workbooks included sections on goal setting, problem solving tasks and included an exercise diary to facilitate skills acquisition by the participants (586). In the adapted and developed workbook "Balanced lifestyle", educational topics were more specific to the population identified in the survey, which included middle-aged women living with hypertension, diabetes mellitus type II, obesity and joint pain (musculoskeletal conditions) (Table 52Table 52). The focus on joint pain (musculoskeletal conditions) was mainstreamed throughout the programme and was included in the first session. However it was addressed during week 1 as the self-management of musculoskeletal conditions. The intention was to provide a holistic approach to the management of the co-morbid conditions listed, and therefore the chronic diseases were also included in the workbook.

[5] http://open.uct.ac.za/handle/11427/1004
[6] http://open.uct.ac.za/handle/11427/12697

Table 52: Topics of the "Balanced Lifestyle" workbook

Topic for the Week	Content
Week 1: Self-management	• What is high blood pressure (hypertension) • What is diabetes mellitus type II (sugar) • Being overweight • Musculoskeletal conditions (joint pain) • Self-management
Week 2: Exercise	• Exercises • Types of exercises • Steps to success with exercise • An exercise routine
Week 3: Managing common symptoms of musculoskeletal conditions.	• Symptom management • Action charts for common symptoms o Pain o Stiffness o Swelling o Difficulty doing activities o Pacing and activity o Tiredness
Week 4: Stress Management	• What is stress? • Managing stress • Sleep • Communication with your health carer
Week 5: Eating Well	• Balanced nutrition • Portion sizes • Losing weight
Week 6: Continuing as a successful self-manager	• Action planning for the future • Reflection on changes

7.2.7 Health education

The topics of the workbook as indicated in Table 52 were covered in the weekly education sessions. The health education information was written at the level of Grade 4 (a scholar in their fourth year of primary school at approximately 10 years of age) as 36% of participants in the survey had attended primary school and 50% secondary school. This was done to ensure that the health education information would be understood by all the participants of the survey.

The need for dietary information was emphasised after the results of the epidemiological survey indicated that 81% of the participants were classified as being overweight or obese. The BMI of those individuals with joint pain (musculoskeletal conditions) was 1.1 times higher than those without joint pain (musculoskeletal conditions), but both groups were still classified as being obese. It was therefore clear that dietary information should focus not only on weight loss, but also on healthy food options and portion sizes according to food-based dietary guidelines specifically for South African populations. The "Eating Well" chapter was compiled in collaboration with the Department of Dietetics and Human Nutrition at the University of the Free State. The dietician compiled the chapter according to the specific guidelines suitable for women living with hypertension, DM II and obesity, utilising the revised food-based dietary guidelines for South Africa (602). Specific cultural foods were also included in the workbook to ensure that the foods listed were culturally acceptable to the participants.

The health education information in the workbook was compiled in English as the source language and then translated into Sesotho as the target language to ensure better understanding of the information. The option would be given to each participant to indicate her language preference when given the workbooks with the health education information. As previously mentioned, a research assistant who was fluent in both Sesotho and English was identified and trained by the researcher as a research assistant to lead the intervention programme. Due to the student's training as a physiotherapist, she would also have the necessary theoretical training to be able to convey the health education material of the intervention to the participants.

The researcher also explored the readability of the workbook to ensure that the information would reach the target audience. According to Calderon et al., (2006) readability is the semantic and syntactic characteristics of the written word. Readability can be determined by using readability formulas which

provide and can indicate the skills needed to decipher and understand the written text. (603) Although readability formulas are regarded as an objective measure of language complexity, the formulas at the same time have faced criticism among researchers as they are only based on two variables, the first one being word length and the second one sentence length, which may not be clear predictors of language difficulty, especially in adult populations. (604)

The Flesch Reading Ease formula is used to determine the reading difficulty of written material for adults and has been incorporated into the Microsoft Word software. Rather than utilising the Flesch Reading Grade level, the Flesch Reading Ease scores range from 0 – 100, with the lower scored indicating more difficult reading material (605). The Flesch Reading Ease Score for the workbook was calculated as 76.3, which according to the range of scores is not too difficult to read. The most important consideration for the present study is that the workbook was translated into Sesotho and therefore the Flesch Reading Ease formula which only calculates the reading difficulty in English is only an indicator and not a predictor of the difficulty level of the reading material of this study.

7.2.8 Self-efficacy and self-management

Self-efficacy is a construct derived from the social cognitive theory, a theory involving a triadic reciprocal causation model in which behaviour, understanding and the environment all influence each other in a dynamic fashion (606). The social cognitive theory includes motivational and self-regulatory mechanisms, which is more comprehensive than social learning and/or the behavioural approach to human action on which the theory is built. More importantly social cognitive learning is viewed as the acquisition of knowledge through cognitive processes of information with the "social" part acknowledging the environmental origin of human thoughts and action; whereas the "cognitive" section recognizes the contribution and influence of the cognitive processes to human motivation and action. The social cognitive theory explains the nature of the bidirectional reciprocal influences through five basic human capabilities including symbolizing, forethought, vicarious learning, self-regulation and self-reflection. According to the social cognitive theory almost all forms of learning can occur vicariously by observing the behaviour of others and the consequences of their behaviour. This is especially true in group format interventions. The acquisition of knowledge vicariously is critical for both the learning (in this instance the participant) and human performance (607).

Self-efficacy derives from four sources: performance accomplishment, vicarious experience, verbal persuasion and physiological state. Performance accomplishment is the most important source of efficacy information as this is based on personal mastery experience. Vicarious experience is obtained through observation of others successful or unsuccessful performances and may account for a major part of learning throughout life, especially during adult learning (608). Vicarious experience is therefore an important part of the acquisition and change of human behaviour, but the nature of the cognitive processes involved in vicarious learning however remains obscure (609). Verbal persuasion is frequently used in health education, while it is less powerful than performance accomplishment and vicarious experience. Physiological states, particularly anxiety may influence the individual correctly or not that she is able to perform or maintain a given action or change (608).

Self-efficacy is an individual's belief in their ability to succeed in different situations (485) and people with high levels of self-efficacy believe themselves able to cope with their illness both in managing its treatment and in coping with symptoms. Interventions focussing on changing self-efficacy beliefs have been reported to improve disease outcome by up to 30%, decrease number of symptoms, improve symptom management and reduce cost of medical management in patients with arthritis and other chronic conditions (334, 610, 611).

Bandura (1977) proposed a link between a person's beliefs about her ability to perform a given behaviour or task and her subsequent performance of that behaviour (334). The researcher also stated that efficacy expectations determine how much effort people will use and for how long they will persist in the face of obstacles and tend to avoid certain experiences. The researcher also stated that efficacy expectations determine how much effort people will use and for how long they will persist in the face of obstacles and tend to avoid certain experiences (612). Self-efficacy is a dynamic construct with the efficacy judgement changing over time as new information and experiences are acquired by the individual (606). In the clinical context, a patient's self-efficacy expectancies could be enhanced if the individual is more likely to engage in activities previously avoided due to fear (440).

Self-efficacy of individuals is of essence especially in studies utilizing group format interventions, not because of respect for individualism, but because a strong sense of self-efficacy is vital for success regardless whether it is achieved individually or by group members putting their personal capabilities to

best use. A committed and loyal group creates an environment where the individual feels obligated to do their part as the group pursuits their aim. In the group the members are respected for their personal contributions to group accomplishments (613). Self-efficacy is therefore an important motivational construct which influences an individual's choices, goals, efforts, emotional reactions, coping and persisting at a task. Self-efficacy changes as a result of learning, experience and feedback and is therefore an important motivational construct which influences an individual's choices, goals, efforts, emotional reactions, coping and persisting at a task (606). Multiple factors affect self-efficacy and it may be that simply meeting in a supportive group environment results in the changes observed in health education programmes rather than the content or method of delivery of the course itself. A change in self-efficacy beliefs is associated with in an increase in self-management ability (334).

Individuals living with a chronic disease have to make day-to-day decisions about to self-manage their diseases and their lives and lifestyle habits can have a major impact on the quality of their life.(614). Approaches to self-management vary, but the majority of self- management interventions are usually led by a health care professional where the participants are affected by the same condition and the intervention is delivered in a group setting (426, 494, 615).

One of the key aspects of self-management is empowering the patient in choosing meaningful and realistic goals, and the process is designed to facilitate self-directed behavioural change (616). Paulo Freire's work accurately describes empowerment as both a process and an outcome (616). The process is when the purpose of the intervention and education is aimed at increasing the patient's ability to think critically and act autonomously. The outcome is when the patient experiences an enhanced sense of self-efficacy as a result of the process. The fundamental principles of empowerment include the fact that the patient has to be involved and provide almost all of his/her own chronic condition care; the patient's self-management decisions during their daily life have the greatest impact on his/her health and well-being; the patient has to remain in control of the self-management of his/her condition at all times and the health care professionals are responsible for ensuring that the patient has an adequate understanding of the chronic condition to be able to make informed self-management decisions (616). To achieve this goal, the workbook and health education topics were specifically designed to ensure that the participants would be knowledgeable regarding their respective health conditions.

In the absence of any effective medical cure for chronic diseases of lifestyle, the emphasis on improving the quality of life and functional capacity of the individuals, utilising disease self-management has to become the focus (491). Randomised controlled trials have been conducted to determine the effectiveness of self-management programmes on, among others: individuals diagnosed with arthritis (337); self-management of a chronic disease in a "real-world" setting following the principles of Lorig et al., (2001) (334, 426); on individuals with knee OA (617), and on individuals with chronic HIV infection (338). The results showed significant improvement in health behaviours, self-efficacy and health status.

The results of the epidemiological survey indicated that the prevalence of joint pain (musculoskeletal conditions) for all women in the target population was 58.2%. The goal of the intervention programme was to improve physical functioning of the participants, increase their general well-being and reduce their pain. Barlow et al., (1998) used a social cognitive theory approach which encouraged participants to utilise and incorporate their education lessons learned each week to manage their disease (618, 619). The social cognitive theory approach incorporates problem solving, goal setting and cognitive techniques to encourage self-efficacy and in the long-term facilitate change of behaviour of the individual (618, 619). Fear of pain is often a bigger limiting factor than the experience of pain itself and, once the participants felt confident enough to be able to perform the exercises without pain and also control their pain, they become more confident that their condition was manageable leading to the individual becoming more active and improve their physical functioning. Taking into account the literature regarding social cognitive theory, an action chart on how to deal with pain was included in the workbook and discussed during the education session to lessen the threat of pain.

To summarise, empowerment should be viewed as a philosophy, an overall approach and not just as a strategy in managing chronic diseases (616). Health education programmes should be a priority for the management of CDL both in urban and rural communities, and more especially in musculoskeletal conditions. It is well established that patients who have access to accurate information regarding their health problems and are knowledgeable regarding their self-care, are more likely to take an active role in disease management and to adhere to treatment recommendations (12).

7.2.9 Exercise

It is stated in the literature that all CDL and obesity share the same modifiable risk factor of inactivity (19, 20, 61). Exercise can improve physical variables including emotional health, depression, mood disturbances and self-efficacy (297-302). Although few studies have investigated the mood state of individuals at multiple time points after exercise, it is well known that the exercise-enhanced mood generally lasts for three to four hours (620) (621). Other benefits of exercise stated are enhanced mental performance, concentration (402, 621-626), and better quality of sleep (627). Studies have also indicated that exercise can reduce perceived feelings of anger, time pressure and time urgency in daily life (623). Therefore, involvement in regular exercise may or may not increase the number of years lived, but may most certainly enhance the quality of years lived by an individual (628).

The results of the systematic reviews revealed that both traditional and less conventional exercise programmes were utilised. Traditional exercise programmes included warming up, cardio-vascular exercises, muscle stretches, strengthening of upper and lower limbs and abdominal muscles and finally cooling down. Less conventional exercise programmes included yoga stretching, Tae-Bo and hot bathing. Based on the literature and the target population, the exercise component of the intervention included aerobic exercise, strengthening exercises and also muscle stretches.

The exercise programme was developed using the American College of Sports Medicine Guidelines and included aerobic exercises, strengthening exercises and stretching exercises (629-632), as well as the novel programme developed by Parker. Specific exercises were also chosen by the researcher taking the need for safety in an older population and limited availablity of equipment into account. Please refer to Appendix 29for a full description of the exercise programme utilised in the study. Due to the mean age of the participants (52 years) and the fact that most of the participants were living with more than one health condition, it was decided that the duration of the supervised exercise programme would be started at 45 minutes during the first week and increased every week until 60 minutes of exercise was achieved during the third week and thus would be maintained for the six weeks (594, 633). The last 15 minutes would include physical games for the enjoyment of the participants (634). It would be emphasised by the research assistant that participants should perform the aerobic exercises according to the Borg Scale level of "somewhat hard" to ensure that participants were exerting themselves at the correct level of intensity. (Appendix 30) The level of exertion "somewhat hard" has been found to

reflect an effort of 60% of maximum heart rate (265, 635). Appropriate illustrations were selected to be able to illustrate to participants what was meant by “somewhat hard”.

The cultural acceptability of the exercises was also considered, and specific adaptations were made depending on what was culturally acceptable to participants during the pilot study. The participants in the pilot study indicated during the first session that they enjoyed dancing activities and ball activities. The researcher gave each of them the opportunity during the first session to have a turn to show the type of dance that they enjoyed the most – this would then serve as aerobic exercises during the following sessions. Some of the cultural dances, however, entailed moving on their knees. As most of the participants were older women, these were not included in the routine because the floor of the community hall was hard and many participants had knee pain. Therefore, a safer form of dancing was included. Line dancing was introduced to the participants and after the first session they enjoyed the aerobic sessions and especially the music that accompanied these sessions. As part of cooling down at the end of the exercise sessions, cultural and traditional dances were encouraged. The participants fully engaged in the sessions by singing traditional songs while performing the dances.

As the participants indicated that they enjoyed activities that involved balls, the researcher and the research assistants included activities utilising different sizes balls. (Appendix 29)

In addition the workbook included examples of exercises for the participants to use at home, as well as exercise planning forms and weekly exercise diaries to encourage participants to exercise independently and ultimately increase their activity levels. The chapter in the workbook on exercise included information on how to exercise safely, and information on when to stop exercises due to illness or joint pain.

7.2.10 Relaxation

Relaxation training was included in both the workbooks from which the “Balanced Lifestyle” workbook was adapted, and was thus incorporated into the intervention. Relaxation is one of the commonly used approaches in the treatment of chronic pain and has been found to be effective for decreasing chronic headaches in patients (636-638). There were 12 participants who indicated that they experienced

headaches on the Brief Pain Inventory body chart. Although relaxation may be regarded as a simple task, the skill of relaxation is one that needs to be practised in order to master the technique (636). Hence, relaxation training was included in the workbook chapter on stress management and practised in a facilitated manner in the groups.

7.2.11 Practical considerations and finalisation

The intervention was based on information gained from several sources but input from possible participants in the programme would have been particularly useful and this is acknowledged as a weakness of the development process. More engagement with the community might have led to further enrichment of the process and unfortunately the researcher had no public involvement in the development of the intervention. On the other hand, the intervention was piloted on participants who would have met the inclusion criteria of the study and their comments were solicited and resulted in modification of the programme. The pilot study and subsequent changes made did ensure that the unique local perspective towards certain activities in the intervention did inform the intervention (See 8.2.6 Changes made after pilot study).

Several factors had to be considered and challenges overcome before the start of the intervention programme. The first was to ensure the availability of the community hall for the intervention programme as the hall was the only suitable venue in the area that could be used for the purpose of the study. The challenge was to ensure that the venue was unlocked on the specific dates given to the participants. As the person in charge of the venue was only fluent in Sesotho, the researcher requested a staff member of the University of the Free State who is fluent in Sesotho to contact the person in charge telephonically a day in advance of the intervention dates to confirm that the venue would be unlocked.

The second challenge was to find a suitable person to facilitate the exercise classes as well as the educational session of the intervention programme. Fortunately, a fourth year physiotherapy student who was fluent in both Sesotho and English was identified by the researcher and trained as a research assistant. The student had a better understanding of the cultural norms, due to her upbringing in a small Sesotho community and the theoretical training empowered her to be able to convey the

information in the workbook. No additional training was needed for the student(s) regarding the execution of the exercises in group format as all physiotherapy students are assessed during their third year as part of their clinical exposure in Community Service Learning on how to compile and present exercise and educational classes in group format for various health conditions, ages and cultures. The researcher, however, had the responsibility of ensuring that the research assistant was familiar with the content of the topic as well as the exercises for the specific week. This researcher and three other research assistants would also be present during each session to ensure that exercises were performed correctly by participants.

Participants in the intervention group would receive a telephonic reminder or text message before each intervention date as encouragement to adhere to the programme. The reminders were in accordance with the "green prescription" intervention in New Zealand where participants received at least three telephone calls during the study to encourage and support them in ensuring that they adhered to the physical activity required during the study (639).

The final stage of development of the intervention included piloting of the planned intervention. A pilot study was conducted as it was necessary to ensure that the intervention would be culturally appropriate and feasible as planned. Once this had been done (described in 8.2.5) the intervention programme was adapted and finalised and the randomised trial was initiated.

7.2.12 Adverse events

Participants in the intervention study were screened and physically examined by a qualified medical practitioner to exclude any risk factors for participating in the study. A trained paramedic was present during baseline measurements, each exercise session once a week for the duration of the study as well as endpoint data collection, to ensure that the best possible care was available for the participants in case of an emergency. In the event of an incident taking place, the participant would receive immediate post-injury care by the researcher or paramedic on hand and referred to the sister in charge at the clinic immediately, or referred for management to the National District Hospital in Bloemfontein. All adverse events would be declared in written format to the sister in charge at the clinic and kept on record at the

clinic, National District Hospital and on file by the researcher. All health-related incidents of participants during the intervention would be recorded on the weekly intervention programme for transparency.

8 IMPACT OF A NON-PHARMACOLOGY INTERVENTION PROGRAMME: A PRAGMATIC, RANDOMISED CONTROL TRIAL.

8.1 Introduction

As discussed in Chapter 2 and supported by the findings of the sub-study on the prevalence and impact of musculoskeletal conditions in Chapter 6, it was apparent that chronic diseases of lifestyle, obesity and musculoskeletal pain resulted in a large burden of functional limitations in women attending this particular primary health care clinic in Bloemfontein. An intervention programme was designed specifically to meet the needs of this group of women. This programme was informed by the narrative and systematic literature reviews, as well as their demographic and functional characteristics.

It was hoped that such a targeted intervention programme would not only improve the quality of life of participants, but would also improve their health conditions and in the long term encourage other community members to change their lifestyle and behaviour.

It was hypothesised that a non-pharmacological intervention programme that targeted musculoskeletal conditions, and which included exercises, behavioural changes and education, would bring about functional improvement and also reduces the impact of diabetes mellitus type II, hypertension and obesity. In addition, as many of the intended recipients of such a programme would have co-morbidities, it was important to include participants in the study who were representative of the clinic population.

8.1.1 Aims and objectives

The aim of the sub-study was thus to explore the effectiveness of a non-pharmacological six weeks intervention programme for middle aged women presenting with joint pain (musculoskeletal conditions).

The objectives of the intervention component were to determine whether the six week intervention as described in Chapter 7, would result in a significant difference, when compared to the standard of care in the following parameters:

- joint pain as measured by the Brief Pain Inventory (Short Form (this was the primary outcome measure);
- health-related quality of life in women with joint pain (musculoskeletal conditions), as measured by the EQ-5D-3L; and
- physical function as measured by the Simmonds battery of functional tests and the six-minute walk test.

Further objectives were to explore the relationship between:

- joint pain (musculoskeletal conditions) and co-morbidities of individuals as measured by blood pressure, body mass index, venous glucose readings and cardiovascular fitness using the three-minute step test.

Finally we wished to establish the extent to which the intervention programme became integrated into the community and the sustainability of the intervention programme after six weeks.

8.2 Methods

8.2.1 Research design

A pragmatic (640), experimental randomised controlled design was adopted to determine the effectiveness of usual care against a non-pharmacological intervention programme utilising a workbook modified and adapted from existing programmes, for the women identified in the survey. The trial was pragmatic in that it intended to test the impact of the intervention within "a real world" context. The pragmatic explanatory continuum indicator summary (PRECIS) tool was developed to reflect the continuum from explanatory to pragmatic trials and one of the characteristics of pragmatic trials is that eligibility criteria are less rigid. In some cases, there may not even be inclusion and exclusion

criteria (24). The implications for this study are that, as many of the target population have both MSC and CDL (and or obesity), a programme designed for this context should include participants with co-morbidities.

8.2.2 Participants

The sampling frame included all women attending the community clinic between the ages of 40 and 64 years who tested positive on screening for joint pain during the survey described in Chapter 6 and who had indicated their willingness to participate in Phase III of the study. Co-morbidities, such as diabetes mellitus type II, hypertension and obesity during Phase I (described in Chapter 6) were not exclusion criteria. As it was necessary to contact participants during the course of the study, participants needed to be contactable telephonically.

8.2.2.1 Participation criteria

All women attending the community clinic between the ages of 40 and 64 years who met the following criteria were eligible for inclusion:

- Reporting pain, aching, swelling, stiffness (tightness) in or around joints or back which is not related to an injury / accident within the last three months (which included the last seven days) (Questions 29 a and 29 b in the survey questionnaire).
- a minimum education level of Grade 4 (typically that of a scholar in their fourth year of primary school at approximately 10 years of age) to be able to complete and understand the workbook;
- able to understand English and /or Sesotho;
- willing to commit to the intervention for two hours, once a week, for six weeks; and
- access to a telephone to allow telephonic communication.

Certain CDL and risk factors such as obesity, hypertension and/or diabetes mellitus Type 2, were not exclusion criteria and subjects with these co-morbidities were thus enrolled.

Exclusion criteria included:

- other self-reported CDL including cancer, cardio-vascular diseases (coronary heart disease), stroke, depression and chronic respiratory diseases ;
- an increased risk for participating in exercise, the latter was determined by screening of participants and a physical examination performed by a qualified medical practitioner with a special interest in Community Health; and
- neurological disorders or being confined to a wheelchair.

8.2.2.2 Screening, randomisation, blinding

Stratification is commonly used when a researcher wishes a randomly selected sample to be representative of the population on some important characteristic of interest (641). This characteristic might have a confounding effect on the outcome of an intervention and, in the current study; obesity was identified as a variable which might well confound the outcome. The literature review revealed that obesity was commonly co-morbid in hypertension, diabetes mellitus type 2 and, most relevant to this study, joint pain (musculoskeletal conditions) (Table 4). In addition, 81% of the survey sample was classified as being obese or overweight. As the sample size would be relatively small, the researcher was concerned that, despite randomisation, there may have been a preponderance of participants with obesity in one or other of the groups. To prevent this, participants meeting the above criteria were stratified according to three BMI levels (normal weight, overweight and obese) by the researcher and randomisation was done for each group separately. The 187 individuals identified in the survey who had indicated their willingness and commitment to take part in the intervention part of the study, were randomly contacted. Eligible women enrolled into the study were then randomly selected by using the Microsoft Excel random function to divide the participants into a usual care group (control group) and an intervention group. The randomisation was performed by the researcher.

8.2.2.3 Sample size

The researcher invited 187 women to participate. Ten women were included in the pilot study to determine the feasibility and acceptability of the intervention study and the rest of the willing women were then included for the implementation of the intervention.

The sample size was based on the pain severity score, as this was the primary outcome measure. Pain was chosen as joint pain (MSC) was the criterion for inclusion in the study. In addition, previous studies using the six weeks exercise and education intervention programme have also demonstrated a reduction in pain and improvements in quality of life, and this data was available to utilise for the calculation (364)(Table 53). Therefore reducing pain was a primary target of the intervention.

Table 53: Sample size calculation

	Value
Anticipated mean score at six weeks of control group	5.30
Anticipated mean score at six weeks of intervention group	3.80
Standard deviation	2.00
Significance level	0.05
Critical Value of t	2.00
Power Goal	0.80
Actual Power for Required N	0.80
Required N (per group)	29

Statistica Sample Size calculation

A minimum sample of 29 participants in each group was required to achieve an 80% power goal using the expected parameters.

8.2.3 Instrumentation

It was anticipated that an effective intervention would lead to changes in lifestyle which would impact on the activity limitations and participation restrictions associated with musculoskeletal conditions as well as on accompanying chronic diseases. Blinding was applicable to the research assistants who were taking the baseline assessments, venous blood glucose and blood pressure of the participant. Measurements were taken at baseline and at six weeks.

8.2.3.1 Impairments (including pain)

Random serum glucose levels were determined by a finger prick test. Random serum glucose levels were determined by a research assistant using the method as described in section 6.3. A level of ≥ 5.6mmol/L was defined as metabolic syndrome (41) and a venous plasma glucose concentration of greater than 11,1mmol/l, would classify the participant as being diabetic (41, 591, 642).

Blood pressure of participants was determined by a research assistant after a five minute rest in the sitting position, according to WHO guidelines using the method as described in section 6.3.

The impact of cardiovascular fitness on function was measured using the Kasch Pulse Recovery test which is widely used in clinical settings, and the six-minute walk test (408, 438, 439). The Kasch Pulse Recovery test is scored as the number of heart beats per minute over a period of one minute, the pulse rate taken after five seconds after cessation of a three-minute step test. A lower heart rate indicates better cardiovascular fitness (409).

Body weight of participants were determined by a research assistant using a calibrated electronic digital scale (Pure Pleasure code: TF –SA 10155) accurate to 0.05kg and the height of each participant was recorded by the same research assistant to the nearest 0.1 cm using a Seca Leceister 214 portable stadiometer. The measurements for body weight and height were determined using the procedure as described in section 6.3.

The Brief Pain Inventory (Short Form) contains three important elements which are not included specifically in other pain measurement instruments available. The first element is generalised questions which clarify to the participant that it is normal to experience some form of pain on a regular basis, but the aim of the questions is to determine whether the participant has experienced more pain than he/she would normally expect. The second element is the assessment of the impact pain has on various functional levels and the last element is to explore the effectiveness of medication through the Pain Management Index. The Brief Pain Inventory (Short Form) is a self-administered questionnaire which was initially used in research with the focus on cancer patients, but since it has been validated for use in non-cancerous pain (413). The Brief Pain Inventory has been translated into numerous languages including Sesotho.

8.2.3.2 Functional limitations

The International Physical Activity Questionnaire (IPAQ) was used to monitor the physical activity of the participants. The short form of the questionnaire comprises four generic items. The questions are related to the physical activity of the participants in the last seven days. Reliability and validity have been tested in 12 countries (442, 480). Pedometer readings were also taken in the intervention group to determine whether the physical activity levels of participants increased. The control group (usual care group) did not receive pedometers as the psychological effect of wearing a pedometer on the activity levels of participants has been well described in the literature (423).

The six-minute walk test is used to measure the maximum distance that a participant can walk in six minutes and is used clinically in determining function in patients with cardiovascular or pulmonary diseases. The six-minute walk test is a useful instrument because of its similarity to normal activities of daily living. The test according to Steffen (2002) is a better measure of exercise endurance than maximal exercise capacity (409). Studies have shown good construct validity and good test-retest reliability for the test (436, 438, 439).

An exercise/activity diary was included in the generic wellness workbook provided for each participant in the intervention group to determine her compliance to the programme and to determine her level of activity from baseline measurement to the completion of the study.

The Simmonds battery of functional tests was performed to determine the functional impact the joint pain (musculoskeletal conditions) had on the participants. The performance battery consists of a series of nine tasks. Please refer to Table 31 in Chapter 5 for a detailed description of the Simmonds battery of functional tests. The coin test and the pen-pick up test were not included as participants were fully functional and the aim of these items of the test was to determine their arm and lower limb functioning (416). The validity of the Simmonds battery of functional tests has been established in musculoskeletal diseases as well as systemic diseases with optimum management predicted (415-417).

The measurements were taken at baseline and again six weeks after completion of the intervention study.

8.2.3.3 Personal Factors

Standardised questionnaires were used to determine the health-related quality of life of the participants using the EQ-5D-3L and the Brief Pain Inventory (Short form) to determine the impact of pain (See Chapter 5 for the description of the translation of these instruments). The WHODAS 2.0 did not perform well during the epidemiological survey and did not display concurrent or divergent validity. It was thus not used as an outcome measure in the intervention component of the study.

The Self-efficacy for Managing Chronic Disease six-item scale in Sesotho was used to determine the efficacy of the education programme (Chapter 5). The scale has previously been found to be valid and reliable for measuring self-efficacy in chronic conditions, especially in arthritis (488, 490).

An acceptability questionnaire was designed by the researcher using the available literature to determine the attitude of the participants in the intervention group towards the programme (334, 338). Five simple questions were formulated asking the participants what they liked most, and/or least about the programme, what they would change or add to the programme and whether they liked the self-management booklet that was developed and modified by the researcher.

8.2.3.4 Intervention

The intervention described in Chapter 7 took place for two hours, once a week for six weeks, from 8 April 2016 to 13 May 2016. Six weeks was chosen as, in addition to the evidence for this duration given in 7.2.2, this was to be a pragmatic trial and it was thought unlikely that participants would be prepared to attend for much longer than this if the intervention were to be rolled out as part of routine care. The intervention took place during the morning only on a weekday as this was the only time that the community hall was available for the study.

8.2.4 Research setting

The research setting is described in some detail as, consistent with the ICF framework; environmental factors can have a large impact on functioning and disability, both physical and emotional. The

community hall where the research was conducted serves ten formal and informal community settlements. Next to the hall is a Secondary school as well as a number of informal spaza community shops run from railway metal containers. The community hall is currently in disrepair. There are broken windows and the entrance door is secured with chains as the hinges have been removed. The grounds of the hall are surrounded by barbed wire and the garden has not been cared for in years, with plant overgrowth, and the one side has become a rubbish heap for the community. The surrounding little shops built in a half circle around the hall on the same plot are not being used and have been vandalised. The inside of the hall had to be cleaned by the research team before commencement of the study due to infestations of rodents and doves. The researchers transported chairs and tables to the venue each time the sessions took place and were also responsible for preparing the facilities for use by the participants.

8.2.5 Pilot study

The pilot study was conducted at the community hall as this was the only venue available close to the clinic for the intervention phase of the study. Twenty participants were contacted telephonically from the master list of the survey to invite them to take part in the pilot study. Ten participants indicated their willingness to participant. Nine of these attended the baseline measurement session and were screened and physically examined by a qualified medical practitioner to exclude any risk factors. The screening took place at the community clinic in a treatment cubicle to ensure the privacy of participants. All nine participants were declared fit to take part in the three week intervention programme.

The pilot study took place from 18 February to 4 March 2015. Baseline measurements were obtained for nine participants, but one participant withdrew after the first week due to work commitments. The pilot study was completed on eight participants to determine the feasibility and acceptability of the workbook and the intervention programme. The exact same testing procedures were followed as described for the actual intervention. The results of the pilot study were not included in the results of the main study as the pilot study was only conducted for three weeks and not six weeks as planned for the intervention.

8.2.6 Changes made after pilot study

After completion of the pilot study the following changes were made to ensure accuracy of measurement during the intervention study. Participants found it challenging to complete the questionnaires on their own and this resulted in incomplete questionnaires. Upon reflection it was decided that fieldworkers would be trained by the researcher to assist with completion of the questionnaires. Four fieldworkers previously used during the epidemiological survey who were fluent in English and Sesotho were trained regarding completion and understanding of the questionnaires to assist in the main study. Each fieldworker would be assigned to the same participants at baseline and again after six weeks to ensure consistency regarding the structured interview.

8.2.6.1 Self-efficacy six-item scale (SE-6)

No changes were made to any concepts in the translated version of the self-efficacy six-item scale questionnaire. Minor changes were made to wording, and grammatical errors were corrected in the questionnaire. Unfortunately the time to complete the individual questionnaires was not established during the session.

8.2.6.2 International Physical Activity questionnaires (IPAQ)

No changes were made to any concepts in the translated version of the International Physical Activity questionnaire. Minor changes were made to wording, and grammatical errors were corrected in the questionnaire. Participants did, however, find it difficult to distinguish between the hours and minutes per day that they took part in both vigorous, mild physical activities and sitting activities. The activities were well understood, but they struggled to differentiate between the time frames. No changes were made as the integrity of the standardised questionnaire would then have changed. Therefore, the decision was made that the fieldworkers would clarify the concepts for the participants during the completion of the questionnaires.

8.2.6.3 Acceptability questionnaires

No changes were made to the acceptability questionnaire – participants were clear about the concept of informing the researcher what they liked or disliked about the workbook and the intervention programme. It was not necessary to determine the time for completion of the questionnaire as the questions posed were open-ended questions and were intended to be completed after taking part in the intervention and after working through the workbook.

The physical outcome measures of the study were performed by research assistants trained by the researcher to perform the tests, while the fieldworkers assisted participants with the completion of the questionnaires. Blinding was applicable to the research assistants who took the baseline measurements of the Simmonds functional tests, venous blood glucose and blood pressure of the participants, as well as the fieldworkers who assisted with the completion of the questionnaires. During the pilot study participants could move to testing stations randomly to save time, as some assessments/outcomes took longer to complete than others. Upon reflection it was decided by the researcher that assessment stations should be numbered and participants should be instructed to follow the exact sequencing to ensure the validity of the battery of tests. If the sequencing was not the same for all participants it would lead to discrepancy of results as some participants would have longer resting period between stations that did not require as much physical activity as other testing stations. After three weeks, data of the eight participants who completed the pilot study were obtained.

Two exercises were changed after the pilot study. Two of the exercises posed a danger to participants as they had to walk around in a circle and when the music stopped they had to sit on the nearest chair. The chairs tended to slip on the surface of the hall and so this exercise was replaced for safety reasons. Another exercise involved playing netball against each other in teams as the participants had indicated that they enjoyed ball activities. The two teams however became too competitive and bumped into each other which also posed a danger and had to be adapted.

8.2.7 Procedure

The study conformed to the principles of the Declaration of Helsinki (643). The trial was registered as a clinical trial at the Pan African Clinical Trial registry (PACTR201511000689333) (Appendix 32). Ethical approval was obtained from the Human Research Ethics Committee, of the Faculty of Health Sciences, at the University of Cape Town and the Ethics Committee of the Faculty of Health Sciences, at the University of the Free State. (HREC Ref: 605/2013 and ECUFS Nr: 185/2013) Approval was also obtained from the head of the Department of Health in the Free State, as well as the head of the community clinic before commencement of the pilot study and execution of the study. A copy of the permission letter for the execution of the intervention study at the community clinic was given to the sister in charge of the community clinic as well as the person in charge of the community hall. The person in charge of the community hall received a calendar indicating the days on which the intervention was to take place at the community hall. A flow diagram of the study procedure is presented below in Figure 17 and Figure 18.

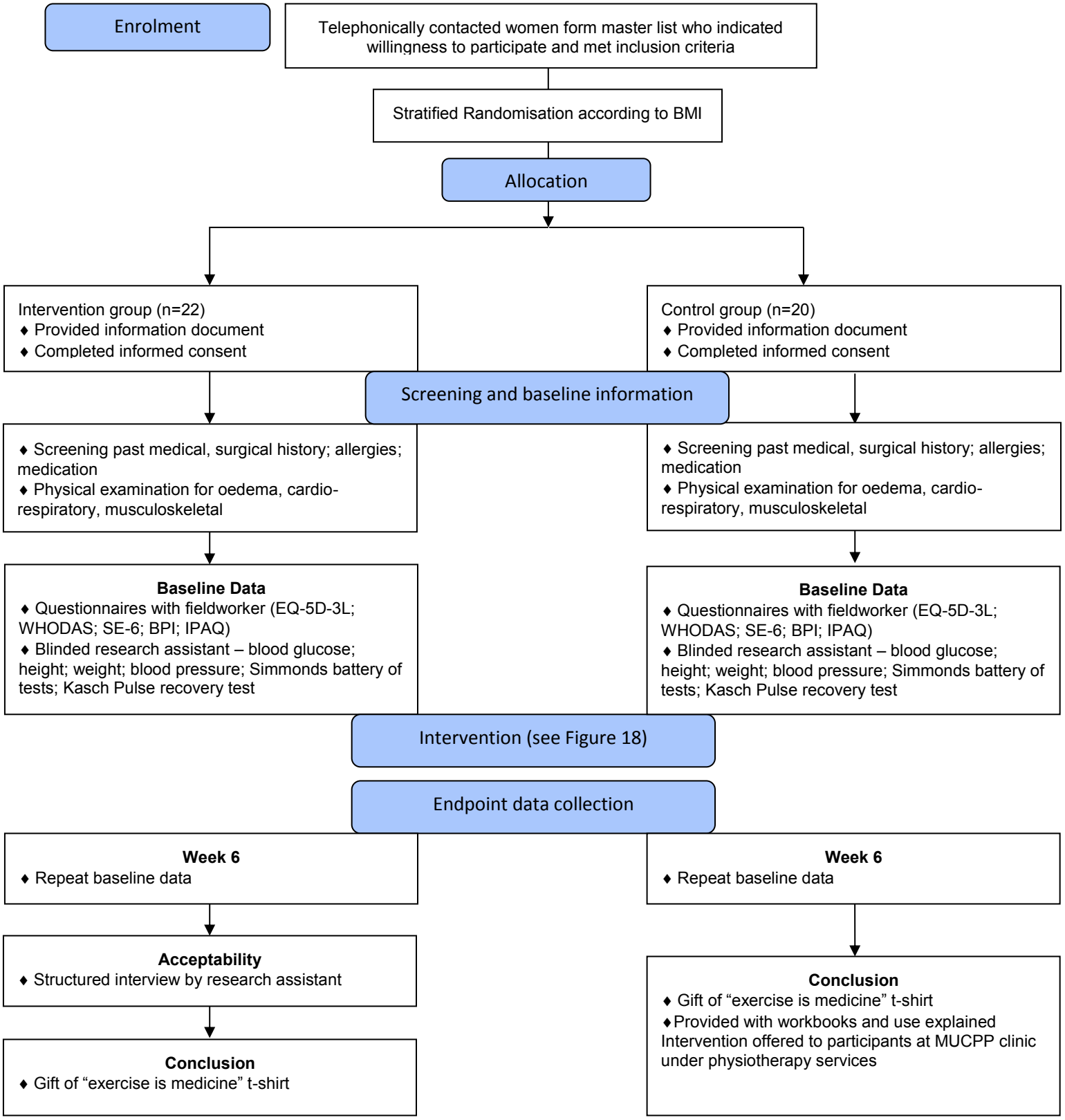


Figure 17: Flow chart of enrolment, screening and data collection process

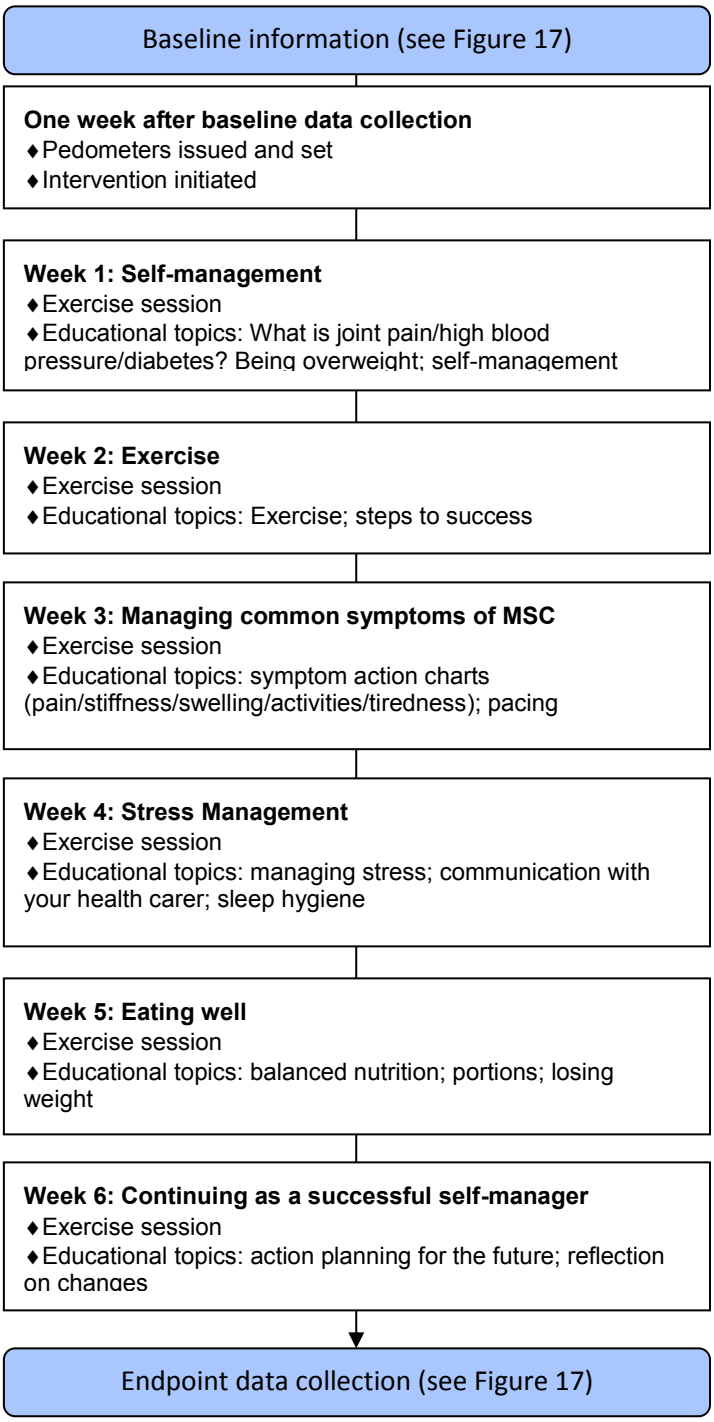


Figure 18: Flow chart of study intervention

All participants who screened positive for only joint pain or joint pain and at least one of the co-morbid conditions: hypertension, diabetes mellitus type II or obesity and who indicated their willingness and commitment to take part in the intervention part of the study were contacted telephonically to invite them to enrol in the six week intervention programme. Once their participation was confirmed telephonically, the eligible women were randomly divided by the researcher into a usual care control group and an intervention group. After sampling, participants were contacted telephonically from the master list to confirm their participation in Phase II of the study. The intervention group received a date and time for screening and a physical examination to exclude risk factors by a qualified medical practitioner. Once all the participants had been cleared for possible risk factors they received a calendar indicating the time and dates for the two hour exercise sessions. An information leaflet describing the study was then handed to the participants in their preferred language – English, or Sesotho (Appendix 33). An informed consent form complying with the elements as required by the ethics committees was read by, or read to, the participants and signed before completing the questionnaire (Appendix 34).

Reminder text messages were sent to all participants to remind them of the date for the baseline measures and, in the case where the participant only indicated a landline, the participants were contacted telephonically.

Blinding was applicable to the fieldworkers responsible for assisting the participants with the completion of the questionnaires including the EQ-5D-3L and the International physical activity questionnaire. The research assistants, who were blinded to which participants were in the control group and intervention group, took the venous blood glucose levels, weight, height and blood pressure of participants as described under instrumentation (section 8.2.3.1), performed the Simmonds battery of functional tests, six-minute walk test as well as the three- minute step test. The same research assistant performed the same test in each instance during the baseline and after six weeks to ensure reliability of the testing procedure. The research assistants were trained by the researcher to ensure that the tests were performed according to the procedures as described in the literature.

All the measurements were taken in a separate room to protect the privacy of the participants except for the Simmonds battery of functional tests, six-minute walk test and three-minute step test that were performed in the community hall. The information was kept strictly confidential but was disclosed to the participants.

At the start of the study an information session was held with participants in the intervention group to explain why exercise is important, and also how to use the workbook during the structured education classes as well as at home. Emphasis was placed on goal setting as encouraged by the workbook. In addition all participants received pedometers (model E01758) after the first intervention session, which would encourage activity. The pedometers were individualised for each participant according to the manufacturer's guidelines. This procedure included entering the weight of the participant as well as the stride length of the participant. The stride length was set in centimetres. The stride length is seen as the distance measured heel to toe as the participant is walking. The usual care group did not receive a workbook or pedometer. Participants were requested to wear comfortable clothes, suitable for exercises during the intervention programme.

A weekly educational programme, discussion group and exercise class lasting two hours were held for six weeks at the community hall for the intervention group, while the control group went about their daily lives as usual. Both the usual care control group and the intervention group were instructed to adhere to their medical treatment as usual. The end-point of data collection was after six weeks of the intervention programme.

During the intervention programme sandwiches with a protein filling, fruit and water to drink were made available to participants. This was the first meal of the day for many of the participants. The same sandwiches and water were made available to participants for the control and the intervention group during baseline measurements and end point of data collection.

The control group and the intervention group received a date and time indicated on a calendar to attend a session at the community hall for measurements to be taken after six weeks. All the participants were contacted telephonically to remind them of the date and time for the measurements to be taken and the day before the endpoint of data collection a text message was also sent to participants to remind them of the session.

The workbook was offered to the usual care group at the end point of data collection after the six weeks of the intervention. Arrangements were made for the structured programme to continue at the community clinic on a weekly basis under the guidance of the community service physiotherapist serving the community and the physiotherapy student on the community clinical block. The intervention group was encouraged to continue with the group exercise programme and to invite other women to join the group. The control group was invited and encouraged to join the group and to utilise the workbook given to them. The programme and the workbook were made available to the community physiotherapist to utilise for the purpose.

Participants received no other remuneration other than reimbursement for their travel costs to attend the exercise sessions as well as the baseline measurement and endpoint measurements.

Data were captured by the researcher on an Excel spread sheet, and a second person verified the captured data to ensure accuracy before statistical analyses.

8.2.8 Statistical analysis

Descriptive statistics were used to describe the demographic characteristics of the participants. An Independent t-test (parametric data) or Mann-Whitney U test (non-parametric data) was used to establish equivalence between the groups on admission to the study and any difference at six weeks. Repeated measures ANOVA were used to explore group and time interactions. The computer software program Statistica (version 7) (StatSoft, Tulsa, Oklahoma, USA) was used for data analysis.

8.3 Results

8.3.1 Enrolment

Figure 19, is a flow chart which tracks the recruitment and follow-up of the participants. In total 187 participants were eligible and invited to participate in the study, but on the day of baseline measurements 145 participants did not attend despite telephonic contact indicating that they would attend. The remaining 42 participants were randomised into a control and intervention group. Twenty participants were allocated to the control group and 22 participants into the intervention group. Five participants were lost to follow-up in the control group for reasons outlined in the flow chart. Post-hoc analysis indicated no difference in the baseline rank ordering of age (p=0.213), pain (0.824) or self-reported HRQOL (p=0.081). No attrition bias could thus be detected between those who remained in the study and those who were lost to follow-up.

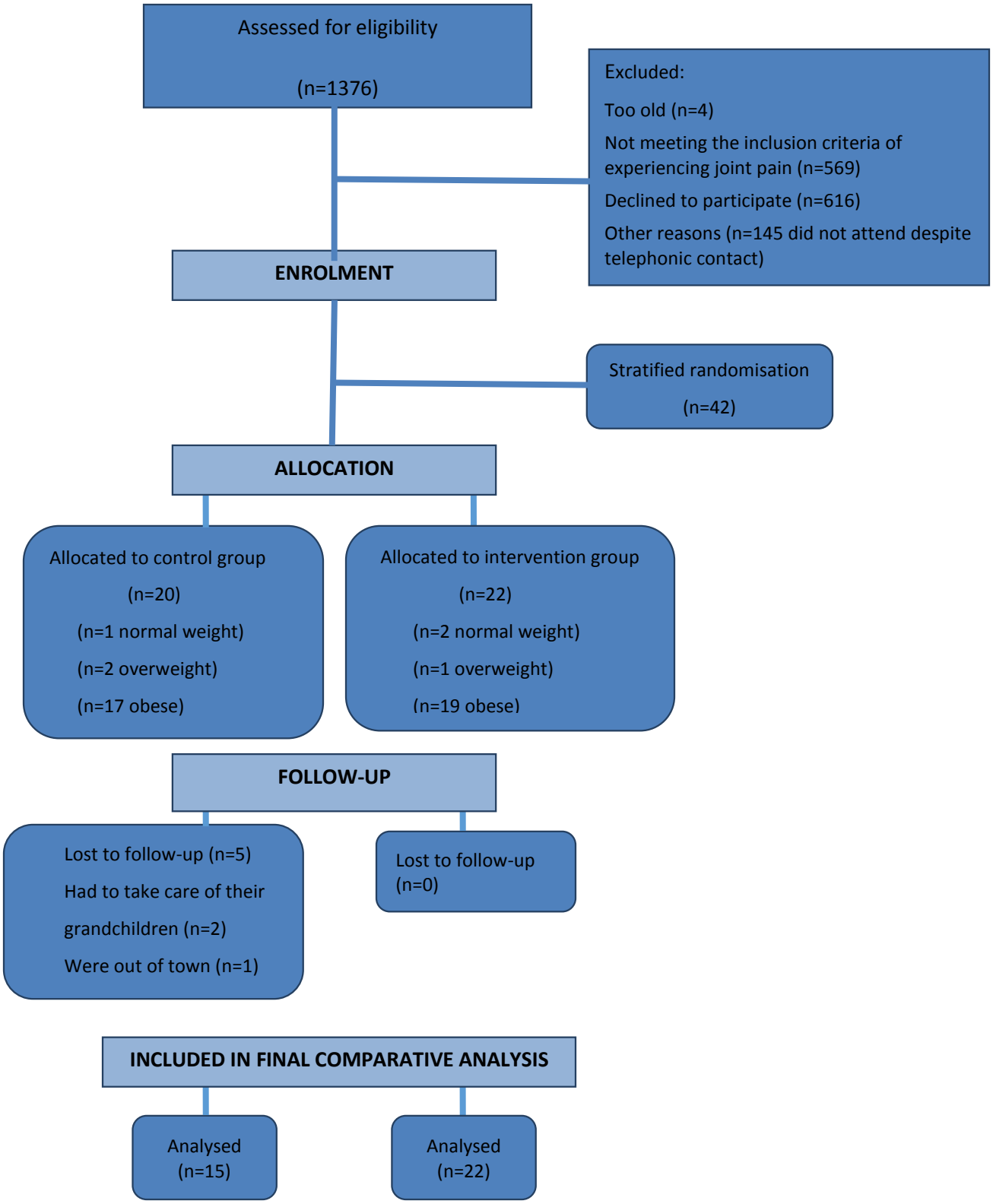


Figure 19: Flow diagram of recruitment and retention

8.3.2 Attendance

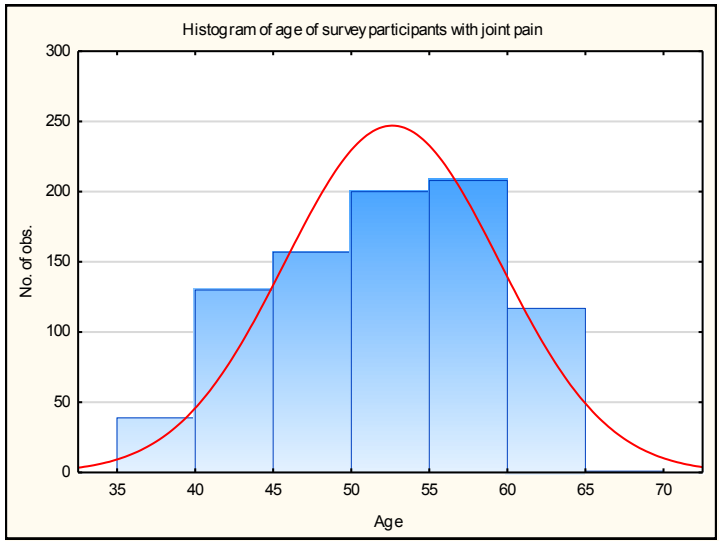
Table 54, indicates the attendance of participants during the six weeks of the intervention programme. The same participant was absent during week two and four while different participants were absent during the intervention period. As can be seen in Table 54 below, one participant attended for four weeks, while the rest all attended for either five or six weeks of the six week intervention programme. There were thus 16 sessions missed out of a total of 6*22 =132 possible attendances, an attendance rate of 87.9%

Table 54: Non-attendance of intervention programme over six weeks

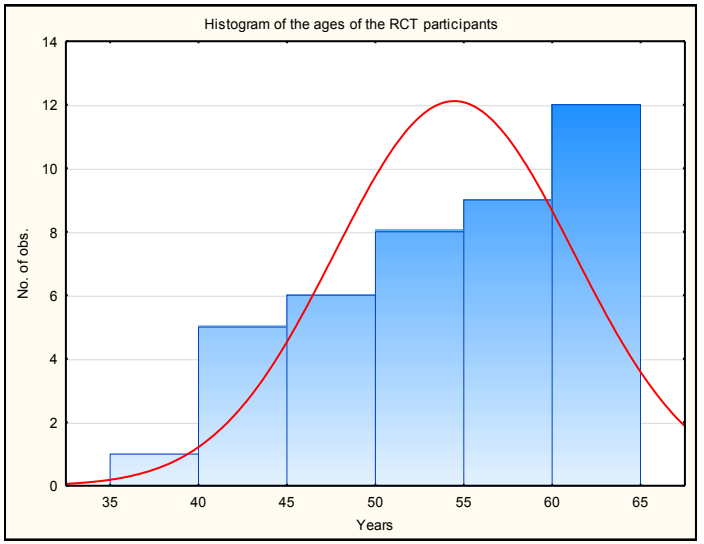
Week	Number of non-attendance	Reason for non-attendance
1	0	N/A
2	2	One participant had flu, and one participant attended an ophthalmology appointment which was made three months earlier.
3	3	One participant attended her mother's funeral, one was out of town for family commitments, one was ill, but did not disclose the nature of her illness.
4	1	One participant took her elderly mother to the diabetic clinic for a follow-up visit.
5	4	One participant was admitted to hospital after her blood glucose levels were too high and she complained of visual disturbances; two participants had family commitments, one participant did not disclose her reason for non-attendance.
6	4	Two participants had flu, one attended a doctor's appointment due to a urinary tract infection; one participant did not disclose her reason for non-attendance.

8.3.3 Comparison of demographic information of the survey participants with joint pain (population) and randomised, control trial participants (sample)

The ages of the participants for both the survey and the randomised, control trial (RCT) groups were not normally distributed (W = 0.962; p = 0.000 and W= 0.956; p = 0.013 respectively), and non-parametric tests were used to compare them. (Figure 20) The median age of the participants in the survey group was 52 years (inter-quartile range (IQR): 46-58 years, and range of 40-65 years). The median age of the participants of the randomised, control trial group was 56 years (IQR: 50-61 years and range of 40-64 years) and was significantly higher (p = 0.014) than the median age of the survey group.



(n=854)



(n=41,n=1 missing data)

**Note that each category includes the upper bounds of that category.*

Figure 20: Histogram of the age distribution of the survey and randomised, control trial sample

As can be seen in Figure 20 above, there were more older people in the randomised, control trial group but this was not statistically significant (t=-1.7, p=0.087.) A considerably larger proportion of the survey population lived in houses with four or more occupants. (Table 55) and the difference in proportions was significant (Chi-Square=18.71, p<0.001).

Table 55: Demographic and living conditions of the participants in the survey with joint pain and randomised, control trial sample

Variable	Categories	Survey (n = 854)	Survey percentage	RCT (n = 42)	RCT percentage	Between Groups (Chi-Square test)
Language	Sesotho	586	68.22%	26	62%	Chi-square=1.34* p = 0.512
	Isixhosa	146	17.58%	8	19%	
	Setswana	113	13.15%	8	19%	
	English	5	0.58%	0	0%	
	Afrikaans	1	0.12%	0	0%	
	Zulu	3	0.35%	0	0%	
	Missing	0	0%	0	0%	
Race	African	852	99.77%	42	100%	N/A
	Coloured	2	0.23%	0	0%	
Marital Status	Married	382	44.47%	14	33%	Chi-square=3.68* p =0.159
	Never married	300	34.92%	18	36%	
	Widowed/Separated/Divorced	172	20.61%	13	31%	
House ownership	Own	664	77.30%	35	83%	Chi-square= 0.37 * p = 0.543
	Friend/family	186	22.24%	7	17%	
	Other	2	0.23%	0	0%	
	Missing	2	0.23%	0	0%	
Type of dwelling	Brick	717	83.47%	34	81%	Chi-square= 0.15 * p = 0.699
	Informal	132	15.95%	8	19%	
	Missing	5	0.58%	0	0%	
Number of residents per household	Three or less	175	20.50%	21	50%	Chi-square= 18.71* ***p <0.001***
	Four or more	679	79.50%	21	50%	
	Missing	2	0.23%	0	0%	

Note that frequency of missing data was not included in Chi-Square analysis.

**Calculation only included cells greater than 5.*

A comparison of the education level and employment status of the two groups (Table 56) indicated that the two groups were equivalent, apart from the literacy levels (as per inclusion criteria) and employment status. Over 90% of the randomised, control trial group were unemployed compared to 79% the survey group (p=0.041).

Table 56: Education level and employment status of the participants in the survey with joint pain and the randomised, control trial sample

Variable	Categories	Survey (n = 854)	Survey percentage	RCT (n = 42)	RCT percentage	Between Group (Chi-Square)t)
Literacy	None	114	13.27%	0	0%	N/A
	Read only	19	2.21%	0	0%	
	Read/write	720	84.40%	42	100%	
	Missing	1	0.12%	0	0%	
Education	None/Primary	392	45.90%	16	0%	
	Secondary/Tertiary	462	54.10%	26	62%	Chi-square= 0.69 * p = 0.406
Current employment status	Unemployed/Housewife/Pensioner	671	78.57%	39	92.8%%	Chi-square= 4.14 *
	Worker - Full time	183	21.43%	3	7.2%	***p = 0.041***
	Missing	6	0.70%	0	0%	
Reason for unemployment (n = 376 and n =33)	Cannot find work	204	54.26%	17	52%	N/A
	Health problems	149	39.63%	14	42%	
	Family care	16	4.26%	2	6%	
	Disabled	2	0.53%	0	0%	
	Husband prevents	2	0.53%	0	0%	
	Missing	3	0.80%	0	0%	
Receive grant benefits	No	608	71.36%	28	67%	Chi-square= 0.21 * p = 0.6468
	Yes	246	28.64%	14	33%	
**Type of grant benefits (n = 246 and n =14)	Disability	98	39.84%	5	35%	N/A
	Pension	129	52.44%	9	64%	
	Disability and pension	13	5.28%	0	0%	
	Not known	6	2.44%	0	0%	

*Note that frequency of missing data was not included in Chi-Square analysis. *Calculation only included cells greater than 5.*

***Note that the type of grant is for those individuals who indicated that they do receive grant benefits.*

In summary, the participants in the randomised, control trial group were older, fewer participants were employed and they lived in households with a greater number of inhabitants than the population in the survey.

8.3.4 Comparison of health-related information of the survey group with joint pain and the randomised, control trial group

Table 57: Health variables of the participants in the survey with joint pain and the randomised, control trial sample

Variable	Survey (n=854)			RCT (n=41)			Between Groups (Wilcoxon Two Sample test) (Z score)
	n	Median	IQR	n	Median	IQR	
Weight (kg)	851	80.5	65.0 – 93.0	41	93.8	76.3-100.8	***p =0.015*** (2.440)
Height (cm)	850	158	153 – 163	41	156	153.0-159.0	p = 0.067 (-1.829)
BMI (kg/m^2)	850	32	27.0 – 37.7	41	37.2	31.8-41.9	***p = 0.002*** (3.044)
Haemoglucose (mmol/l)	849	5.5	4.6 – 7.0	41	5.8	5.4-9.1	***p = 0.045*** (2.839)
Systolic BP (mmHg)	849	147	133 – 159	41	143	133.0-155.0	p = 0.305 (-1.026)
Diastolic BP (mmHg)	849	91	84 - 99	41	92	84.0-99.0	p = 0.669 (-0.427)

(n = 854 and n=41 n = 1 missing data)

The median weight, BMI and haemoglucose levels of the participants in the survey group were significantly lower ($p < 0.05$) than those of the randomised, control trial group (Table 57). The median BMI value of the participants from both the survey and randomised, controlled trial groups fell within the classification of being obese, and the proportion of those with obesity in the intervention sample was significantly higher ($p<.001$) (Table 58).

Table 58: Health variables of the participants in the survey with joint pain and the randomised, control trial sample

	Survey (n=853)	Survey Percentage	RCT (n=41)	RCT Percentage	Between Groups (Chi-Square test)
Diabetes mellitus type II*	157	18.41%	11	27%	p = 0.177 (Chi-square=1.819)
Hypertension**	(n=849)		(n=41 n=1 missing data)		p = 0.734 (Chi-square=1.279)
Normal	270	32.21%	15	37%	
Stage I	309	36.18%	15	37%	
Stage II	158	18.50%	8	20%	
Stage III	112	13.11%	3	7%	
Obesity***	(n=851)		(n=41 n=1 missing data)		*p < 0.001* (Chi-square=30.74)
Underweight	13	1.52%	0	0%	
Normal	147	17.19%	3	7%	
Overweight	181	21.17%	3	7%	
Obese	510	60.12%	34	83%	

*Diabetes mellitus type II (non-fasting blood glucose >7.8mmol/L)
**Normal: Systolic blood pressure 120-139mmHg, diastolic blood pressure 80-90mmHg
Stage I hypertension: Systolic blood pressure 140-159mmHg, diastolic blood pressure 90-99mmHg
Stage 2 hypertension: Systolic blood pressure 160-179mmHg, diastolic blood pressure 100-109mmHg
Stage 3 hypertension: Systolic blood pressure ≥ 180mmHg, diastolic blood pressure ≥110mmHg
***Underweight: BMI < 18.5; Normal weight: BMI 18.5-24.9; Overweight: BMI 25-30; Obese: BMI > 30 = 4
(n= 853 and n=41 n=1 missing data)

8.3.5 Comparison of demographic information of the control and intervention groups at baseline

The median age of the participants in the control group was 53 years (IQR: 49-58 range) and was not significantly different (p = 0.276) from the median age of the intervention group, which was 57 years (IQR: 53-61 an) as seen in Figure 21 below.

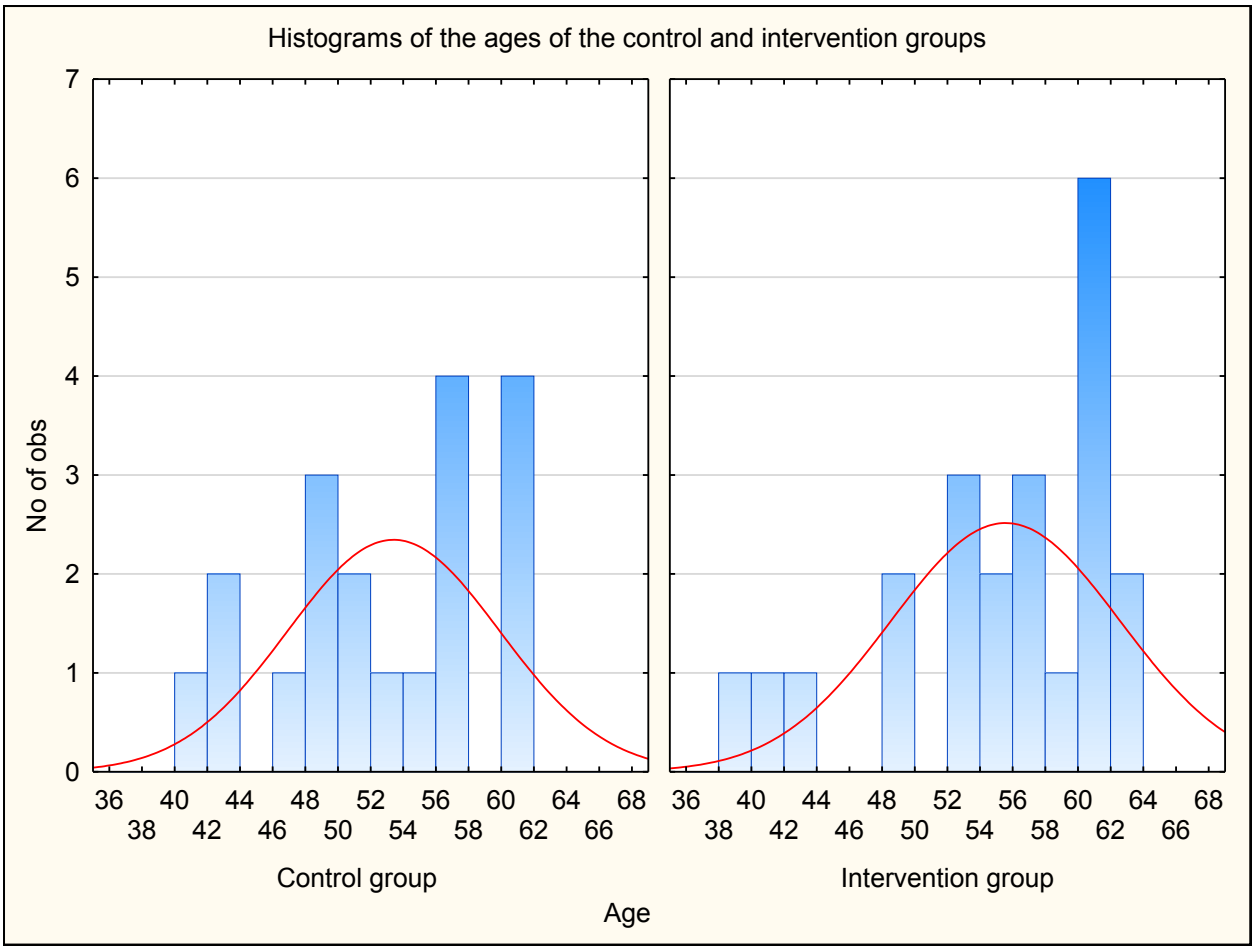


Figure 21: Descriptive statistics regarding the age of the participants in the control and intervention group

(n=42)

There was no difference in proportions between control and intervention group and any demographic or living condition variable, although a larger proportion of the control group spoke Sesotho (75% compared to 50%). (Table 59) In the control group 40% of the participants had never been married while, 32% of the participants in the intervention group had never been married. Over 75% of both groups lived in brick houses and owned their own homes.

Table 59: Demographic and living conditions of the participants in the control and intervention group

Variable	Categories	Control (n = 20)	Control percentage	Intervention (n = 22)	Intervention percentage	Between Groups (Fisher's Exact tests)
Language	Sesotho	15	75%	11	50%	p = 0.285
	Isixhosa	2	10%	6	27%	
	Setswana	3	15%	5	23%	
Race	African	20	100%	22	100%	N/A
Marital Status	Married	7	35%	7	32%	p = 0.671
	Never married	8	40%	7	32%	
	Widowed	4	20%	6	27%	
	Separated/divorced	0	0%	2	9%	
House ownership	Own	17	85%	18	81%	p = 1.000
	Friend/family	3	15%	4	18%	
Type of dwelling	Brick	15	75%	19	86%	p = 0.445
	Informal	5	25%	3	14%	
Number of residents per household	1	1	5%	2	9%	p = 0.866
	2	3	15%	3	14%	
	3	7	35%	5	23%	
	4	2	10%	4	18%	
	5	6	30%	8	36%	
	6	1	5%	0	0%	

The participants in both the control group and the intervention group could read and write, and 60% of the participants in the control group and 64% in the intervention group had secondary education (Table 60). The unemployment rate in the control group (70%) was significantly different (p = 0.003) from that of the intervention group (86%). The two reasons given by participants in both the control and intervention group for unemployment was the inability to find a job and health problems. A small number of participants in both groups received grant benefits. In the control group 40% received a benefit, while 27% in the intervention group received a benefit. A pension was the type of grant that was received by most of the participants who received a benefit, with 88% of the control group and 33% in the intervention group receiving the benefit.

Table 60: Education level and employment status of the participants in the control and the intervention group

Variable	Categories	Control (n = 20)	Control percentage	Intervention (n = 22)	Intervention percentage	Between Groups (Fischer's Exact test)
Literacy	Read/write	20	100%	22	100%	p = 1.000
Education	Primary	8	40%	8	36%	p = 1.000
	Secondary	12	60%	14	64%	
Current employment status	Unemployed	14	70%	19	86%	**p = 0.003**
	Pensioner	6	30%	0	0%	
	Worker - Part time	0	0%	3	14%	
Reason for unemployment (n = 14 and n = 19)	Cannot find work	7	50%	10	53%	p = 0.971
	Health problems	6	43%	8	42%	
	Family care	1	7%	1	5%	
Receive grant benefits	No	12	60%	16	73%	p = 0.515
	Yes	8	40%	6	27%	
Type of grant benefits (n = 8 and n =6)	Disability	1	13%	4	67%	p = 0.091
	Pension	7	88%	2	33%	

(n=42)

There was therefore no significant difference between the two groups, apart from the higher percentage of unemployed participants and the lower percentage on pension in the intervention group.

8.3.6 Health-related information

8.3.6.1 Comparison at baseline

At baseline there were no differences in the median of the health variables of the participants in the control and intervention groups (Table 61).

Table 61: Health variables at baseline of the participants in the control and intervention group

Variable	Control			Intervention			Between Groups (Mann Whitney U test)
	n	Median	IQR	n	Median	IQR	
Weight (kg)	15	99.3	80.1-104.8	22	88.9	76.3-96.4	p = 0.159 (Z = 1.408)
Height (cm)	15	157	154-162	22	155	153-158	p = 0.245 (Z =1.163)
BMI (kg/m^2)	15	38.3	33.5-45.2	22	36.1	31.4-38.9	p = 0.246 (Z = 1.160)
Haemoglucose (mmol/l)	15	5.6	5.1-6.1	22	7.3	5.4-10.0	p = 0.246 (Z =-1.161)
Systolic BP (mmHg)	15	141	126-159	22	141.5	133-150	p = 0.828 (Z= 0.217)
Diastolic BP (mmHg)	15	90	84-99	22	92	83-96	p = 0.865 (Z= 0.170)

(n=37)

8.3.6.2 Comparison at six weeks

To investigate possible differences within and between groups, the Sign test was used to compare median values within groups and the Wilcoxon Two Sided test (also known as the Mann Whitney U Test) was used to compare median values between groups. There were no significant within-group differences from baseline to six weeks in either group. In addition, there were no significant between-group differences at six weeks (Table 62).

Table 62: Health variables of the control participants and intervention participants at baseline and after six weeks

Variable	Score	Control Group (n=15) (Sign test)		Intervention Group (n=22) (Sign test)		*Between Groups (Wilcoxon Two Sample Test)*	
		Baseline	After 6 weeks	Baseline	After 6 weeks	*Baseline*	*After 6 weeks*
BMI (kg/m^2)	Median (IQR)	38.3 (33.5-45.2)	38.6 (33.4-44.8)	36.1 (31.4-38.9)	35.9* (31.7-39.6)	p = 0.246 Z= 1.160	p = 0.259 Z = 1.129
	Median difference within group (IQR)	0.0 (-0.7-0.5) p = 0.789 Z = -0.267		-0.1 (-0.4-0.2) p = 0.264 Z = 1.118		p = 0.793 Z = 0.263	
Haemoglucose (mmol/l)	Median (IQR)	5.6 (5.1-6.1)	6.0 (5.3-8.1)	7.3 (5.4-10.0)	6.5 (5.5-8.3)	p = 0.246 Z = -1.161	p = 0.599 Z = -0.526
	Median difference within group (IQR)	-0.4 (-1.2–0.2) p = 0.121 Z = 1.549		0.1 (-0.9-1.7) p = 0.831 Z = -0.213		p = 0.252 Z = -1.145	
Systolic BP (mmHg)	Median (IQR)	141 (126-159)	144 (133-152)	141.5 (133-150)	146.5 (139-155)	p = 0.828 Z = 0.217	p = 0.687 Z = -0.403
	Median difference within group (IQR)	-0.7 (-25.0-16.0) p = 1.000 Z = -0.000		-4.5 (-17.0-8.0) p = 0.286 Z = 1.066		p = 0.853 Z = 0.186	
Diastolic BP (mmHg)	Median (IQR)	90 (84-99)	90 (83-94)	92 (83-96)	90.5 (83-104)	p = 0.865 Z = 0.170	p = 0.988 Z = -0.016
	Median difference within group (IQR)	1.0 (-6.0-8.0) p = 0.789 Z = 0.267		-1.0 (-9.0-5.0) p = 0.663 Z = 0.436		p = 0.556 Z = 0.588	
Resting pulse rate (bpm)	Median (IQR)	71 (63-79)	75 (73-92)	72 (63-83)	76.5 (68-82)	p = 0.8284 Z = -0.217	p = 0.7806 Z = 0.279
	Median difference within group (IQR)	-3.0 (-13.0-0.0) p = 0.061 Z = 1.870		0.5 (-13.0-8.0) p = 1.000 Z = -0.000		p = 0.330 Z = -0.975	

Variable	Score	Control Group (n=15) (Sign test)		Intervention Group (n=22) (Sign test)		*Between Groups (Wilcoxon Two Sample Test)*	
		Baseline	**After 6 weeks**	**Baseline**	**After 6 weeks**	***Baseline***	***After 6 weeks***
Pulse rate after one minute (bpm)	Median (IQR)	88 (82-107)	93 (84-106)	85 (77-99)	91.5 (84-99)	p = 0.5155 Z = 0.650	p = 0.6425 Z = 0.464
	Median difference within group (IQR)	-2.0 (-7.0-3.0) p = 0.789 Z = 0.267		-0.5 (-11.0-7.0) p =1.000 Z = 0.000		p = 0.841 Z = -0.201	

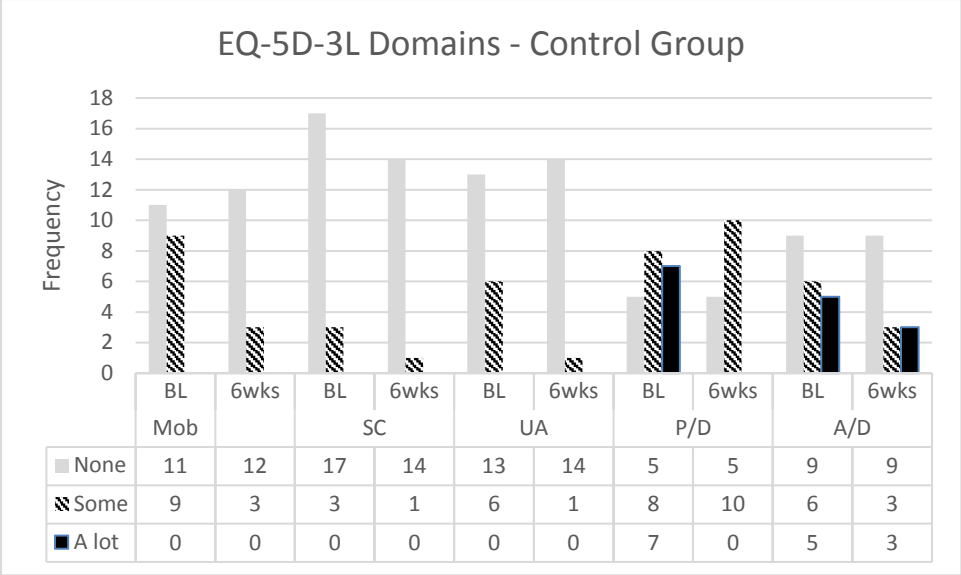
*Note that the body weight of the participants in the intervention group increased but the BMI is reported to be lower. This could be due the mathematical calculation of the median in the data analysis software.

To summarise, there was no significant difference between the health variables of the control group versus the intervention group at baseline and at six weeks.

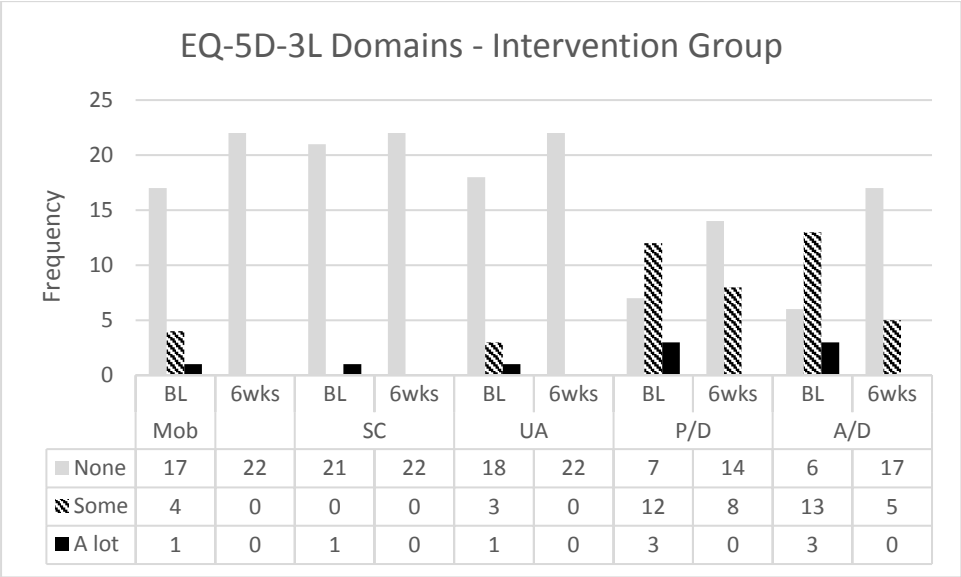
8.3.7 Health-related quality of life

The quality of life experienced by participants within and between the control and intervention group is summarised in

Table 63. For detailed information regarding the comparison of quality of life experienced between and within the control and the intervention group please refer to Appendix 36.



BL=Baseline, 6wks = 6 weeks
Mob=Mobility, SC=Self care, UA=Usual Activities, P/D =Pain/Discomfort, A/D=Anxiety/Depression
n=20 at Baseline, n=15 at six weeks



BL=Baseline, 6wks = 6 weeks
Mob=Mobility, SC=Self care, UA=Usual Activities, P/D =Pain/Discomfort, A/D=Anxiety/Depression
None = No problems Some = Some problems A lot = a lot of problems
n=22 at Baseline, n=22 at six weeks

Figure 22: EQ-5D-3L domains in the control and intervention groups

Table 63: Dimensions for the quality of life experienced by participants in the control and intervention group

EQ-5D-3L Item	Group	Time	p-value (within-groups) (Sign test)	Mean (SD) (between groups)	p-value (between groups) (Wilxocon Two Sample test)
Mobility	Control	Baseline	p = 0.134	21.4 (26.4)	Baseline:
		After 6 weeks	Z = 1.500	21.2 (15.3)	p = 0.178
					Z = 1.346
	Intervention	Baseline	*p = 0.074*	17.4 (26.4)	After 6 weeks:
		After 6 weeks	Z = 1.789	17.5 (15.3)	***p = 0.034***
					Z = 2.126
Self-care	Control	Baseline	p = 0.480	19.2 (12.7)	Baseline:
		After 6 weeks	Z = -0.707	19.7 (9.1)	p = 0.844
					Z = 0.197
	Intervention	Baseline	No	18.9 (12.7)	After 6 weeks:
		After 6 weeks	variance	18.5 (9.1)	p = 0.248
					Z = 1.156
Usual Activities*	Control	Baseline		20.5 (24.1)	Baseline:
		After 6 weeks	p = 0.248	19.7 (9.1)	p = 0.362
			Z = 1.155		Z = 0.912
					After 6 weeks
	Intervention	Baseline	p = 0.134	17.9 (24.1)	p = 0.248
		After 6 weeks	Z = 1.500	18.5 (9.1)	Z = 1.156
Pain/Discomfort	Control	Baseline	p = 0.149	22.1 (29.8)	Baseline:
		After 6 weeks	Z = 1.443	22.3 (27.9)	p = 0.123
					Z = 1.156
	Intervention	Baseline	***p = 0.043***	16.9 (29.8)	After 6 weeks:
		After 6 weeks	Z = 2.021	16.7 (27.9)	p = 0.077
					Z = 1.768
Anxiety/Depression	Control	Baseline	p = 0.505	18.2 (29.9)	Baseline:
		After 6 weeks	Z = 0.667	21.4 (25.9)	p = 0.700
					Z = -0.385
	Intervention	Baseline	***p = 0.010***	19.5 (29.9)	After 6 weeks**:**
		After 6 weeks	Z = 2.582	17.4 (25.9)	p = 0.171
					Z = 1.369

** Usual activities include work, study, housework, family or leisure activities. Note that a positive z score indicates improvement and a decrease in the level of problems reported.*

(Control n=15, Intervention n=22)

There was no association between group and score in any of the domains at baseline (Table 64). At six weeks the Intervention group reported significantly fewer problems in mobility (p = 0.034). There were no significant within-group differences found in the control group, but the intervention group improved in the pain/discomfort (p = 0.043) and anxiety/depression domains (p = 0.010).

Table 64: Comparison of the Index and VAS scores in the control and intervention group

		Control Group (n=15) (Sign Test)		**Intervention Group (n=22) (Sign Test)**		***Between Groups (Wilxocon Two Sample Test)***	
		Baseline	**After 6 weeks**	**Baseline**	**After 6 weeks**	***Baseline***	***After 6 weeks***
EQ-5D-3L Index score	Median (IQR)	0.7 (0.1 – 0.7)	0.7 (0.7 – 1.0)	0.7 (0.4 – 0.8)	1.0 (0.8 – 1.0)	p = 0.160 Z = 1.404	**p = 0.019** Z = 2.344
	Median difference within group (IQR) p-value	-0.3 (0.0 – -0.7) P = 0.121 Z = 1.549		-0.3 (0.0 – 0.-6) ***p = 0.010*** Z = 2.593		p = 0.913 Z = 0.109	
EQ-5D-3L VAS	Median (IQR)	50 (50 – 50)	60 (50 – 80)	60 (50 – 70)	70 (50 – 80)	*p = 0.055* Z = 1.918	p = 0.270 Z = 1.102
	Median difference within group (IQR) p-value	10 (-10 – 30) p = 0.267 Z = 1.109		10 (-10 – 30) p = 0.823 Z = -0.224		p = 0.729 Z = 0.346	

Note: An increase in scores indicates an improvement in HRQOL

(Control n=15, Intervention n=22))

The median EQ-5D-3L Index scores in both the control and intervention group increased from baseline to six weeks, but this was only significant in the participants in the intervention programme (p = 0.010) (Table 64). The intervention group also improved more (from 0.7 to 1.0) and there was a significant between-group difference at six weeks (p = 0.019).

The correlation between the Index and the VAS scores at baseline in all participants was rho = 0.17, p = 0.280

Although both groups showed improvement in the quality of life VAS score, there was no significant difference in the median difference between the control and intervention groups (p = 0.913). As the difference in score at baseline approached significance (p = 0.055), the median difference within groups was compared and found to be non-significant.

8.3.8 Self-efficacy for managing chronic diseases

The Self-efficacy for Managing Chronic Disease six-item scale consists of six items namely fatigue, discomfort, emotion, symptoms, tasks and do things, scored between 0 (not at all confident) and 10 (totally confident). A higher score indicates higher self-efficacy. The scale showed good internal consistency at baseline with Cronbach's alpha (α) at baseline equal to 0.887 (control group: α = 0.863 and intervention group: α = 0.894) and excellent internal consistency at six weeks after intervention with α equal to 0.904 (control group: α = 0.869 and intervention group: α = 0.933).

The scores, which are numerical, were normally distributed (SW $p < 0.05$) and parametric statistics were used.

At baseline, scores for all the domains were equivalent. There were significant within-group improvements in the intervention group in the fatigue (p = 0.024) and discomfort (p = 0.022) items and the difference in fatigue between the two groups approached significance after six weeks (p = 0.053). (Table 65)

Table 65: Self-efficacy of managing chronic disease of participants in the control and the intervention group

Managing Chronic Diseases Item	Group	Time	Mean (SD)	Mean difference (SD) and within-group comparison (Paired T-test)	Comparison of mean values between groups (Unpaired T-test)
Fatigue	Control	Before	7.0 (3.3)	1.1 (3.5)	Baseline:
		After 6 weeks	5.9 (2.5)	p = 0.262	p = 0.2102
				t Value = 1.17	t Value = 1.63
					After 6 weeks:
	Intervention	Before	5.7 (2.7)	-1.7 (3.3)	*p = 0.053*
		After 6 weeks	7.5 (2.1)	***p = 0.024***	t Value = 4.005
				t Value = -2.44	
Discomfort	Control	Before	6.3 (3.0)	0.4 (2.3)	Baseline:
		After 6 weeks	5.9 (2.7)	p = 0.510	p = 0.418
				t Value = 0.68	t Value = 0.673
					After 6 weeks:
	Intervention	Before	5.6 (2.5)	-1.5 (2.7)	p = 0.156
		After 6 weeks	7.1 (2.2)	***p = 0.022***	t value = 2.105
				t Value = -2.49	
Emotion	Control	Before	6.7 (2.9)	0.8 (2.6)	Baseline:
		After 6 weeks	5.9 (2.6)	p = 0.258	p = 0.375
				t Value = 1.18	t Value = 0.807
					After 6 weeks:
	Intervention	Before	5.9 (2.7)	-1.1 (3.2)	p = 0.236
		After 6 weeks	7.0 (2.5)	p = 0.144	t Value = 1.454
				t Value = -1.52	
Symptoms	Control	Before	6.2 (2.8)	0 (2.5)	Baseline:
		After 6 weeks	6.2 (2.6)	p = 1.000	p = 0.241
				t Value = 0.00	t Value = 1.421
	Intervention	Before	5.0 (3.1)	-1.5 (3.8)	After 6 weeks:
		After 6 weeks	6.5 (2.6)	*p = 0.078*	p = 0.734
				t Value = -1.86	t Value = 0.117
Tasks	Control	Before	7.1 (2.5)	-0.1 (3.3)	Baseline:
		After 6 weeks	7.3 (2.5)	p = 0.880	p = 0.400
				t Value = -0.15	t Value = 0.728
	Intervention	Before	6.4 (2.6)	-0.2 (2.8)	After 6 weeks:
		After 6 weeks	6.6 (2.1)	p = 0.760	p = 0.385
				t Value = -0.31	t Value = 0.774

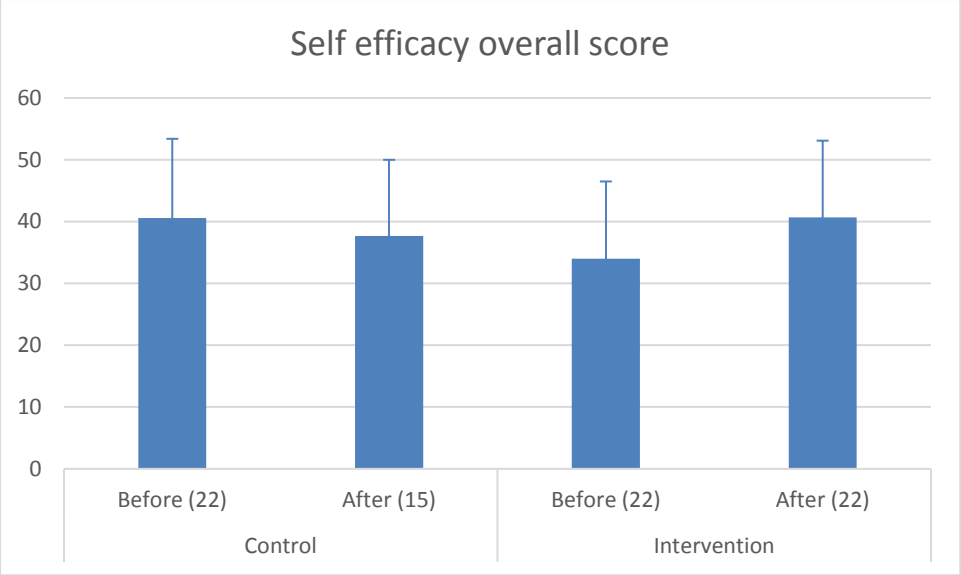
Managing Chronic Diseases Item	Group	Time	Mean (SD)	Mean difference (SD) and within-group comparison (Paired T-test)	Comparison of mean values between groups (Unpaired T-test)
Do things	Control	Before	7.3 (2.3)	1.5 (3.9)	Baseline:
		After 6 weeks	5.8 (2.8)	p = 0.162	p = 0.097
				t Value = 1.47	t Value = 2.905
	Intervention	Before	5.9 (2.6)	-0.2 (3.3)	After 6 weeks:
		After 6 weeks	6.1 (2.7)	p = 0.751	p = 0.755
				t Value = -0.32	t Value = 0.099

Note: An increase in scores indicates an improvement in self-efficacy.

(Control n=15, Intervention n=22)

To increase the responsiveness of the Self-efficacy scores, the total was calculated out of 60 as this is how the instrument was scored by the designer (426, 495). The correlation between the EQ-5D-3L Index score and the total Self Efficacy scores was r = 0.27; p = 0.082

There were no significant within- or between-group differences in the overall self-efficacy score (Table 66). As the intervention group had a lower mean score at baseline (although not significant, p=0.097) , the mean difference between the two groups from baseline to six weeks was calculated and found to be significantly greater in the intervention group (p = 0.040). As can be seen from Figure 23 the control group got worse, while the intervention group improved.



Note: An increase in scores indicates an improvement in self-efficacy. The error bars indicate the standard deviation (Control n=15, Intervention n=22)

Figure 23: Self-efficacy overall score between control and intervention group

Table 66: Self-efficacy of managing chronic disease overall score of participants in the control and the intervention groups

Managing Chronic Diseases	Group	Time	Mean (SD)	Mean difference (SD) and within-group comparison (Paired T-test)	Comparison of mean values between groups (Unpaired T-test)
Overall score	Control	Before	40.6(12.8)	-3.6 (12.8) p = 0. 296 t = 1.09	Baseline: p = 0.141 t Value = -2.27 After 6 weeks: p = 0.387 t Value = 0.88
		After 6 weeks	37.7(12.3)		
	Intervention	Before	34.2(12.5)	+6.5(14.8) p = 0. 055 t = -2.04	
		After 6 weeks	40.7(12.4)		
Change in score	Control	From baseline to six weeks	-3.6(12.8)	N/A	***p= 0.040*** t Value=2.13
	Intervention	From baseline to six weeks	6.5 (14.9)	N/A	

Note: An increase in scores indicates an improvement in self-efficacy.

(Control n =15, Intervention n =22)

The overall scores for the scale were also calculated as the mean of the six items. The mean overall scores of the control group and of the intervention group were similar at baseline (p = 0.141) and after six weeks (p = 0.387) as can be seen in Table 66. The mean decrease in the overall score of the control group was not significant (p = 0.296). The mean increase in the overall score of the intervention group also was not significant (p = 0.055).

8.3.9 Brief Pain Inventory

All of the participants in the control group and the intervention group indicated that they had experienced pain other than everyday kinds of pain (minor headaches, toothache and sprains).

8.3.9.1 Sites of pain for the control and intervention group at baseline

Most of the participants reported pain at more than one site. At baseline, the most common site of pain in the control group was the knee joint (12), followed by the ankle (10) and the hip joint (6). Participants reported bilateral pain in 18 joints, which included all peripheral joints. In total, there were 52 pain sites. The most common site of pain in the intervention group was the knee joint in participants (23), followed by the ankle (15) and the shoulder joint (10). Participants reported bilateral pain in 28 joints, which included all peripheral joints. In total, there were 90 pain sites.

Table 67: Sites of pain for the control and intervention group at baseline

Control (n=15)	Count (n) (%)	Intervention (n=22)	Count (n) (%)
Knee	12 (23.1%)	Knee	23 (23.5%)
Ankle	10 (19.2%)	Ankle	15 (16.7%)
Lumbar	5 (9.6%)	Lumbar	6 (6.7%)
Thoracic	4 (7.7%)	Thoracic	8 (8.9%)
Shoulder	5 (9.6%)	Shoulder	10 (11.1%)
Headache	3 (5.8%)	Headache	5 (5.6%)
Elbow	3 (5.8%)	Elbow	7 (7.8%)
Hip	6 (11.5%)	Hip	7 (7.8%)
Hand	3 (5.8%)	Hand	4 (5.5%)
Cervical	0 (0%)	Cervical	3 (3.3%)
Whole body	0 (0%)	Whole body	0 (0%)
Wrist	0 (0%)	Wrist	1 (1.1%)
Lower limb	1 (1.9%)	Lower limb	1 (1.1%)
Feet	0 (0%)	Feet	0 (0%)
SIJ	0 (0%)	SIJ	0 (0%)
Number of sites	52 (100%)	Number of sites	90 (100%)

At six weeks, the most common site of pain in the control group was the knee joint (9), followed by the shoulder (7) and the ankle joint (5). Participants reported bilateral pain in 28 joints, which included all peripheral joints. In total, there were 35 pain sites, whereas the most common site of pain in the intervention group was the knee joint (7) participants, followed by the lumbar spine (6); the shoulder joint (5) and the wrist joint (5). Participants reported bilateral pain in eight joints, which included all peripheral joints. In total, there were 39 pain sites. The number of pain sites had decreased from baseline to after six week for both groups.

Table 68: Sites of pain for the control and intervention group after six weeks

Control (n=15)	Count (n) (%)	Intervention (n=22)	Count (n) (%)
Knee	9 (25.7%)	Knee	7 (17.9%)
Ankle	5 (14.3%)	Ankle	3 (7.7%)
Lumbar	4 (11.4%)	Lumbar	6 (15.4%)
Thoracic	2 (5.7%)	Thoracic	2 (5.1%)
Shoulder	7 (20.0%)	Shoulder	5 (12.8%)
Headache	0 (0%)	Headache	3 (7.7%)
Elbow	4 (11.4%)	Elbow	3 (7.7%)
Hip	2 (5.7%)	Hip	0 (0%)
Hand	0 (0%)	Hand	1 (2.6%)
Cervical	1 (2.9%)	Cervical	2 (5.1%)
Whole body	0 (0%)	Whole body	0 (0%)
Wrist	1 (2.9%)	Wrist	5 (12.8%)
Lower limb	0 (0%)	Lower limb	0 (0%)
Feet	0 (0%)	Feet	0 (0%)
SIJ	0 (0%)	SIJ	1 (2.6%)
Number of sites	35 (100%)	Number of sites	39 (100%)

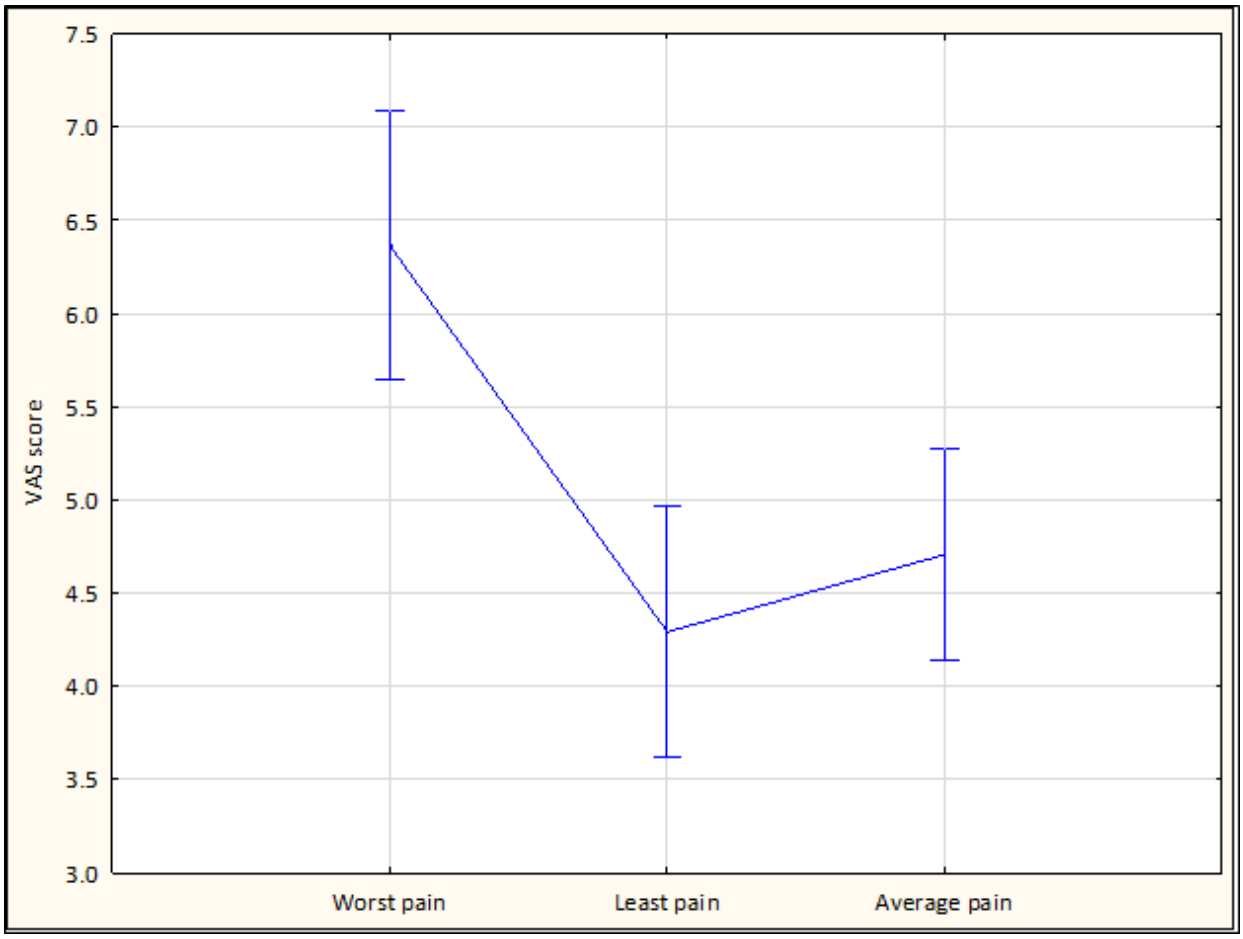
(Control n=15 and Intervention n = 22) Please note that the sites of pain are noted per area and not specifically for the left or the right side of the body.

8.3.9.1.1 Pain descriptors of the Brief Pain Inventory

Within the Brief Pain Inventory, the Pain Severity Scale was determined using the following four items: pain at its worst in the last 24 hours; pain at its least in the last 24 hours; pain on the average; pain participants experience while completing the questionnaire. A higher score on the Pain Severity Scale indicates worse or more severe pain. The average pain severity experienced by the participants was calculated by dividing the four item scores by four. This Pain Severity Scale showed good internal consistency at baseline and six weeks after intervention with Cronbach's alpha equal to 0.801 and 0.895 respectively.

A repeated measure ANOVA, indicated that there was a significant difference between the levels of pain reported in both groups and that the difference lay between the worst pain and the other two

levels of pain. The need to test the discriminative validity of the instrument was identified by the researcher, to establish if the participant understood the numerical concepts required by the instrument.



F= 22.8, p<.001 n=37

Figure 24: VAS scores for worst pain, least pain and average pain

Pain now was not included as there was no expectation that it would be higher, lower or the same, whereas the other descriptors were self-evident. There was no significant within- or between-group difference in any item, including the mean score for pain severity either at baseline or at six weeks (Table 69) apart from a within-group increase in % pain relief in the intervention group ($p = 0.003$)(Figure 25)

Table 69: Pain descriptors in last 24 hours between control and intervention group

Brief Pain Inventory	Group	Time	Mean (SD)	Mean difference (SD) and within-group comparison (Paired T-test)	Comparison of mean values between groups (Unpaired T-test)
Worst pain	Control	Before	6.5 (2.4)	-1.2 (3.2) p = 0.170 t Value = 1.45	Baseline: p = 0.3993 t Value = 0.85 After 6 weeks: p = 0.8884 t Value = 0.14
		After 6 weeks	5.3 (3.2)		
	Intervention	Before	5.9 (2.3)	-0.7 (3.6) p = 0.387 t Value = 0.88	
		After 6 weeks	5.2 (3.2)		
Least pain	Control	Before	3.7 (1.7)	+0.1(3.9) p = 0.895 t Value = -0.13	Baseline: p = 0.4149 t Value = -0.83 After 6 weeks: p = 0.3470 t Value = -0.95
		After 6 weeks	3.9 (3.2)		
	Intervention	Before	4.3 (2.1)	+0.5 (3.4) p= 0.485 t Value = -0.71	
		After 6 weeks	4.8 (2.8)		
Average pain	Control	Before	4.4 (1.6)	+0.2(2.5) p = 0.760 t Value = -0.31	Baseline: p = 0.5588 t Value = -0.59 After 6 weeks: p = 0.9661 t Value = -0.04
		After 6 weeks	4.6 (2.5)		
	Intervention	Before	4.7 (1.7)	-0.1 (2.7) p = 0.876 t Value = 0.16	
		After 6 weeks	4.6 (2.6)		
Pain right now	Control	Before	5.1 (3.3)	-1.7 (3.9) p = 0.123 t Value = 1.65	Baseline: p = 0.6305 t Value = 0.49 After 6 weeks: p = 0.8230 t Value = -0.23
		After 6 weeks	3.3 (3.0)		
	Intervention	Before	4.7 (2.4)	-1.2 (4.0) p = 0.184 t Value = 1.38	
		After 6 weeks	3.5 (3.2)		
Percentage pain relief with pain treatments or medication	Control	Before	58.0 (28.3)	+12.9 (31.7) P = 0.153 t value = -1.52	Baseline: p = 0.4723 t Value = 0.528 After 6 weeks: p = 0.5017 t Value = 0.461
		After 6 weeks	72.1 (22.6)		
	Intervention	Before	50.0 (35.2)	+31.5 (40.5) ***p = 0.003*** t Value = -3.45	
		After 6 weeks	77.6 (23.9)		

Brief Pain Inventory	Group	Time	Mean (SD)	Mean difference (SD) and within-group comparison (Paired T-test)	Comparison of mean values between groups (Unpaired T-test)
Mean score for pain severity	Control	Before	5.0 (1.9)	-0.7 (2.7) p = 0.328 t Value = 1.014	Baseline: p = 0.897 t Value = 0.13 After 6 weeks: p = 0.760 t Value = -0.31
		After 6 weeks	4.3 (2.6)		
	Intervention	Before	4.9 (1.6)	0.4 (2.9) p = 0.582 t Value= 0.55	
		After 6 weeks	4.5 (2.6)		

(Control n=15 and Intervention n = 22)

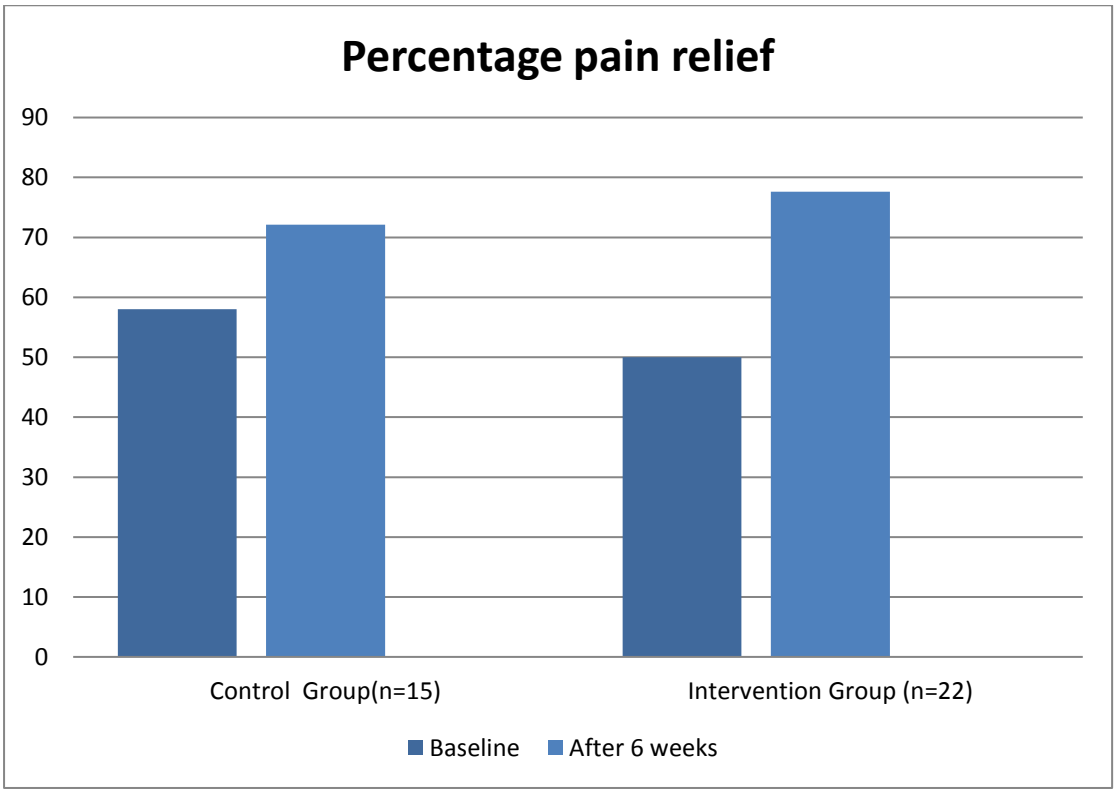


Figure 25: Percentage pain relief experienced by control and intervention group

8.3.9.1.2 Pain interference

The Pain Interference scale of the Brief Pain Inventory consists of seven items, and these are: general activity; mood; walking ability; normal work (both work outside the home and housework);

relations with other people; sleep; and enjoyment of life. This interference scale showed excellent internal consistency with Cronbach's alpha (α) at baseline equal to 0.983 and six weeks after intervention with α equal to 0.957.

Table 70: Pain interference with activities in the last 24 hours between control and intervention group

Brief Pain Inventory	**Group**	**Time**	**Mean (SD)**	**Mean difference (SD) and within-group comparison (Paired T-test)**	**Comparison of mean values between groups (Unpaired T-test)**
General activity	Control	Before	3.2 (2.7)	+0.2 (4.2)	Baseline:
		After 6 weeks	3.5 (3.3)	p = 0.810, t Value = -0.24	p = 0.342, t Value = -0.96
	Intervention	Before	4.1 (3.0)	-0.6 (5.4)	After 6 weeks:
		After 6 weeks	3.5 (3.5)	p = 0.611 t Value = 0.52	p = 0.946 t Value = -0.07
Mood	Control	Before	4.5 (3.9)	-1.5 (5.4)	Baseline:
		After 6 weeks	2.9 (2.8)	p = 0.294 t Value = 1.09	p = 0.620 t Value = -0.50
	Intervention	Before	5.0 (3.1)	-0.9 (4.8)	After 6 weeks:
		After 6 weeks	4.2 (3.1)	p = 0.408 t Value = 0.85	p = 0.217 t Value = -1.26
Walking ability	Control	Before	3.7 (3.8)	- 0.1 (5.9)	Baseline:
		After 6 weeks	3.6 (3.7)	p = 0.965 t Value = -0.05	p = 0.126 t Value = -1.57
	Intervention	Before	5.7 (3.6)	-1.3 (5.7)	After 6 weeks:
		After 6 weeks	4.5 (3.6)	p = 0.315 t Value = 1.03	p = 0.444 t Value = -0.77
Normal work*	Control	Before	3.4 (3.1)	+0.4 (5.6)	Baseline:
		After 6 weeks	3.5 (3.4)	p = 0.816 t Value = -0.24	p = 0.179 t Value = -1.37
	Intervention	Before	5.1 (3.8)	-0.7 (5.9)	After 6 weeks:
		After 6 weeks	4.4 (3.7)	p = 0.597 t Value = 0.54	p = 0.473 t Value = -0.73

Brief Pain Inventory	Group	Time	Mean (SD)	Mean difference (SD) and within-group comparison (Paired T-test)	Comparison of mean values between groups (Unpaired T-test)
Relations with other people	Control	Before	3.8 (3.7)	-0.7 (5.4) p = 0.639 t Value = 0.48	Baseline: p = 0.404 t Value = -0.84
		After 6 weeks	3.1 (3.5)		
	Intervention	Before	4.9 (3.8)	-0.5 (6.5) p = 0722 t Value = 0.36	After 6 weeks: p = 0.349 t Value = -0.95
		After 6 weeks	4.4 (4.1)		
Brief Pain Inventory	**Group**	**Time**	**Mean (SD)**	**Mean difference (SD) and within-group comparison (Paired T-test)**	**Comparison of mean values between groups (Unpaired T-test)**
Sleep	Control	Before	5.9 (3.4)	-2.0 (4.8) p = 0.125 t Value = 1.63	Baseline: p = 0.360 t Value = 0.93
		After 6 weeks	3.9 (3.5)		
	Intervention	Before	4.9 (3.5)	-0.4 (5.4) p = 0.752 t Value = 0.32	After 6 weeks: p = 0.613 t Value = -0.51
		After 6 weeks	4.5 (3.6)		
Enjoyment of life	Control	Before	3.9 (4.3)	-0.9 (5.6) p = 0.532 t Value = 0.64	Baseline: p = 0.359 t Value = -0.93
		After 6 weeks	3.0 (3.1)	-0.9 (5.4) p = 0.479 t Value = 0.72	After 6 weeks: p = 0.2427 t Value = -1.19
	Intervention	Before	5.1 (3.5)	-0.9 (5.6) p = 0.532 t Value = 0.64	Baseline: p = 0.631 t Value = 0.49
		After 6 weeks	4.4 (3.6)	0.9 (5.4) p = 0.479 t Value = 0.72	After 6 weeks: p = 0.823 t Value = -0.23
Mean score for pain interference	Control	Before	4.1 (2.8)	-0.7 (4.7) p = 0.548 t Value = 0.62	Baseline: p = 0.364 t Value = -0.92
		After 6 weeks	3.3 (2.9)		
	Intervention	Before	5.0 (3.1)	-0.7 (5.1) p = 0.524 t Value = 0.65	After 6 weeks: p = 0.377 t Value = -0.90
		After 6 weeks	4.3 (3.3)		

*(Control n=15 and Intervention n = 22) *Normal work includes both work outside the home and housework*

Similar to the pain descriptors, no significant within or between group differences were found with regard to the different pain interference items or the total Pain Interference Score (Table 70).

8.3.9.1.3 Concurrent validity of BPI

The concurrent validity of the BPI was tested against the EQ-5D-3L pain dimension. There were no significant differences in the mean of the BPI, pain now, VAS score across the pain dimension levels of no pain, some pain and severe pain in the EQ-5D-3L ($F = 2.34$, $p = 0.108$).

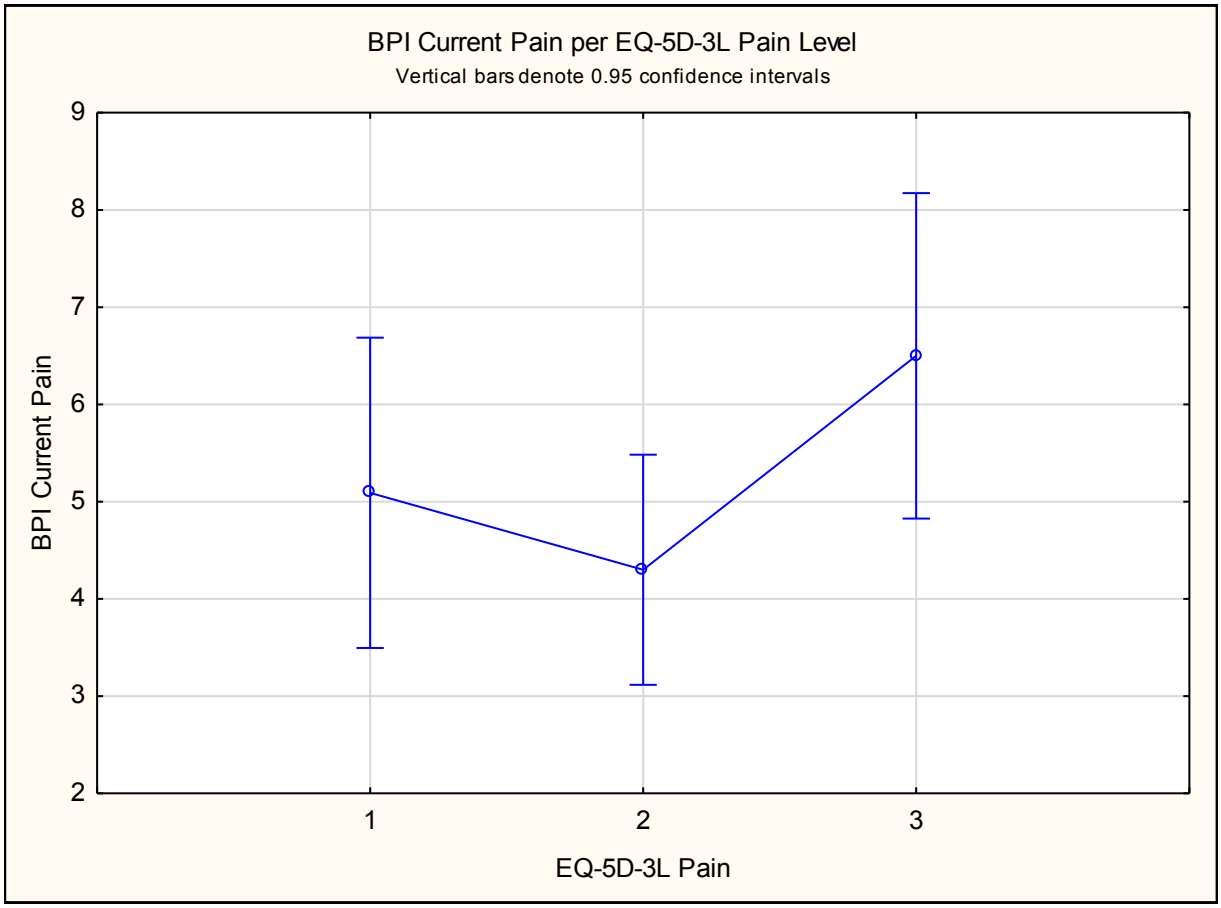


Figure 26: BPI current pain per EQ-5D-3L pain level

8.3.10 Comparison of International Physical Activity Questionnaire between and within the control and the intervention group

The sample size for the International Physical Activity Questionnaire (IPAQ) data was small (n=18) as can be seen in Table 71 below. In order to calculate the IPAQ categories of physical activity, complete data sets are needed and therefore participants were excluded from data analysis if they responded to questions with "Don't know / Not sure". Due to the large number of missing

responses with regards to the number of days and time, which made it difficult to calculate the number of minutes of physical activity per week, analysis was consequently restricted to comparing the number of respondents who reported doing vigorous, moderate or low physical activity. Due to missing information, only five participants in the control group and 13 participants in the intervention group could be compared at baseline, and after six weeks only four participants in the control group and 12 in the intervention group provided information.

Table 71: Number of participants indicating level of activity between control and intervention group

IPAQ	Group	Time	Percentage of participants	p-value (Fisher's Exact Test)
Vigorous	Control	Before	60%	Baseline: p = 1.000 After 6 weeks: p = 0.250
		After 6 weeks	75%	
	Intervention	Before	54%	
		After 6 weeks	100%	
Moderate	Control	Before	20%	
		After 6 weeks	Missing data	
	Intervention	Before	31%	
		After 6 weeks	Missing data	
Low	Control	Before	20%	
		After 6 weeks	25%	
	Intervention	Before	15%	
		After 6 weeks	0%	

*** Vigorous-** vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling
Moderate - moderate physical activities; like carrying light loads, bicycling at a regular pace, or doubles tennis
Low - walking at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure
(n=12 intervention group n=4 control group)

As the intervention group reported spending 100% of their time on vigorous activity, the validity of the IPAQ in this group was questionable. In addition, the large amount of missing responses further raised concerns and this measure was not used in further analysis.

8.3.11 Pedometer readings

The participants in the intervention programme were encouraged during the educational sessions each week to increase their activity levels and received pedometers to monitor their activity levels.

Unfortunately, this was not successful due to participants losing, breaking or resetting the pedometers and there was no objective measure to monitor compliance with the set goals.

8.3.12 Comparison of Simmonds battery of functional tests between and within the control and the intervention group

The results of the Simmonds Test Battery are in Table 72. There was a significant within group difference for all items except for the sit-to-stand in the control group and the belt-tie in both groups. The intervention group performed significantly better at six weeks on the sit-to-stand ($p = 0.013$) and distance walked ($p = 0.020$) items. However, as the distance walked was significantly different at baseline, the change in score was compared and this was not found to be significant, with the change in the control group being greater than that seen in the intervention group ($t = -0.13$, $p = 0.890$).

Table 72: Simmonds battery of functional tests between control and intervention group

Simmonds functional test	Group	Time	Mean (SD)	Mean difference (SD) and within-group comparison (Paired T-test)	Comparison of mean values between groups (Unpaired T-test)
Walk normal (sec)	Control	Before	18.92(2.84)	2.5 (2.3)	Baseline:
		After 6 weeks	16.42(2.19)	***p = 0.001***	p = 0.537
				t Value = 4.16	t Value = 0.388
	Intervention	Before	18.31(3.00)	2.5 (2.9)	After 6 weeks:
		After 6 weeks	15.81(2.18)	***p = 0.001***	p = 0.404
				t Value = 4.09	t Value = 0.714
Walk fast (seconds)	Control	Before	13.41(1.27)	1.2 (2.0)	Baseline:
		After 6 weeks	12.25(1.90)	***p = 0.039***	***p = 0.013***
				t Value = 2.27	t Value = 6.94
	Intervention	Before	12.25(1.34)	0.8 (1.0)	After 6 weeks:
		After 6 weeks	11.42(1.28)	***p = 0.001***	p = 0.120
				t Value = 4.01	t Value = 2.537
Unloaded reach (centimetres)	Control	Before	28.73(7.33)	-8.7 (10.0)	Baseline:
		After 6 weeks	37.40(6.40)	***p = 0.005***	p = 0.681
				t Value = -3.33	t Value = 0.172
	Intervention	Before	27.77(6.16)	-6.9 (5.6)	After 6 weeks:
		After 6 weeks	34.64(5.92)	***p = <0.001***	p = 0.186
				t Value = -5.76	t Value = 1.8218

Simmonds functional test	Group	Time	Mean (SD)	Mean difference (SD) and within-group comparison (Paired T-test)	Comparison of mean values between groups (Unpaired T-test)
Sit-to-stand (seconds)	Control	Before	2.00(0.39)	0.2 (0.4)	Baseline:
		After 6 weeks	1.85(0.53)	p = 0.1874	p = 0.064
				t Value = 1.39	t Value = 3.664
	Intervention	Before	1.74(0.41)	0.2 (0.4)	After 6 weeks:
		After 6 weeks	1.51(0.24)	***p = 0.010***	***p = 0.013***
				t Value = 2.82	t Value = 6.840
Put sock on (seconds)	Control	Before	10.91(6.56)	2.5 (4.4)	Baseline:
		After 6 weeks	8.45(4.71)	***p = 0.049***	p = 0.277
				t Value = 2.15	t Value = 1.221
	Intervention	Before	8.91(4.48)	2.2 (3.9)	After 6 weeks:
		After 6 weeks	6.70(3.76)	***p = 0.015***	p = 0.218
				t Value = 2.64	t Value = 1.574
Loaded reach (centimetres)	Control	Before	19.20(5.49)	-12.5 (8.8)	Baseline:
		After 6 weeks	31.73(6.90)	***p = <0.001***	p = 0.460
				t Value = -5.54	t Value = 0.559
	Intervention	Before	20.91(7.58)	-9.6 (7.5)	After 6 weeks:
		After 6 weeks	30.55(6.85)	***p = <0.000***	p = 0.609
				t Value = -6.01	t Value = 0.267
Reach up (seconds)	Control	Before	3.80(0.83)	1(1.1)	Baseline:
		After 6 weeks	2.77(0.73)	***- p= 0.003***	p = 0.774
				t Value = 3.66	t Value = 0.084
	Intervention	Before	3.72(0.83)	1.3 (0.9)	After 6 weeks:
		After 6 weeks	2.46(0.44)	p = <0.000	p = 0.116
				t Value = 6.60	t Value = 2.596
Distance walk (metres)	Control	Before	476.47(80.69)	-62.5 (71.3)	Baseline:
		After 6 weeks	538.93(59.76)	***p = 0.004***	***p = 0.020***
				t Value = -3.40	t Value = 5.915
	Intervention	Before	534.05(63.18)	-59.4 (67.7)	After 6 weeks:
		After 6 weeks	593.41(60.43)	***p = 0.001***	***p = 0.011***
				t Value = -4.11	t Value = 7.312
					Mean difference:
					p = 0.894
Belt-tie (seconds)	Control	Before	10.60(1.99)	-0.6 (4.3)	Baseline:
		After 6 weeks	11.20(4.16)	p = 0.603	p = 0.065
				t Value = -0.53	t Value = 3.638
	Intervention	Before	9.03(2.72)	-0.1 (2.0)	After 6 weeks:
		After 6 weeks	9.10(2.54)	p = 0.871	p = 0.066
				t Value = -0.16	t Value = 3.613

(Control n=15, Intervention n=22)

8.3.13 Acceptability

There was an attendance rate of 87.9% for the six week intervention programme. Participants were asked during a group session what they liked most and least of the programme, as well as what they would change about the programme (Table 73; Table 74; Table 75 and Table 76) are indicated below. The responses of the participants were categorised/grouped together. In some instances if a participants responded in the group, other participants indicated their agreement to the statement and the data was presented as the total number of participants in agreement with the statement. As can be seen from the responses, the participants enjoyed the intervention programme.

Table 73: What participants liked most about the programme

Comment	Frequency
"I feel so much better".	3
"I do things at home easier like hanging up washing".	3
"I enjoyed the exercises with others".	2
"I liked coming to the exercises every week".	1
"I enjoyed it.	2
"I made new friends".	3
"I don't know".	3
"I am looser – move easier".	2
"The dancing".	3

Table 74: What participants liked least about the programme

Comment	Frequency
"Liked it".	22

Table 75: What participants would change in the programme

Comment	Frequency
"More dancing".	9
"More playing with the balls".	6
"Like it".	4
"Why can you not always come – we want to go on with you".	9
"More games".	4
"Nothing".	13

Table 76: What participants thought about the workbook

Comment	Frequency
"It helped me".	6
"I showed it to my friend".	2
"I used it".	1
"Don't know".	11
"Too much to read".	2

8.3.14 Adverse outcomes

No harm to participants was experienced during the intervention.

8.3.15 Summary

There were 20 participants allocated to the control group, of whom five were not available for the six week follow-up. All 22 participants randomised to the intervention group remained in the study. The intervention sample resembled the survey population from which it was drawn, apart from being older, with fewer of the women in employment and living in houses with more household members. They had a higher haemoglucose score and a higher BMI.

The demographic data of the control group and the intervention group were equivalent, apart from the larger proportion of unemployed participants in the intervention group as well as having fewer members on pension in the intervention group. With regard to health status, there was no difference either at baseline or at six weeks between the groups. With regards to HRQOL at six weeks, the intervention group reported significantly fewer problems in mobility as well as in

pain/discomfort and showed a trend towards fewer problems with anxiety/depression. The index score showed significant within-group improvement in the intervention group and, after having been equivalent at baseline, was significantly higher in the intervention group at six weeks. The VAS improved in both groups, but no significant changes were found. On the Self-efficacy scale, the intervention group showed within- group improvements in the fatigue and discomfort items and the difference in fatigue between the two groups approached significance at six weeks. The change from baseline to six weeks in the overall self-efficacy score was significantly greater in the intervention group.

The lower limbs were the most common sites of pain in both groups, and included the knee (most reported), followed by the ankle and then the hip. The number of sites of pain decreased from 52 sites in the control group at baseline to 35 sites after six weeks, and 90 sites in the intervention group at baseline to 39 sites after six weeks. No difference was found between the groups on any of the subsections of the BPI, apart from a within-group increase in the percentage pain relief through treatment. There was a lack of concurrent validity between the BPI and the EQ-5D-3L VAS score. The IPAQ results were not analysed due to the large number of incomplete responses and the questionable validity of the findings. Within-group improvement was found on most of the items on the Simmonds battery of functional tests with the intervention group performing better than the control group on the sit-to-stand and the distance walked items.

The acceptability questionnaire revealed that the participants had all enjoyed the intervention and, apart from including more dancing and games, they would not change the programme and would like it to continue. The attitude towards the workbook was more ambiguous, with 13 either having no comment or reporting that it was too much to read.

8.4 Discussion

8.4.1 Introduction

The aim of the sub-study was to explore the effectiveness of a non-pharmacological six weeks intervention programme for middle aged women presenting with only musculoskeletal conditions or musculoskeletal conditions and at least one of the following co-morbidities: hypertension, obesity or diabetes mellitus type II. The main findings of the sub-study were that in general the intervention had little effect on the health condition or BMI of the participants. However there was evidence that

mobility (including distance walked), pain/discomfort, anxiety/depression and fatigue on the EQ-5D-3L HRQOL instrument were positively affected by attendance at the class. In addition, the high compliance with attendance, 88%, and the positive responses to the Acceptability Questionnaire, indicated that the intervention was well received and appropriate for this group of women. Another finding is that the numerical scales, such as the VAS of the EQ-5D-3L, the BPI and the IPAQ did not perform well and, despite the inclusion criterion of literacy, the participants did not appear to have an adequate level of numeracy to respond appropriately.

8.4.2 Sample

There was a somewhat disappointing response in the recruitment phase, and many of the eligible potential participants did not respond to the recruitment invitation. Although the sample was similar in most respects to the population, the larger number of unemployed and older participants in the intervention sample, could indicate that those who were younger and in employment were unable to make the time available to attend. The larger household size might also imply that they had greater family responsibilities, but these hypotheses are untested.

Another explanation for the difference between the more unemployed sample and the survey population is that social position in society is strongly correlated with the health outcomes of an individual. Individuals from deprived backgrounds experience more disability in their lives (644) and a strong positive correlation is found between income, whether a person's household or individual income, and their health outcomes (645). Most of the participants in the intervention group (79%) were unemployed. More than half of the participants (52%) in the intervention group stated that not being able to find a job was the reason for their unemployment while 42% indicated that their health problems prevented them from being employed. Therefore, although receiving some income, most of the individuals in the intervention could be classified as being in the lower range of socio-economic status despite living in brick houses.

The differences discussed above do not necessarily imply that the results cannot be generalised to the survey population as the survey population and the intervention group were similar in most respects. However, the timing of the intervention (e.g. on weekdays and during the day) might be a factor that could be altered in the future. If classes were offered outside of working hours, it might allow more participants to attend.

8.4.3 Health conditions and impairments

There is ample evidence that exercise has benefits for individuals with chronic diseases of lifestyle (114, 332, 646-649). This study did not set out to prove that exercise is beneficial in general, but that the intervention programme given, resulted in these benefits. However, participation in the intervention did not result in any health condition advantages, which was unexpected. The reasons are not immediately obvious, but could be ascribed to insufficient exercise dosage due to a lack of adherence, environmental barriers and/or the lack of individualised exercise programmes. The dosage of exercise, once a week for 45 to 60 minutes, is too small to bring about physiological improvement and the participants might not have supplemented this with increased extra-class activity up to the desired 150 minutes per week (650-652). According to Shephard (1978) as cited in Dishman (1985) individuals who perceive their health as being poor are unlikely to adhere to an exercise programme and if they decide to do so, they are likely to do as little exercise as possible (402, 653). The participants in the intervention programme were encouraged during the educational sessions each week to increase their activity levels and received pedometers to monitor their activity levels. Unfortunately, this was not successful due to participants losing, breaking or resetting the pedometers and there was no objective measure to monitor compliance with the set goals. The IPAQ was also intended to monitor the levels of physical activity, but this too proved to be unreliable. Although the participants did give feedback in the group every week during the educational session regarding completion of the goal setting activities in the workbook, this does not necessarily imply that participants did comply with the set goals.

The individuals' knowledge of, attitude towards and beliefs about their health and physical activity; their perceived needs and abilities to perform the activity as well as their environment all influence their ability to adopt and maintain physical activity (654). Although the workbook addressed the educational aspects surrounding activity, environmental barriers might have outweighed the individuals' intention to increase their activity levels (654). Environmental factors can also hinder or facilitate exercise programmes or physical activity (655-658). Factors such as safety, facilities, family and community attitudes, and appropriate equipment (e.g. good walking shoes) might have resulted in participants missing their activity targets. The influence of environmental factors was not adequately explored in this study and should be studied further.

A second consideration is that exercise programmes should be individualised in people with chronic diseases of lifestyle taking into account the individuals' current fitness levels, choosing the most

appropriate practical levels of exercise intensity, duration and frequency of the exercise sessions (332, 594). Therefore, the way forward might be to not use a restricted standard programme which stipulates 20 minutes or 40 minutes of exercises typically used for improving fitness, but to individualise the programme so that the goals of the individual with chronic diseases are met (332). This strategy should be explored in the future, with more targeted exercise programmes being developed for individuals. The disadvantage of this is that developing a more targeted programme for each individual would require a greater level of expertise than the simply presenting a uniform programme.

8.4.4 Health-related quality of life

8.4.4.1 EQ-5D-3L Domains and index score

As reported in many studies of community dwelling participants, the most commonly reported problems were in the anxiety/depression, pain/discomfort, mobility and performing usual activities domains (406, 659-661). The high number of participants reporting pain was as per the inclusion criteria, but 11 participants in the control and 14 in the intervention group (59.5%) reported problems with anxiety/depression. These figures are higher than the anxiety/depression experienced by isiXhosa speaking individuals living with a disability in an urban population (16.9%) and rural (2.1%) (659), while being slightly fewer than the 63.5% in the socially and culturally diverse suburb of Woodstock in Cape Town (661). The reason for the differences in reported anxiety/depression could be due to socio-economic circumstances of the specific community. It is noteworthy that the intervention resulted in a large decrease in the numbers reporting problems over the course of the study. This decrease is reflected in the significant improvement in the EQ-5D-3L Index score.

In contrast to the articles reviewed in Chapters 3 and 4, which did not report significant improvements in HRQOL, the intervention group reported a significant improvement in the EQ-5D-3L Index score. Whereas both groups reported a median score of 0.7 at baseline, the intervention group increased to 1 over the course of the study, whereas the control group remained the same. This is a clinically significant change as the Index score represents a Quality Adjusted Life Year (QALY). An improvement of 0.3 QALY implies that the intervention group gained almost one third of a year of healthy life, provided that the benefit of the intervention does last for one year. To put

this QALY gain into perspective, the National Institutes of Health Care and Excellence of the United Kingdom (NICE), which uses the EQ-5D-3L index to calculate the cost-utility of different interventions, suggests that £20,000-£30,000 is a reasonable amount to pay per QALY (662, 663). The gain of the intervention group would justify the expenditure of approximately £7,000 or R150 000 at current exchange rates. Although obviously the threshold cost of a QALY gain in a high income country, such as the United Kingdom, would be far higher than in South Africa, the gain in HRQOL in the intervention group is clearly considerable. Further cost-utility analysis is recommended to determine what the actual cost of the intervention offered was, but this was beyond the scope of this particular study.

8.4.4.2 EQ-5D-3L VAS

Although the median health score of the control and the intervention groups improved from baseline to after six weeks, the EQ-5D-3L VAS did not demonstrate greater improvement in the intervention group. The median scores were low, 50 to 60, even when compared to similar groups in South Africa. The mean EQ-5D-3L score for individuals living with HIV in the high-density suburb of Khayelitsha, in Cape Town was 60.4 (664); in a resource-poor community in the Western Cape 61.7 before HAART treatment (30) and 66.1 in isiXhosa-speaking individuals with disabilities in a rural community and 60.3 in an urban community (659). According to Deaton (2008,) people in high income countries are more likely to be satisfied with their health and they become less satisfied with their health with age. The rate at which health satisfaction decreases with age is greater in low and middle income countries like South Africa. It seems that income provides some protection against the effect of aging on self-perceived health. Individuals between the ages of 50-59 years are less satisfied with their health even in more affluent countries (665). The median age of the control group of the present study was 56 years, and for the intervention group 52 years, which would fall within the boundaries of the above-mentioned age group. The possible reason for this age group experiencing less satisfaction with their health is that the group might be particularly intolerant of the first signs of aging (665). As mentioned above, the median health score for the rural sample in the study of Jelsma et al., (2007) was 66.1 and for the urban sample slightly lower at 60.3 (659). The lower scores in the present study could be attributed to the different cultures, and also the differences in the age groups of the two studies as well as the study conducted by Jelsma et al (2007) including males (659).

However, the validity of the VAS is somewhat questionable in this context. Forty two percent of the respondents scored 50 on the scale, which may indicate a lack of understanding of what the scale represents. In addition, concurrent validity was poor as there was no correlation between the EQ-5D-3L Index and the VAS scores. The validity of the isiXhosa versions of both the WHODAS-2 and the VAS of the EQ-5D-3L was established in an urban, under-resourced area (406, 466), in Cape Town. However, both appeared to lack concurrent validity in the current group of participants and this is discussed further below.

8.4.5 Self-efficacy

The Self-efficacy scale did perform better than the EQ-5D-3L VAS but there were some aspects that require caution. The internal consistency was high and there was a trend towards correlation with the EQ-5D-3L Index score. However, there was some clustering around mid-scores (5 for individual scores and 30 for the total) and full scores (6 for individual and 60 for the total).

The standard deviations of the mean scores were high and no within- or between-group difference was noted. Nevertheless, the amount of change in the intervention group was found to be significantly greater than in the control group. Self-efficacy plays an important role in the management of a chronic disease and it has been found that there is a correlation between self-efficacy and pain in musculoskeletal conditions such as low back pain, rheumatoid arthritis and fibromyalgia as well as other chronic diseases including diabetes mellitus (23, 335, 426, 440, 487-490). According to the model of Bandura, self-efficacy is obtained by an individual through five sources: information, vicarious experience, verbal encouragement and persuasion, accomplishment of certain goals or activities and finally the physiological state of the individual (485). Bandura also states that “the more dependable the experiential sources, the greater are the changes in perceived self-efficacy”(485). Therefore, the combination of the workbook based on self-efficacy theory (22, 334, 428, 619) in addition to the intervention programme, improved the self-efficacy of the intervention group.

There is a definite shift in responsibilities of the day-to-day management of chronic diseases away from the health care professional to the individual living with the chronic disease (619). Self-management and self-efficacy may be the mechanisms to bridge the gap between the patient’s needs and the capacity of the present health system services to meet the needs of the individuals

living with chronic diseases (619). The emphasis on training self-efficacy as a key component of the intervention could be introduced into other health promotion programmes within a similar population.

8.4.6 Chronic pain

The intensity of chronic pain is linked more with emotional and psychosocial factors than with the pain intensity itself (666). An important role is played by depression and anxiety in the reporting of pain intensity and the higher the pain intensity the bigger the role that is played by the anxiety experienced by the individual (667). Therefore, the impact of pain on the quality of life or participants should be considered rather than the pain intensity when treatment for pain is assessed clinically or in research (668). It is suggested that the intensity of chronic pain should be interpreted in the light of other outcome measures such as quality of life and satisfaction with the treatment, which in the case of the present study is, the intervention programme (669). As the HRQOL index showed improvement and the satisfaction with the intervention was high, it would be expected that the pain would decrease over the six weeks. Disappointingly, the Brief Pain Inventory did not observe any decrease in pain severity or in pain interference with function in the intervention or the control group.

It could be that the intervention did not have an influence on the pain reported, but, as the EQ-5D-3L pain/anxiety domain showed a significant improvement in the intervention group and the number of sites of pain decreased from 90 to 35, this was unlikely. It would also be surprising that the percentage reporting pain relief in both groups increased from approximately 55% to 75% in both groups in the absence of any improvement in pain. Another explanation for this result is that the participants were insufficiently numerate to respond appropriately. This is partially supported by the large number of respondents who chose the mid-point of 5 (16-30%), but refuted by the repeated measures ANOVA which did indicate appropriate differences between the scores of the different levels.

The model upon which the intervention was based, is that individuals should decrease their attempts to control or avoid pain and instead focus on living life to the fullest. They should participate in activities that they enjoy and pursue personal goals despite pain, which could have been emphasised more during the intervention programme (670). It is possible that with education

the pain intensity and pain interference of the intervention group could decrease further over time as it was emphasised to the participants in the intervention group that they should increase their physical activity levels. However, as noted in Section 8.4.3, the commitment to activity outside of the weekly sessions was not measured and lack of compliance with this aspect of the programme might have been responsible for the poor outcome with regard to pain relief.

In summary, the effect of the intervention on pain, as measured by the BPI, is not clear, as the BPI failed to capture the results seen with the EQ-5D-3L VAS.

8.4.7 Functional impact

Of interest was the fact that the participants in both groups showed an improvement in function over the course of the six weeks in almost all the items of the Simmonds battery of functional tests. The only item in which the intervention group performed better was the sit-to-stand item. Although sit-to-stand was not specifically included in the intervention programme, half squats and lunges were included which potentially strengthened the leg muscles of the participants which could have led to the improvement in the sit-to-stand item. The problem of inadequate monitoring of extra-sessional physical activity has been discussed previously and an inadequate increase in exercise dosage might be the reason that no impact was noted (652). As previously stated, at least 150 minutes per week of moderate-intensity physical activity or 60 minutes of vigorous intensity aerobic activity (651), is necessary to bring about health benefits for an individual.

8.4.8 Behavioural changes

Although there was improvement in certain outcomes in the individuals after the six week intervention programme, the changes were not significant. A systematic review and meta-analysis examining the effectiveness of behavioural interventions targeting diet and physical activity in low-income adults found that the interventions had a small positive effect on behaviour (671, 672). Most of the studies included in the review primarily targeted women and the interventions were often delivered by a healthcare professional. The analysis of the variation in physical activity studies in the review, showed a trend towards studies being more effective if a single behaviour change was targeted, rather than two behaviours. This substantiates the argument that human self-regulation draws on limited resources which might be best applied to one single behavioural change at a time

(671, 672). As more than one behavioural change was targeted in the intervention programme used in the present study, this may have led to a reduced impact. In future studies it is suggested that one behavioural change be targeted at a time. As the workbook was used to facilitate behaviour changes, the researcher also explored the readability of the outcome measure questionnaires utilised in the study as well as the readability of the workbook to explore whether this could have an influence on the outcome measures (See Chapter 6, Development of the Intervention).

The most important consideration for the present study is that the questionnaires and the workbook were translated into Sesotho and the participants were language proficient in Sesotho and consequently the Flesch Reading Ease formula which only calculates the reading difficulty in English is only an indicator and not a predictor of the difficulty level of the reading material of this study. In the questionnaire on acceptability of the intervention, more than half of the respondents were ambivalent regarding the use of the workbook. It is suggested that the contents and layout of the workbook be refined further to meet the requirements of participants with low levels of literacy. More use of pictorial material and less content should be explored in the future and subjected to further validation and cognitive debriefing.

8.5 Acceptability and feasibility

Both the attitudes of the peers in the exercise class as well as the attitude of the research assistants during the entire six weeks intervention programme may have contributed to the compliance of the participants to attend the weekly exercise programme and could have contributed to the improved HRQOL detected. The physical environment may also influence the exercise programme including the weather, the convenience of the exercise setting and the actual geographic proximity of the facility to home (673). The issues of environmental barriers was minimised in the current study in that the facility utilised for the intervention programme was centrally located, within walking distance for most of the participants or easily accessible via taxi. An ethical consideration taken into account during the study was that participants received taxi money in advance each week to ensure that they would be able to afford to attend the next exercise session the following week. The time of year and time of day of the exercise programme was ideal as the summer months and winter months in the Free State are accompanied by extreme temperatures that could have influenced the joint pain that the participants were experiencing.

The feedback received regarding the sessions was consistently positive. The importance of including culturally acceptable and enjoyable items in the programme (634), such as dancing, was highlighted. Despite a lack of improvement in the impairment and functional measures, the participants perceived their HRQOL to have improved considerably, as measured by the EQ-5D-3L Index score. It is also possible that their Self-efficacy improved through the education sessions and the interactions with their peers.

As discussed above, the attitude towards the workbook was not so positive and the content and structure might need to be revisited for future use. On a positive note is that the feedback regarding the group sessions were something the participants liked and they perceived the outcome as good.

8.6 Strengths and limitations of the study

The major strength of the study is that it complies with the STROBE statement checklist (674) of items that should be addressed during randomised controlled trials. The checklist will be used to critique the study. The full STROBE statement checklist is attached as Appendix 37. The major weaknesses, including a smaller sample size than anticipated and the questionable validity of some of the outcome measures, are discussed.

8.6.1 Strengths

The strengths of study when analysed against the STROBE statement checklist are described. The scientific background and the explanation of the rationale for the study are provided, with the aim of the study as well as the objectives of the study being listed. The trial design is described and no changes to the methods were made after the trial commenced. Changes made after the pilot study are described and explained. The eligibility criteria for participants as well as the settings and locations where the data was collected are described in detail. The intervention for each group is described either in the text or provided as an appendix to allow replication, including how and when the intervention was performed. Information about how and when outcomes were assessed is provided. Changes made to the trial outcomes after the trial commenced, with reasoning are identified. Calculation of the sample size is shown and as no interim analyses and stopping guidelines were applicable during the study, no mention is made of this criterion.

The randomisation process is described in full as well as the allocation and the concealment mechanisms. The implementation method as well as the blinding after assignment is also discussed. Statistical methods used to compare the groups as well as the intervention with the survey population are listed. Baseline data as well as data after six weeks are set out in the results section. The numbers analysed for each group as well as number of participants are included in the results. No harm to participants was experienced during the intervention and therefore none is mentioned in the reporting of the study. Limitations, generalisability as well as interpretation of results are discussed. The registration number and name of trial registry is provided. Sources of funding and role of the funders is mentioned under acknowledgements.

8.6.2 Limitations

A fundamental limitation to the study was the small sample size. Individuals from low-income groups are more difficult to recruit successfully to interventions and therefore the small sample size is not unique to the present study (675-677). The sample size was calculated using data from a similar study in a primary health care clinic (PHCC) in Cape Town with a target of 37 women in each group. The calculated sample size was not reached in the study despite numerous attempts during enrolment to increase the number of participant willing to participate in the study. Ultimately only 42 participants were randomised into a control and intervention group. A further five participants were lost to follow-up in the control group. The study was thus underpowered and in some cases a Type 2 error might have occurred.

A further limitation resulting from the small sample size is the validity of performing repeated statistical analyses on a small data set as has been done in this study.

Although the participants showed commitment towards the intervention programme, and adhered to the workbook, there is no certainty that the participants committed themselves to their set goals as determined by themselves in the workbook. The increased levels of physical activity would have been verifiable if the pedometers which were to be used by participants had not been lost, re-set or broken. Therefore the researcher had to rely on self-reporting of the participants regarding their increased physical activities during the week. The accuracy of self-reporting of physical activity is affected by socio-demographic characteristics of the individuals and gender, with females not reporting their physical activity levels accurately (678). In addition, physical activity self-reporting is

not as accurate amongst obese individuals, with these individuals tending to over-report their physical activity (678-682).

The amount of physical activity between sessions was not monitored as the use of pedometers was not feasible and the IPAQ was not a reliable measure in this group. The lack of a measure of physical activity is a major weakness of the study. It is not possible to determine whether the small or negligible effect size for improvement in impairment, activity limitation and participation restriction (including HRQOL) was due to non-compliance or a lack of impact of physical activity. The researcher did not enquire about exercise participation during the survey and subsequently it was impossible to quantify how the intervention participants performed in relation to the survey population. Future studies will need to identify more appropriate outcome measures for physical activity.

Another limitation was the basis of categorising people as having/not having joint pain, due to the specific wording of the questions in the questionnaire. Although these questions were based on the COPCORD questionnaire, the definitions should have been clearer and the inclusion criteria had been better defined. Smaller exercise groups might also have yielded better results as the relatively large size of the group (n=22) might have impacted on group dynamics during the intervention.

The lack of a longer follow-up is a further weakness of the study which should be remedied in future studies.

As raised earlier in the discussion, it appears that human self-regulation draws on limited resources which might be best applied to one single behavioural change at a time, for example increasing physical activity levels, rather than addressing more than one behavioural change as in the present study (683). The analysis of the variation in physical activity studies in the systematic review, showed a trend towards studies being more effective if a single behaviour change was targeted, rather than two behaviours.

An unexpected limitation of the study was that the outcome measures used did not perform well and lacked concurrent validity. The items which were less complex and relied on categorisation, such as the EQ-5D-3L domains performed well, but the validity of the numeric scales, such as the VAS and BPI was questionable. The concept used in the questionnaires could have been foreign to a population that is naive to research; especially evaluative questions regarding their health and

physical activity levels. Despite the fact that the questionnaires were translated into Sesotho, and both cognitive debriefing and a pilot study were undertaken, the results indicate that numerical concepts and scales which utilise fine distinctions, such as mild, moderate, and severe, are not well understood by all participants (Cf the WHODAS 2, discussed in Chapter 6). This could have influenced the results of the study and therefore it is suggested that a future study should be conducted to determine the validity and reliability of the questionnaires in the Sesotho culture before these measurement tools are used in further research.

The poor performance of the outcome measures utilising numbers, for example the EQ-5D-3L VAS and the Brief Pain Inventory, suggests there might be a discrepancy between the numeracy levels of populations for which the questionnaire was initially developed and the population of the present study. No evidence could be found regarding the numeracy skills of an older population in South Africa. However, it is evident that poor numeracy and literacy skills are of grave concern in South Africa (684, 685).

The data of the study is not generalisable to the general population at large but rather only to the clinic population, which introduced a recruitment bias to the study. A population based survey would have been a better design but given funding and time constraints a convenience sample in the clinic was utilised and therefore introduced the potential recruitment bias to the study.

It would have been ideal to monitor the activities external to the study which might have influenced the outcome. Housework, additional physical work and other factors may have influenced the outcome but were not controlled. However, as this was a pragmatic trial, based in the community with clinic participants, it would not have been possible to prevent the participants from carrying out activities which might have confounded the results. It is hoped that the randomisation process would have resulted in similar confounding activities in both groups but this was not monitored. Thus a limitation of the study was that these activities were not identified or documented.

8.7 Conclusions and Recommendations

This was a pragmatic study with several flaws, including a smaller sample size than planned and concerns about the validity of the outcome measures which relied on numerical literacy. It may thus be useful to regard it as a pilot study for a larger, multi-centre intervention. However, the following conclusions have been reached. The intervention improved the HRQOL of the participants and

significantly increased their index score. It may have resulted in improved Self-efficacy, particularly with regard to the management of fatigue, discomfort and the overall score. It may have resulted in a decrease in pain as evidenced by the reduction in the EQ-5D-3L domain of pain/discomfort, the number of pain sites and the increased percentage pain relief in the BPI.

In light of the above, the intervention would appear to have promise and further investigation appears to be warranted. The following recommendations are thus proposed.

8.7.1 Recommendations for clinical practice

The positive response to the programme and the high compliance with attendance indicate that there is a place for group-based interventions incorporating physical activity and health education within the primary health care setting. In addition, the impressive increase in QALYS suggests that the programme may well be cost effective. The low recruitment rate which favoured unemployed, older women might require that the timing of the intervention be examined, and late afternoon or weekend classes might have a greater uptake.

The clinic staff should be more involved in the management of CDL and especially MSC by screening patients for these conditions and by ensuring that the patients are referred to physiotherapists for appropriate management by means of community-based intervention programmes and workbooks. Physiotherapists should actively participate in the development of appropriate methods of intervening at community level through the medium of primary health care clinics, and by doing so, reduce the risk of being side-lined and confined to practice within secondary or tertiary institutions, as this may negatively impact on the functioning and quality of life of those individuals with MSC who are unable to access therapy. Establishing a quality primary health care service will ensure a comprehensive response to a growing health care burden, especially in resource-poor settings and may have a potential economic impact.

The lack of effect on impairment and health condition needs to be addressed and more frequent sessions over a longer period of time (e.g. six months) may result in an improvement in these parameters. In addition, a multi-professional intervention may be the way forward, where the dietary sessions are managed by a dietician and the self-management skills by a psychologist. It is also important to recruit local community health workers as peer trainers, who could run the sessions in Sesotho and who have a good understanding of the local culture. The role of the

Physiotherapy Department of the University of the Free State could also be expanded to give students exposure to community-based interventions, especially at primary health care clinics.

8.7.2 Recommendations for policy

The study has provided enough preliminary evidence to show that resources need to be allocated to the non-pharmacological management of joint pain and co-morbidities. Physiotherapists as well as community based staff need to be employed to further develop, test and implement similar programmes at different clinics. The QALYs gained are an indication that the programme may be cost-effective and the health authorities should be encouraged to undertake cost utility analysis of an intervention, modelled on the current programme, but modified in light of the limitations of this study.

8.7.3 Recommendations for further research

Despite the rigorous translation of the questionnaires from English to the target language Sesotho, it seems that participants in the study experienced difficulty with certain constructs used in the questionnaires, especially in the Brief Pain Inventory short form. It is therefore recommended that cultural inferences regarding pain are explored in the Sesotho culture by means of qualitative data. It is also recommended that the validity and reliability of all self-reported measurement tools be tested within the Sesotho cultural context before the translated measurement tools are used in further research. Further, the validity of self-rated health should be explored within physiotherapy intervention studies and specific populations groups within the South African context. In particular the impact of lower levels of numeracy on validity needs to be examined.

It is recommended that a process of questionnaire familiarisation be followed with all participants before commencement of baseline measurements. This would ensure that participants are familiar with what is expected of them especially in populations where participants are naive to research and evaluative research questions. Some of the changes reported could have been as a result of familiarisation with the questionnaire rather than actual change.

Further research should be conducted on the effects of medication on exercise adaptability during intervention programmes designed for individuals living with chronic disease of lifestyle. This is

particularly relevant in the primary setting where individuals do not always receive their medication due to financial constraints experienced by the local governments. The impact of activities outside of the intervention context which might impact on the outcomes should be monitored.

A focus for future work should be an economic evaluation of the specific intervention programme in a primary health care clinic compared to other interventions for individuals living with joint pain, especially due to the financial constraints experienced by the local governments.

Finally, it is recommended that a large multi-centre trial of a modified intervention based on the current workbook and content be undertaken. The questionnaires would need to be validated as discussed above. Aspects which need to be modified include the length and content of the workbook and the incorporation of adequate monitoring of extra-sessional physical activity to ensure sufficient dosage of exercise.

8.7.4 Conclusion

It is important that health care professionals as well as policy makers should explore and improve interventions, to empower groups of disadvantaged people who are often neglected by the health system. These interventions should attempt to change the individuals' health behaviours and reduce the existing health inequalities. Establishing a quality primary health care service will ensure a comprehensive response to a growing health care burden; especially in resource-poor settings and in the long term may have a potential economic impact on health care in South Africa.

9 CONCLUSIONS AND RECOMMENDATIONS

9.1 Introduction

The study was undertaken to develop and ultimately test a non-pharmacological intervention which included exercise and health education for women with MSC attending a clinic in a poorly resourced area of the Free State in South Africa. In pursuit of this aim, several sub-studies were undertaken to inform the development of the intervention. This final chapter discusses the extent to which each of these sub-studies met the stated objectives and how the results influenced the decisions made with regard to the intervention programme.

9.2 Preparation and development of the intervention

The first sub-study aimed to establish the prevalence and nature of musculoskeletal conditions within the target population of adult middle-aged women. The prevalence of joint pain, experienced in either the short or long term (within the last three months) was high in the target population (62.1%). It was found that for the majority of the participants the joint pain typically had been present for over a year and was most intense after activity or after sleeping or resting. They had also experienced joint pain within the previous three months at severe to very severe levels and experienced joint stiffness that lasted more than 30 minutes, in the mornings. This pain diminished with activity. Most of the participants used over the counter medication to manage their joint pain.

The results indicated that the majority of participants with joint pain (musculoskeletal conditions) were also living with hypertension, a small number of participants with joint pain (musculoskeletal conditions) were living with diabetes mellitus type II and more than 10% of the participants with joint pain (musculoskeletal conditions) were living with both hypertension and DM II. There was no association found between DM II and joint pain (musculoskeletal conditions) in this specific population, while the association between joint pain (musculoskeletal conditions) and hypertension approached significance. With regard to risk factors for CDL, it was found that the majority of the participants in the study were overweight or obese, but the majority of the participants never used alcohol, smoked or used snuff.

The second aim of the study was to determine the impact of musculoskeletal conditions on activity limitations and participation restrictions within the target population. It was no surprise that participants with joint pain (musculoskeletal conditions) reported a poorer quality of life, both with regard to the EQ-5D-3L Index score and the more global VAS score. The HRQOL dimensions affected included mobility, usual activities, pain/discomfort and anxiety/depression. Those with joint pain (musculoskeletal conditions) experienced a mild effect on participation such as family life, work and social life, and a moderate effect on their financial position. They were currently not working or had altered their employment. They experienced fatigue and depression, and reported significantly more difficulty with concentration, walking long distances, washing and dressing, and also with interacting with unknown people and friends than those individuals without joint pain (musculoskeletal conditions).

It was thus clear that joint pain (musculoskeletal conditions) was widely prevalent in this group, often in the presence of co-morbidities. In addition it had an impact on HRQOL and functioning. The development of the proposed intervention was thus justified and should address the co-morbidities, poor HRQOL and the functional problems.

The next aim was to modify and adapt existing non-pharmacological programmes into a non-pharmacological intervention programme for the target population, with the programme designed to educate, empower, maximize functional status and improve the quality of life of the women.

The intervention was targeted at women, aged 40 to 64 years with co-morbidities and joint pain. This group was targeted for the intervention as they reported worse HRQOL and more functional problems in the anxiety/depression and pain/discomfort domains of the EQ-5D-3L and they regarded their general health as fair to poor.

The first objective of the development of the intervention component was to modify and adapt existing programmes into an intervention programme based on the results of the systematic reviews and the needs of the participants identified in the survey. The results of the systematic reviews indicated that both traditional and less conventional exercises were utilised, with different models of education provided resulting in moderate improvements in the quality of life of participants living with hypertension, DM II, obesity or MSC, but with only a small number of interventions improving function or reducing pain. Most of the health education used in reviewed studies included information on the specific disease, advice on lifestyle modifications, coping skills training and self-management skills. All of the health education sessions reviewed were culturally relevant for the

participants. A limited number of randomised clinical control trials had been conducted which included HRQOL or QOL outcome measures. In addition, the heterogeneity of samples, lack of effect sizes reporting, and the lack of standardisation of intervention programmes (either exercise or health education) all made comparison of the studies difficult. Therefore, based on the results of the systematic reviews as well as the epidemiological survey, it was clear that a multi-component lifestyle modification intervention programme which included exercise, health education, goal setting and cognitive behavioural principles for individuals living with chronic diseases was indicated.

The intervention programme was designed according to existing guidelines, but tailored to the environment and culture through the inclusion of the participants in the decision-making regarding the appropriate programme. The result was a culturally acceptable, understandable and explanatory intervention programme and workbook incorporating not only education and behavioural change strategies, but also self-efficacy, goal setting and following the principles of adult learning. The programme was designed to be held once a week for two hours (one hour education and one hour supervised exercises) for six weeks and delivered in group format. A workbook titled "Balanced lifestyle" was adapted and modified from a workbook titled "Positive Living" for people living with HIV/AIDS and "Living with Osteoarthritis: patient workbook" which was designed for a similar age group of participants living with a chronic disease. The workbook was also translated into Sesotho as the population were language proficient in English and Sesotho. As part of the development process, participants indicated that they enjoyed dancing and ball activities, which resulted in dancing activities serving as aerobic exercises and as part of cooling down, as well as activities utilising different sized balls being incorporated into the exercise programme.

9.3 Impact of the Intervention

The final sub-study examined whether the intervention would result in a significant difference between the intervention and control groups with respect to least, worst and average pain as measured by the Brief Pain Inventory (Short Form); HRQOL as measured by the EQ-5D-3L; the functional impact of joint pain (musculoskeletal conditions) on the individual and co-morbidities as measured by the Simmonds battery of functional tests and the six-minute walk test. Unfortunately, the recruitment was less than anticipated, possibly due to the timing of the intervention during working hours as there were significantly more unemployed participants, than in the general population.

The programme was well accepted and enjoyed by the participants and on cessation they requested that the programme should be continued at the community clinic. Although the Brief Pain Inventory did not record any decrease in pain severity or pain interference with function in the intervention or in the control group, the intervention group did experience an increase in the percentage pain relief through the intervention programme and the number of sites of pain decreased in both the control and the intervention groups after six weeks. With regards to HRQOL, the intervention group reported significantly fewer problems in mobility as well as in pain/discomfort and showed a trend towards fewer problems with anxiety/depression after the intervention programme. The Index Score, which reflects the QALYs gained, indicated that if the experimental group maintained their improved health status for a year, they would have gained one third of a healthy life compared to those in the control group. The EQ-5D-3L VAS score did not demonstrate greater improvement in the intervention group after six weeks, although the median health score of both groups improved from baseline to after six weeks. There was a significant improvement in the intervention group's self-efficacy in managing their chronic disease after six weeks, especially in managing their fatigue and discomfort. The self-efficacy overall score of the intervention group improved while the overall score of the control group worsened. Both groups showed an improvement in function over the course of the six weeks in almost all the items of the Simmonds battery of tests. The two items in which the intervention group performed better were in the sit-to-stand item and the distance walked item. In conclusion the intervention resulted in a large decrease in the numbers of participants reporting problems over the course of the study in the EQ-5D-3L domains.

An unexpected limitation of the study was that some outcome measures, such as the WHODAS 2.0 (which was not used in the intervention study due to poor validity in the prevalence sub-study), the VAS and BPI did not perform as expected and lacked concurrent validity. Appropriate outcome measures were chosen specifically to cover all components of the ICF. They included measures that had been previously validated in similar low income contexts. A strict translation protocol was followed and cognitive debriefing was done with participants similar to those who would take part in the main study. However, post-hoc analysis of the WHODAS 2.0 after it had been used in the epidemiological study indicated that it was not valid within the context of the study, particularly with regard to convergent and discriminate validity. This was unexpected as it had performed well in similar contexts within South Africa. As a result of these findings, the WHODAS 2.0 was not used as an outcome measure in the intervention study. The dimensions of the EQ-5D-3L appeared to give reliable, intuitively correct results, but the VAS less so.

The numerical concepts used in these questionnaires could have been foreign to a population that is naive to research. Despite a rigorous translation process, cognitive debriefing and a pilot study, the results indicated that numerical concepts and scales which utilise fine distinctions were not well understood by all participants and this factor could have influenced the results of the study.

The final objective was to determine the interrelationship between joint pain (musculoskeletal conditions) and co-morbidities of individuals as measured by blood pressure, body mass index, venous glucose readings and cardiovascular fitness using the three-minute step test. Participation in the intervention did not result in any health condition advantages, which was unexpected, as there is ample evidence that exercise has benefits for individuals with chronic diseases of lifestyle. It is suggested that the dosage of exercise might have been insufficient for physiological changes to occur.

9.4 Recommendations

Based on the experience gained in running the different sub-studies and the results obtained, recommendations for clinical practice, policy changes and identified areas in which further research might be required are put forward.

9.4.1 Clinical recommendations

The following clinical recommendations can be made:

- Based on the prevalence of joint pain (musculoskeletal conditions) in this population, a protocol should be developed for the routine screening of joint pain (musculoskeletal conditions) in community clinics.
- Guidelines should be developed for the management of joint pain in community clinics and especially for physiotherapy management of these musculoskeletal conditions.
- The intervention programme should be continued at the community clinic where the patients were enrolled for the intervention phase of the study as, in addition to the overall positive impact of the programme on HRQOL and self-efficacy, the intervention was received enthusiastically by the participants. The programme should be offered after working hours, or over weekends to allow employed women to take part.
- Consideration should be given to appointing physiotherapists at community clinics or, due to financial constraints within the Department of Health, using community service

physiotherapists to screen individuals who are complaining of joint pain and other chronic diseases of lifestyle at community clinics to determine if exercises can be safely prescribed, followed by providing the individuals with the "Balanced Lifestyle" workbook.

- The self-management approach utilised in the workbook should be utilised during clinical training of students at undergraduate level to ensure that they are able to respond to the growing health burden of South Africa.
- The biopsychosocial model approach should be central to the treatment of patients at community clinics. Staff at community clinics should be empowered to be able to manage patients at clinics with a patient-centred approach rather than a disease centred at approach which seems to be followed at present.
- Health care professionals should not view different cultures as a barrier to implementing patient-centred treatments, but should rather embrace cross-cultural differences when addressing the health needs of the population in South Africa.

9.4.2 Policy recommendations

The following policy recommendations can be made:

- Policy makers should, in collaboration with health care professionals, explore and improve interventions, to empower groups of people who are often neglected by the health system in disadvantaged populations.
- Services at community clinics should be expanded to the include screening of individuals for joint pain and chronic diseases of lifestyle.
- Physiotherapists should be appointed at community clinics to roll out intervention programmes developed for the management of chronic diseases of lifestyle and MSC.
- Establishing a quality primary health care service must be a priority to ensure a comprehensive response to a growing health care burden, especially in resource poor settings. This may in the long term have a potential economic impact on health care in South Africa.
- Health education programmes and awareness campaigns, with the intent to empower the community regarding chronic diseases including joint pain, should be rolled out by local governments and for this purpose partnerships should be formed with universities as well as professional bodies of health care professionals.

- The national health insurance system proposed for South Africa needs to be implemented in phases, with the focus of the initial phase on the burden of diseases including chronic diseases of lifestyle.
- A new strategy should be implemented by government for incorporating non-pharmacology intervention programmes, especially relating to chronic diseases of lifestyle, as part of community based services through primary health care outreach programmes. The strategy should include advocacy on major health issues in South Africa, especially the quadruple burden of disease but should also focus and respond to the issues identified by the communities.

9.4.3 Research recommendations

The primary research recommendation is that, as the sample size was smaller than anticipated and the study may have been under-powered. Further research should be undertaken before the intervention is rolled out to other clinics in the Free State or even nationally. The outcome measures will need to undergo further validation, particularly those based on numerical concepts and the Likert scale. The dosage of exercise would also need to be investigated to determine if an intervention of longer duration (e.g. three months), greater dosage (twice a week for a longer period of time) and a better system of monitoring the extra-class exercise would result in improvement in the impairments and health conditions of the participants. A large, multi-centre trial would assist in determining whether the results of this small study could be generalised to the larger population.

Other related recommendations are that:

- The constructs of all the measurement tools included in the study, but especially the BPI and the IPAQ, need to be validated by means of qualitative research methods in the Sesotho population
- The reliability and validity of the Sesotho versions (including those previously translated) in the Sesotho population, particularly in populations naive to evaluative research questions need to established.
- The prevalence and nature of joint pain amongst rural communities should be determined, as this sample was restricted to those attending a community clinic.
- Research should be conducted on the same population to determine the effects of medication on exercise adaptability during an exercise intervention programme designed for individuals living with chronic diseases of lifestyle and joint pain.

- The effectiveness of the intervention programme delivered by a multi-professional team including a physiotherapist, dietician and a psychologist in middle-aged women living with joint pain and chronic diseases of lifestyle should be investigated.
- The sustainability of the intervention programme after the six weeks session should be investigated as well as the cost-effectiveness of such an intervention programme in the community.
- A qualitative study should be conducted to determine the meaning of living with chronic diseases of lifestyle and the impact of the intervention programme from the perspective of the participants.
- The study setting could be changed to investigate the participant's way of life at home or in their specific community and develop the workbook and exercises accordingly.
- A study should be conducted to determine the interaction of the socio-economic status and chronic diseases of lifestyle in this specific population.
- An investigation into the culture of exercise in the specific population should be undertaken.

9.5 Conclusion

The participants in this study were drawn from the group most disadvantaged by the apartheid policies that were in force for most of their lives. They bear the brunt of poor widespread education, unemployment and caring for families which may have been destroyed by the HIV epidemic. They are a group of women who need the support of the health care system, but often do not receive the care they deserve. This thesis has documented the functional needs of these women and has proved that a relatively low cost intervention can be not only enjoyable and culturally acceptable, but can also improve their health-related quality of life. It should not be too much to expect that the grandmothers of the "born free" generation should eventually be given the support that they need.

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APPENDIX 1

Detailed description of intervention of chronic diseases

Systematic review

The effect of the interventions for adults with diabetes mellitus type II, hypertension or obesity summarised in table format

Author	Condition	Intervention	Effect after intervention
Chaveepojnkamjorn et al., (2009)	Diabetes mellitus type II	The programme consisted of five monthly sessions in small groups, lasting for two hours. Topics included building good relationships, improving knowledge regarding diabetes, dietary control skills, physical exercise skills, improvement in group structure, improvement in training skills for group leaders, self-monitoring, motivation for self-care and sharing experiences. Active learning (exploring, reflecting, sharing and choosing personal solutions) was encouraged.	None of the effects regarding health related quality of life, function and participation were significant.
Deinzer et al., (2009)	Hypertension	Shared decision making practice to empower patients.	None of the effects regarding health related quality of life, function and participation were significant.
Rimmer et al., (2009)	Obesity	Three groups were used: (a) awareness group that received a recommendation to exercise by their physician, information brochure on physical activity, and a toolkit for starting a physical activity programme; (b) personalised exercise programme with lower level of support. Participants received a weekly telephone consultation with a health professional to plan and maintain a physical activity programme, a toolkit, and a monthly newsletter; (c) personalised exercise programme with higher level of support, the same intervention as the lower level support group as well as participation in a monthly onsite exercise support group designed to provide an environment for mutual support and encouragement. All participants received a toolkit containing a tracking device (pedometer), postcards to track daily movement and progress, safety precautions for physical activity, information on how to monitor heart rate during activity, healthy foods and water intake information, and contact information for the National Centre on Physical Activity and Disability.	None of the effects regarding health related quality of life, function and participation were significant.

Moriyama et al., (2009)	Diabetes mellitus type II	The target focus of this programme was the acquisition of self-management skills, the patients analysing and understanding their condition so that they can work with their physiological data to acquiring knowledge of the disease and self-care. They also learned how to use family, peer, and professional support. By making self-supported decisions, the patients were able to manage their diet, exercise and stress. They also acquired disease-specific management skills. Setting goals and then monitoring the goals ensured the continuation of the desired behaviour changes and gave the patients control over their lifestyle.	None of the effects regarding health related quality of life, function and participation were significant.
Bouchard et al., (2010)	Obesity	The supervised weight loss programme contained 55%, 30%, and 15% of energy intake from carbohydrates, fats, and proteins as recommended by the American Heart Association. Food was self-selected with dietician supervision and participants were also instructed to drink water during the study. During the weight loss programme, the calorie restricted groups and the calorie restricted group + resistance training groups took part in a one hour weekly nutritional information session to help them lose weight. The goal was to reduce body weight by 0.5 kg to 1.0 kg. Participants completed a food diary and weighed themselves on a daily basis. The participants were to call the nutritionist for a quick adjustment of caloric intake when reducing body weight was not adequately achieved. Participants in the resistance training group and calorie restriction + resistance training group trained three times per week on non-consecutive days under the supervision of a kinesiologist. One repetition maximum, defined as the heaviest weight that can be moved through the entire range of motion for no more than one repetition, was initially performed for each exercise and repeated at six weeks to change the work load. All training sessions were initiated	None of the effects regarding health related quality of life, function and participation were significant.

		with a warm-up period consisting of five minutes of low-intensity cycling. Participants then performed the load phase of the resistance training which consisting of three series of eight repetitions for nine different exercises (leg press, chest press, leg extension, shoulder press, sit-up, seated row, triceps extension, arm curl, and calf extension) at 80%of their one repetition maximum. Resting periods of 60 to 90 seconds were taken between sets as suggested by the Canadian Society for Exercise Physiology. Both groups performed the same exercises.	
Dyson et al., (2010)	Diabetes mellitus type II	All subjects in the study received usual medical care from their primary care physician, including education about lifestyle management of diabetes mellitus type II from a practice nurse. In addition, subjects randomised to the video intervention received the three lifestyle videos and were requested to watch them in their own time. The videos were developed as three 10 to 15 minute videos entitled 'Food Choices', 'Physical Activity' and 'Weight Management' Each video included a mixture of expert opinion intercut with case studies.	None of the effects regarding health related quality of life, function and participation were significant.
D'Eramo-Melkus et al., (2010)	Diabetes mellitus type II	The intervention consisted of 11 weekly group sessions. The first six sessions, each two hours long, provided culturally relevant cognitive behavioural diabetes self-management training. Each of the six education sessions had specific learner objectives that were addressed by group leaders with participants actively taking part. The group context was critical for support. The first class defined diabetes, as well as diabetes related health risks. Culturally specific materials were used for each session. The focus was on cultural barriers and beliefs that support or hinder healthy dietary intake and ideal body weight. Included in the discussion was the role of social support systems or networks in behaviour change. Class material provided participants with recipes for modifying culturally preferred	None of the effects regarding health related quality of life, function and participation were significant.

		food. A culturally specific video and cookbook were also utilized. Participants discussed personal and cultural influences on their body images and identified ways of reaching their goals. The remaining five weekly group sessions, each an hour long, discussed coping skills training skills. These sessions were led by a clinical psychologist or psychiatric mental health nurse practitioner. Topics discussed included: understanding stress and managing stress; problem identification; problem-solving strategies and communication.	
Oh et al., (2010)	Metabolic syndrome	A six-month therapeutic lifestyle modification programme with 60 sessions was provided, with sessions taking place three times per week during the first three months followed by a maintenance period twice a week during the next three months. Each 90 minute sessions was delivered by the community nurse practitioner. The programme consisted of comprehensive multi-components: health monitoring, counselling, health education, exercise and diet. Health education included defining characteristics of metabolic syndrome and advice on lifestyle modifications such as exercise, diet, and self-care. Participants attended three supervised exercise sessions per week for the first three months and two sessions per week for the next three months. The supervised group exercise programme consisted of yoga stretching, rhythmic aerobic dance (Tae-Bo), warm-up and cool down exercises for 40 minutes per session. To maintain a standardised exercise protocol, participants exercised along with a recorded video. The diet instructions focused on decreasing caloric intake by reducing high-glycaemic foods (e.g., rice, noodles).	None of the effects regarding health related quality of life, function and participation were significant.

Young et al., (2010)	Hypertension	The established intervention targeted increase in physical activity to at least 180 min/week, reduce daily sodium intake to ≤ 2,300 mg, and reduce daily total fat intake ≤ to 30% and saturated fat to ≤ 10% of calories. The established plus Dietary Approaches to Stop Hypertension intervention targeted six behaviours: the same physical activity and sodium requirements as the established intervention plus daily total fat and saturated fat intake goals of ≤25% and 7% of calories, respectively. Additional the participants had to increase daily fruit and vegetable intake to at least nine servings and to increase low fat dairy servings to at least two servings per day. The weight loss goal for both groups was 6.8 kg at six months for participants who were overweight or obese at baseline (BMI values≥25 kg/m2).Both interventions consisted of 18 face-to-face contact sessions during the first six months of the intervention and 12 face-to-face sessions during the remaining 12 months.	None of the effects regarding health related quality of life, function and participation were significant.
Nicolucci et al., (2012)	Diabetes mellitus type II	The training programme for the exercise intervention group consisted of two supervised sessions of progressive mixed (aerobic and resistance) training for 150 minutes per week. A treadmill, step, elliptical, arm or cycle-ergometer was used for the aerobic training. Exercise load was calculated to achieve the prescribed exercise intensity, expressed as a percentage of maximal oxygen consumption. Resistance training consisted of four resistance exercises: chest press, lateral pull-down, leg press and abdominal flexion, or equivalent exercises targeting the same muscles. Subjects also did three stretching exercises. Intensity of exercises was adjusted according to improvements inVO2max and muscle fitness. In addition, energy expenditure was increased progressively by 0.4184 kJ/kg body weight per session every month.	None of the effects regarding health related quality of life, function and participation were significant.

Park et al., (2011)	Hypertension	The 12 week programme consists of group health education (once a week), individual counselling (once during the fourth week), and patient tailored elastic band exercise (twice a week). The education comprised of 12 weekly sessions delivered by pairs of trained nurses. The sessions included an Introduction, definition and symptoms of hypertension, complication of hypertension, medication, checking blood pressure, diet, exercise, stress management, emergency care, smoking and alcohol, self-management strategy, programme evaluation. At the fourth week, individual health counselling by trained nurse was done to encourage the initiation and maintenance of self-management behaviors, and to identify any potential problems in the programme. It took half an hour per participant. Patient tailored elastic band exercise was performed for 12 weeks (twice a week). Exercise therapists classified the participants into several groups with similar fitness levels and two to three sets of 12 to 15 kinds of exercises (15 to 25 repetitions per set) were performed using red Theraband. Exercises included warming up, light stretches and main exercises included shoulder presses, shrugs, front raises, lateral raises, biceps curls, triceps extensions, kick back's, bent over row, seated row, chest presses, leg presses, squats, good morning, abdominal curls, pelvic lifts, crunches cooling down and light stretches.	None of the effects regarding health related quality of life, function and participation were significant.
Vadstrup (2011)]	Diabetes mellitus type II	The group-based rehabilitation programme consisted of an educational component of 90 minutes group sessions held weekly for a total of six weeks. Sessions were limited to eight participants and were taught by a nurse, a physiotherapist, a podiatrist, and a dietician. The educational curriculum included: the patho-physiology of diabetes, blood glucose self-monitoring, dietary instructions, the importance of physical activity, weight loss and smoking	None of the effects regarding health related quality of life, function and participation were significant.

		cessation, neuropathy, foot examinations, hypertension, complications, and medications. A 12 week supervised exercise component consisted of 90-minutes sessions twice a week that included both aerobic and resistance exercise. The sessions were group-based, but a physiotherapist tailored an individual exercise programme for each patient. Dietary education included two three-hour group-based cooking classes and one two-hour session in a local supermarket. The education, exercise, and dietary interventions could overlap and their sequence could differ from patient to patient. The individual counselling programme consisted of individual consultations with a diabetes nurse specialist, a dietician, and a podiatrist over a period of six months. Patients participated in four one-hour sessions of individual counselling with a diabetes nurse specialist. Using the patients' own stories patients received personalized information and guidance about diabetes mellitus type II, medications, risk factors, and late complications, blood-glucoses self-monitoring, and increasing physical activity to the recommended level of 30 minutes of daily exercise. Over the same time period, patients participated in three individual counselling sessions with a dietician. At the initial hour-long visit, patients set personal goals and, in collaboration with the dietician, developed a dietary plan based on biochemical, anthropometrical and medical records and patients' motivation and attitudes. The action plan, progress towards meeting it, and goals were evaluated at the two follow-up visits, each of which lasted 30 minutes.	
Williams et al., (2012)	Diabetes mellitus type II	The intervention took place over six months during which they received the Australian TLC Diabetes programme. Its main component was the Telephone-Linked Care(TLC)	None of the effects regarding health related quality of life, function and participation were significant.

		Diabetes system, an automated interactive telephone System. The Australian TLC Diabetes system has been designed to improve diabetes management by targeting the following key self-management behaviours: blood glucose testing, nutrition, physical activity and medication-taking. Users were asked to call the system weekly using a landline or mobile phone. TLC's responses, including feedback and encouragement, were tailored according to information entered in the TLC database at the start and the answers that it received from participants during all calls.	
Da Vico et al., (2013)	Diabetes mellitus type II	The group education programme was structured in five sessions a week apart from one another, with the participation of eight to 10 patients at a time. The first session was six hours long, with the participation of a physician (60 min), a nurse (150 min), and a dietician (150 min). The subsequent four sessions had were two hours each and were led by the dietician alone, except the last, in which a 30-min participation of the nurse was also planned. The educational curriculum included general information about diabetes and its complications, nutritional needs and functions of different nutrients, characteristics of most common foods, regulation of food intake, parameters for the assessment of nutritional status (i.e., body weight, waist circumference, etc.), sweeteners and ''sugar-free'' products, benefits and risks of physical exercise, methods for physical training, cardiovascular risk factors, and self-monitoring of blood glucose. Although the programme included some traditional formal sessions, most of the time was devoted to interactivity. Participants were invited to perform practical tasks, such as estimate of portions of different foods, choice from a restaurant menu, identification of the amount of different foods with a similar nutrient content, measurement of waist	None of the effects regarding health related quality of life, function and participation were significant.

		circumference. Participants were encouraged to express their feelings toward eating and exercising, and their problems with body weight and shape, and to report their own experiences with non-pharmacological management of diabetes. One of the main features of this programme was the central role of self-monitoring. Patients were asked to self-monitor their blood glucose before and two hours after each meal (i.e., six times a day) at least once a week for all the duration of the programme, irrespective of their pharmacological therapy; this self-monitoring was promoted in order to help the patient to acquire a greater knowledge of the relationships between food intake and blood glucose control. Patients were also asked to compile self-monitoring sheets, reporting their food intake and physical exercise. Another focus of the group programme was enhancement of patients' motivation to change. Benefits determined by modification of dietary habits and increase of physical activity were discussed, with a special attention to those changes that can be directly monitored by patients, and therefore represent a positive reinforcement (e.g., increased physical fitness or reduced dyspnoea in common-day activities, reduction in measured blood glucose levels, etc.) Behavioural techniques for stimuli control were presented to reduce the risk of uncontrolled overeating, and problem-solving techniques were used as a tool to overcome obstacles to lifestyle change.	
Espeland et al., (2013)	Diabetes mellitus type II	The Intensive Lifestyle Intervention included diet modification and physical activity and was designed to induce at least an average 7% weight loss at the first year and to maintain this weight loss in subsequent years. Participants were assigned a calorie goal (1,200 to 1,800	None of the effects regarding health related quality of life, function and participation were significant.

		based on initial weight), with less than30% of total calories from fat (<10% from saturated fat) and a minimum of 15% of total calories from protein. The physical activity goal was 175 minutes or more of physical activity per week through activities similar in intensity to brisk walking. A toolbox approach that guided individualised problem solving for all participants who experienced difficulty in achieving study goals was incorporated in the treatment protocol that allowed adjustments to be made for age-related issues.	
Sakurai et al., (2013)	Obesity	Participants did warm-up exercises for a period of 10 minutes followed by a muscle strengthening routine (10 different resistance training, two sets of 12 repetitions) and exercise using resistance bands for a period of 40 min. Afterwards, participants did balance and aerobic exercise training for a period of 20 minutes. Finally, the participants were instructed to cool down for a period of 5 min. During the exercise, the participants were asked to carry out a subjective intensive exercise (ratings of perceived exertion. Exercise classes comprised of a total of 17 lessons. Dietary modification consisted of a series of four 75 minute nutritional guidance classes that were carried out under the supervision of a nationally registered dietician. The classes involved a comparison of the participants' dietary intake with a healthy, balanced dietary intake, and encouraged the participants' to increase their awareness of a healthy diet through using a food model. In addition, the participants discussed problems of dietary habits and settled issues in a group setting. Nutrition guidance classes comprised a total of five lessons.	None of the effects regarding health related quality of life, function and participation were significant.

APPENDIX 2

Detailed description of intervention of musculoskeletal disorders

Systematic review

The effect of the interventions for adults with musculoskeletal disorders summarised in table format

Author	Condition	Intervention	Effect after intervention
Hansson et al., (2010)	Osteoarthritis	During the first session the patients received education regarding human anatomy, physiology of pain and coping with pain. These sessions were presented by a physiotherapist and occupational therapist. They were also advised to use head and cold when needed. A brainstorming session was included about what patients found difficult to do. During the second session information was provided regarding exercise and physical activity. A practical demonstration of home-training exercises for the lower limbs, were shown by the physiotherapist while the occupational therapist demonstrated different orthopaedic aids. During the third session an orthopaedic surgeon, a nurse and dietician gave information regarding OA, current research, medication and an appropriate diet. An occupational therapist gave feedback of the brainstorming session to patients and also gave ergonomic advice and practical information regarding equipment and technical aids. During the last session an occupational therapist gave information to patients regarding surgery of the hand and demonstrated applicable orthopaedic aids for the hands. Patients also tried hot paraffin wax treatment for the hands. Practical home exercises were demonstrated for the hand as well in this session.	There was an improvement in self-perceived health as well as function to some degree but not in self-efficacy of patients.
Hurley et al., (2012)	Chronic knee pain	The intervention ESCAPE-knee pain participants also received whatever services or interventions their physician considered appropriate. Participants attended 12 supervised sessions twice weekly for 6 six weeks. For 15 to 20 minutes of each session, the supervising physiotherapist facilitated a discussion on a specific topic, advising and suggesting simple coping strategies. After the discussion for 35 to 40 minutes each participant performed a simple individualized exercise regimen to address their disabilities and progressed as they improved. The content of the program was similar whether delivered to individual participants or to small groups of eight participants. To ensure consistency in content and delivery, the same physiotherapist designed, supervised and made changes for progression to all sessions of all the participants in the study. After completion, participants were encouraged to perform home	There was large initial improvement in all the outcome measures of the ESCAPE-knee pain participants, but over time there was no difference between the two groups, except for ESCAPE-knee pain participant's exercise health beliefs and self-efficacy. The was also large improvements in physical function of ESCAPE-knee pain participants that also decreased over time, but were still evident 30 months after completing the program.

		exercises and physical activity, especially walking. Control group received whatever services or interventions their physicians considered appropriate.	
Kamada et al., (2013)	Middle-aged and elderly people	The programme consisted of walking as an aerobic exercise, stretches of muscles including back muscles, adductor muscles, gluteus maximus, knee extensors and flexors. These muscles groups were chosen as key muscle groups for treating lower back pain and knee pain and the exercises given did not require expensive equipment. Marketing strategies including flyers, leaflets, community newsletters, banners, posters and local audio broadcasts were used to promote the programme. Participants also received support from their local communities during the programme.	There was no intervention effect.

APPENDIX 3

List of standardised instruments that are available to measure the different components of the ICF

List of standardised instruments that are available to measure the different components of the ICF

Component	Function	Instrument	Psychometric (Clinimetric Information)	Comments on feasibility for current study	Included as outcome measure in current study
Health component		Self-designed questionnaire based on self-report.	Designed to obtain demographic and medical information. Used by trained fieldworkers.	Only feasible method of obtaining the data.	√
		COPCORD	To record joint pain and disability in specific populations rather than focusing on diseases and syndromes.	Only feasible method of obtaining the data.	√
Impairment	Blood pressure maintenance	Electronic table-model sphygmomanometer.	Gold standard for measuring blood pressure. Used by trained fieldworkers.	Feasible and accurate.	√
	Cardiovascular fitness	Kasch Pulse Recovery (350-352)	Gold standard for measuring cardiovascular fitness. Used by trained research assistants.	Feasible and accurate.	√
		6-minute walk test (353, 354)	Gold standard for measuring cardiovascular fitness.	Feasible and accurate.	√
	Random serum glucose levels	Check classic blood glucose monitoring unit.	Gold standard for measuring blood glucose levels. Used by trained fieldworkers.	Feasible and accurate.	√
	Maintenance of body weight: Weight	Calibrated electronic digital scale accurate to 0.05kg.	Gold standard for measuring weight. Used by trained fieldworkers.	Feasible and accurate.	√

Component	Function	Instrument	Psychometric (Clinimetric Information)	Comments on feasibility for current study	Included as outcome measure in current study
	Maintenance of Body Weight: Height	Stadiometer accurate to the nearest 0.1 cm.	Gold standard for measuring height. Used by trained fieldworkers.	Feasible and accurate.	√
	Pain	Brief Pain Inventory (355-357)	Found to be valid and reliable.	Feasible and accurate.	√
		Glasgow pain scale (358)	Found to be valid and reliable.	Time consuming and detailed.	
		McGill pain questionnaires (359, 360)	Found to be valid and reliable.	Time consuming, detailed.	
		Simmonds battery of functional tests (361-363)	Found to be valid and reliable.	Include upper and lower limb function.	√
		Timed Up and Go Test (352, 364, 365)	Found to be valid and reliable for functional mobility.	Included in Simmonds battery of functional tests.	
		Muscle strength (288, 366-368)	Found to be valid and reliable.	Included in Simmonds Battery of functional tests.	
		GaIt speeds including comfortable- and fast-speed walking (352)	Found to be valid and reliable.	Included in Simmonds battery of functional tests.	
		Functional reach test (369, 370)	Found to be valid and reliable.	Included in Simmonds battery of functional tests.	
Functional activities	Activities of daily living	Functional Independence measure(371-373)	Found to be valid and reliable.	Time consuming and expensive.	
		Oswestry Disability Index (374-376)	Found to be valid and reliable.	Time consuming.	
		Roland-Morris Disability questionnaire (376-378)	Found to be valid and reliable.	Time consuming and only covers specific physical problems and no psychological or social problems.	

Component	Function	Instrument	Psychometric (Clinimetric Information)	Comments on feasibility for current study	Included as outcome measure in current study
		WHODAS 2.0 – components	Found to be valid and reliable in similar settings. Details below.	Short, used in under-resourced areas in South Africa. Compatible with ICF structure.	√
Participation	HRQOL	SF36 (379-381)	Found to be valid and reliable.	Expensive, long, little experience in similar contexts.	
		Medical Outcome Study (MOS) SF 12 (380)	Found to be valid and reliable.	Time consuming and very long.	
		EQ-5D-3L (381-385)	Found to be valid and reliable.	Feasible and accurate, most often used, used in similar context.	√
		The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)(386, 387)	Found to be valid and reliable.	Time consuming.	
		International Physical Activity Questionnaire (291, 388, 389)	Found to be valid and reliable.		√
		Baecke Questionnaire (390-392)	Found to be valid and reliable.	Lacks precision in estimating activity and bias can occur as the word may not mean the same in different populations.	
Personal factors	Demographic	Self-designed questionnaire		Feasible and accurate.	√
	Self-efficacy	Self-efficacy for managing chronic disease 6-item scale (393) (356, 394, 395)	Found to be valid and reliable.	Feasible and accurate.	√
		Arthritis self-efficacy scale (394) [536]	Found to be valid and reliable.	Time consuming and very long.	
		WHODAS 2.0 – component.	As above.	As above.	√

Component	**Function**	**Instrument**	**Psychometric (Clinimetric Information)**	**Comments on feasibility for current study**	**Included as outcome measure in current study**
Environmental and contextual factors		WHODAS 2.0 – components	As above.	As Above.	√
		Self-designed questionnaire		Feasible and accurate.	Feasible and accurate.

APPENDIX 4

COPCORD

MUSCUSLOSKELETAL CONDITIONS AND CO-MORBIDITY QUESTIONNAIRE

(Based on COPCORD Questionnaire)

- This questionnaire is for women between the ages of 40 -64 years attending Primary Health Care Clinics.
- This questionnaire is about 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.** Please make no marks of any kind on the survey which could identify you individually.
- Composite 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: _

Clinic: _

PHASE I:

THE FOLLOWING QUESTIONS ASK ABOUT YOUR PERSONAL DATA AND MEDICAL HISTORY (DEMOGRAPHIC CHARACTERISTICS)

(Q1 – Q7 to be completed by the researcher or research assistant/s)

Q1. **Age:** _ _ _ _ _ _ years old **OR** Date of birth: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Q2. **Weight:** _ _ _ _ _ _ _ _ kg

Q3. **Height:** _ _ _ _ _ _ _ _ cm

Q4. **Body Mass Index:** _ _ _ _ _ _ _ _ kg/m^2

Q5. **Blood sugar Test (reading from folder if available):** _ _ _ _ _ _ _ _ _ _ _ _ _ mmol/ℓ

Q6. **Blood Pressure:** _ _ _ _ _ _ _ _ _ _ _ _ _ mmHg

Q7. **Co-morbidities: (please indicate all applicable)**

Cancer	□ Present	□ Not present	□ Do not know
Sugar (Diabetes Mellitus Type I)	□ Present	□ Not present	□ Do not know
Cardio-vascular diseases (Coronary heart disease)	□ Present	□ Not present	□ Do not know
Depression	□ Present	□ Not present	□ Do not know
Stroke	□ Present	□ Not present	□ Do not know
Chronic respiratory disease	□ Present	□ Not present	□ Do not know

Q8. **Home language:**

□ Afrikaans □ English

□ Sesotho

□ Other (please specify) _

Q9. Ethnic origin / race:

□ African/Black □ Coloured

□ White □ Indian/Asian

□ Other (please specify) _

Q10. Marital status:

□ Never married □ Married / Domestic partner (live with partner)

□ Separated / divorced □ Widowed

Q11. Literacy:

□ Read only □ Read and write

□ None

Q12. Highest level of education:

□ No schooling □ Primary school

□ Secondary school □ Tertiary education

Q13. Where do you live most of the year?

□ Your own home / flat □ Home of a friend / family member

□ Other (please specify) _

Q14. Type of housing:

□ Brick house □ Informal housing

Q15. How many people live with you?

□ I live alone □ 1 person

□ 2 persons □ 3 persons

□ 4 persons □ 5 or more persons

Q16. Your current employment status:

□ Working full-time (40 hours or more a week) □ Unemployed

□ Working part-time (less than 40 hours a week) □ Pensioner

□ "Piece job"

□ Other (please specify) _

Q17. Your current employment (job):

□ Housewife □ Teacher

□ Desk job □ Work at shop or business

□ Factory worker □ Domestic worker

□ Military □ Police

□ Retired □ Unemployed

□ Other (please specify) _

Q18. Unemployment due to:

□ Caring for your family □ Can't find a job

□ Health problems □ Disabled

□ Husband does not allow me to work

□ Too old

□ Other (please specify) _

Q19. Do you receive a government pension or grant:

□ Yes □ No

Q20. If yes, is it a:

□ Disability grant (you can't work due to illness)

□ Pension (old age)

□ Both

Q21. What best describes your history of smoking:

□ Never smoked □ Currently smoke

□ Formerly smoked

□ If yes, how many cigarettes per day? _

□ If yes, at what age did you start? _

Q22. What best describes your history of snuffing:

□ Never used snuff □ Currently use snuff

□ Formerly used snuff

□ If yes, how many times per day do you snuff? _

□ If yes, at what age did you start? _

Q23. What best describes your history of alcohol use:

□ Never used alcohol products □ Currently use alcohol products

□ Formerly used alcohol products

□ If yes, how many times per week do you use alcohol? _

□ If yes, at what age did you start? _

THE FOLLOWING QUESTIONS ASK ABOUT YOUR HEALTH

Q24. How is your general health?

□ Excellent □ Very good

□ Good □ Fair

□ Poor

Q25. Have your ever been diagnosed with?

□ High blood (Hypertension) □ Sugar (Diabetes Mellitus Type II)

□ Obesity (overweight) □ Cholesterol (hyperlipidaemia)

□ Joint pain (Musculoskeletal conditions)

Q26. What is your main reason for visiting the clinic today?

□ To see the sister / nurse □ To see the doctor

□ To get medication □ Both sister and medication

□ Joint pain (Musculoskeletal conditions)

□ Other (please specify) _

Q27. Which of the following conditions did you suffer from in the last three months?

□ High blood (Hypertension) □ Sugar (Diabetes Mellitus Type II)

□ Obesity (overweight) □ Joint or muscle pain

□ Injury or accident □ Heart problems

□ Stomach complaints □ Genitourinary problem

□ Cancer □ Infections (TB /other)

□ Paralysis

□ Other (please specify) _

Q28. Has your doctor or sister / nurse ever told you to follow an exercise programme?

□ Yes □ No

□ Not sure

Q29a. 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

Q29b. 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: _

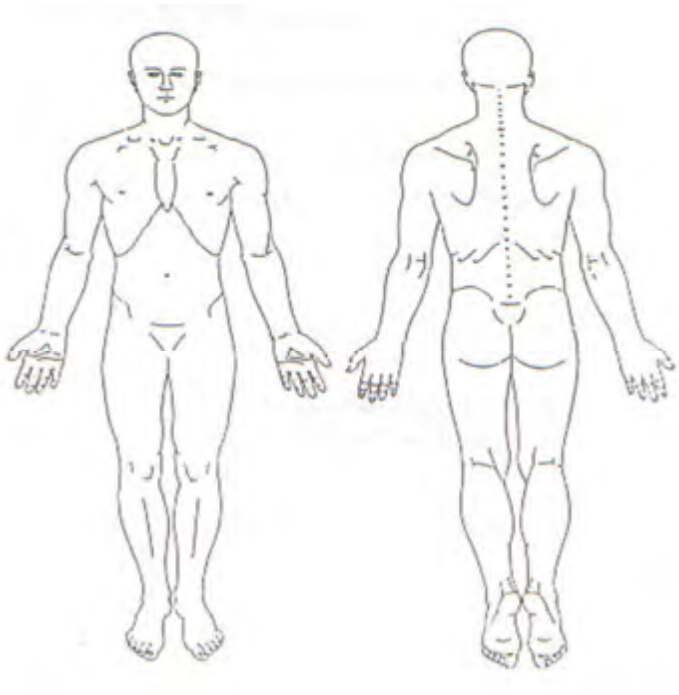
Clinic: _

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

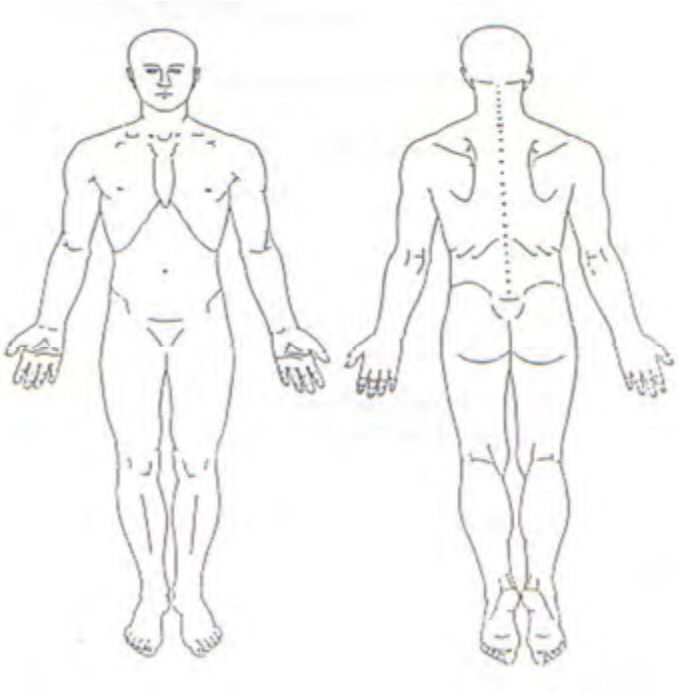
Q1a. **Please indicate on the figure below, with a ✓ all the sites where you have experienced pain in the last 3 months prior to the survey and with a X all the sites where you have experienced swelling.**

Front **Back**



Q1b. Please indicate on the figure below, with a ✓ all the sites where you have experienced pain in the last 7 days prior to the survey 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 – 1 year ago □ More than 1 year ago

Q3. How many days in the last 3 months have you experienced any pain? _ _ _ _ _ _ _ __ _ _ _ _ _ __ _

Q4a. Indicate on the scale the intensity of the pain you experienced during the past 7 days.

□ No pain □ Mild □ Moderate □ Severe □ Very severe

Q4b. Indicate on the scale the intensity of the pain you experienced during the past 3 months.

□ No pain □ Mild □ Moderate □ Severe □ Very severe

Q5. If your pain is recurrent, how long does the episode last?

□ Few days □ 4 – 6 weeks

□ 6 – 12 weeks □ More than 3 months

Q6. When is the pain most intense?

□ In the morning when you wake up □ After an activity (doing something)

□ While resting at night

□ Other (please specify) _

Q7. During the last year have you experienced tightness / stiffness in your joints in the morning after getting out of bed or after a long rest without movement?

□ Yes □ No

□ Not sure

Q8. How long did the tightness / stiffness last?

□ 30 minutes or less □ More than 30 minutes

Q9. Did the tightness / stiffness go away after exercise or movement of the joint?

□ Yes □ No

□ Not sure

Q10. Have you ever been diagnosed or has anyone told you that you have arthritis or other joint diseases like rheumatism?

□ Yes □ No

□ Not sure

Q10a. What was the diagnosis given to you? _ _ _ __ _ _ _ _ _ _ _ _ _ _ __ _ _ _ _ __ _ _ _ _ _

Q10b. Where was the diagnosis made and by whom? _ _ _ __ _ _ _ _ _ _ _ _ _ __ _ _ _ _ __ _ _ _ _ _

_ _ __ _ _ _ _ _ _ _ _ _ _ __ _ _ _ _ __ _ _ _ _ _ _ _ _ _ _ __ _ _ _ _ _ _ _ _ _ _ _ __ _ _ _ _ __ _ _ _ _ _

Q11. Have you been taking any medication for joint or back pain, not related to an injury, in the last 3 months?

□ Yes □ No

□ Not sure

Q12. Is 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)

□ Other prescribed medication

□ Other (please specify) _ _ _ _ _ _ _ _ _ _ __ _ _ _ _ _ _ _ _ _ _ __ _ _ _ _ __ _ _ _ _ _

Q13. Have you received any type of treatment, other than medication, for pain?

□ Yes □ No

□ Not sure

Please specify _ _ _ _ _ _ _ _ _ __ _ _ _ _ _ _ _ _ _ _ __ _ _ _ _ __ _ _ _ _ __ _ _ _ _

Q14. What is the effect, if any, the pain / arthritis has had on your life as outlined below?

	None	Mild	Moderate	Severe
Family relations				
Social relations				
Marital relations (including sexual activities)				
Financial position				
Ability to work				
Hobby				
Games				
Others, please specify				

Q15. Have you stopped working due to the pain / arthritis within the last year?

□ Yes □ No

□ Not sure

Q16. Have you changed you work / job due to the pain / arthritis within the last year?

□ Yes □ No

□ Not sure

Q17. Are you easily depressed or get anxious because of the pain/ arhtritis?

□ Yes □ No

□ Not sure

Q18. Do you experience abnormal sleeping patterns because of the pain / arhtritis?

□ Yes □ No

□ Not sure

Q19. Do you feel physically tired due to the pain / arthritis (not able to manage everyday tasks)?

□ Yes □ No

□ Not sure

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE.

APPENDIX 5 (a)

WHODAS 2.0

WHODAS 2.0

WORLD **H**EALTH **O**RGANIZATION
DISABILITY **A**SSESSMENT **S**CHEDULE 2.0

12-item version, self-administered

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 30 minutes?	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

Please continue to next page...

.

WHODAS 2.0

WORLD **H**EALTH **O**RGANIZATION
DISABILITY **A**SSESSMENT **S**CHEDULE 2.0

12
Self

In the past 30 days, how much difficulty did you have in:						
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*** ____

This completes the questionnaire. Thank you.

APPENDIX 5 (b)

WHODAS 2.0 scoring instructions

Scoring instructions for the WHODAS 2.0

Firstly the summary score is calculated for each participant by assigning a numerical value to the self-reported 5-point Likert scale where none=0, mild=1, moderate=2, severe=3 and extreme=4 for each of the 12 items. The 12 scores for each participant were then added together.

Secondly, the summary score was converted into a global score with a metric range from 0 to 100 where 0 was no disability and 100 was full disability. This global score was interpreted as the degree of functional limitation.

The full classification of the WHODAS 2.0 global scores are: 0%-4% no problems; 5%-24% mild problem; 25%-49% moderate problem; 50%-95% severe problem and 95%-100% extreme problem.

APPENDIX 6

EQ-5D-3L

Health Questionnaire

English version for South Africa

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 ❑

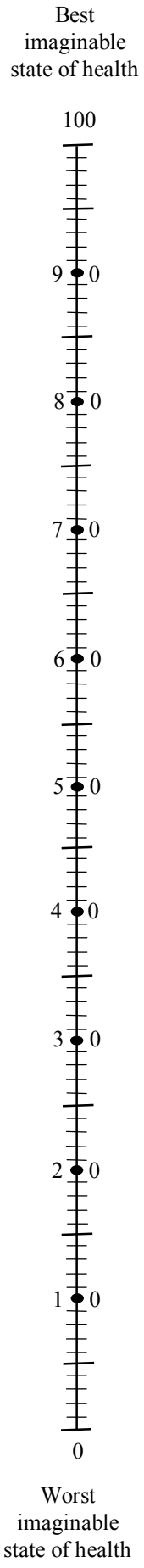
I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) 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



APPENDIX 7

Self-efficacy for managing chronic disease Six 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?

Not at all confident	1	2	3	4	5	6	7	8	9	10	totally confident

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?

Not at all confident	1	2	3	4	5	6	7	8	9	10	totally confident

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?

Not at all confident	1	2	3	4	5	6	7	8	9	10	totally confident

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?

Not at all confident	1	2	3	4	5	6	7	8	9	10	totally confident

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?

Not at all confident	1	2	3	4	5	6	7	8	9	10	totally confident

6. How confident are you that you can do things other than just taking medication to reduce how much your illness affects your everyday life?

Not at all confident	1	2	3	4	5	6	7	8	9	10	totally confident

APPENDIX 8

Brief Pain Inventory Short Form

STUDY ID #:_____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #: _____

Brief Pain Inventory (Short Form)

Date: ____/____/____ Time: _____

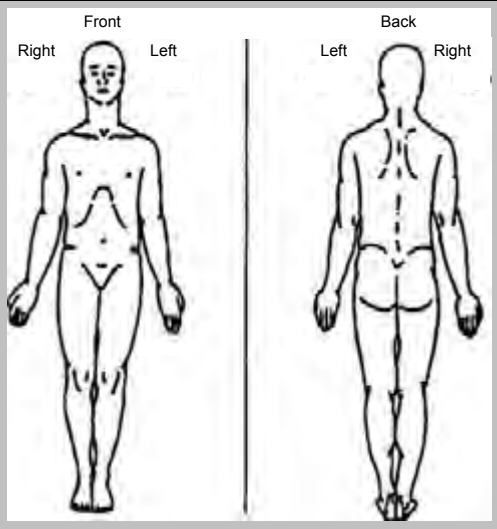
Name: _____ _____ _____

Last First Middle Initial

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 every-day kinds of pain today?

1. Yes 2. 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 24 hours.

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 24 hours.

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

STUDY ID #:__________ DO NOT WRITE ABOVE THIS LINE HOSPITAL #: __________

Date: ____/____/____ Time: ________

Name: _________________ _________________ _____________

Last First Middle Initial

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

____

8. In the last 24 hours, 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, during the past 24 hours, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

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

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

APPENDIX 9

International Physical Activity Questionnaire (IPAQ)

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

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 your 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** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   _____ **days per week**

   ☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   _____ **days per week**

   ☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent 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.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

APPENDIX 10

Acceptability Questionnaire

MUSCUSLOSKELETAL CONDITIONS AND CO-MORBIDITY QUESTIONNAIRE

TO DETERMINE ACCEPTABILITY TOWARDS THE INTERVENTION PROGRAMME

- This questionnaire is for women between the ages of 40 - 64 years attending the intervention programme at MUCPP community hall
- 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 questionnaire which could identify you individually.

INSTRUCTIONS

- Please give your honest opinion

Thank you very much for your co-operation

ID code _ _ _ _ _ _ _ _ _

Date: _

Age: _

PHASE III:

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 11

Comparison of translation: COPCORD questionnaire

COPCORD epidemiological survey questionnaire

English version	Translated version	Moderated version	Comments
	LENANE LA DIPOTSO LABOKUDI BA MESIFA LE MASAPO A MMELE*(MUSCULOSKELETAL)* LE LENANE LA DIPOTSO LA MAFU A TSAMAELLANANG *(CO-MORBIDITY)*	**LENANE LA DIPOTSO LABOKUDI BA MESIFA LE MASAPO A MMELE*(MUSCULOSKELETAL)* LE LENANE LA DIPOTSO LA MAFU A TSAMAELLANANG *(CO-MORBIDITY)***	Sentence structure corrected.
	(E theilwe hodima Lenane la Dipotso la COPCORD)	(E theilwe hodima Lenane la Dipotso la COPCORD)	
	Lenane lena la dipotso ke la basadi ba pakeng tsa dilemo tse 40-70 ba tsamayang Ditliniki tsa Tlhokomelo ya Motheo ya Bophelo bo Botle	Lenane lena la dipotso ke la basadi ba pakeng tsa dilemo tse 40-70 ba tsamayang Ditliniki tsa Tlhokomelo ya Motheo ya Bophelo bo Botle	Spelling correction
	Lenane lena la dipotso le mabapi le bohloko ba manonyeletso, monono o fetang tekano, kgathello e phahameng ya madi le mofuta wa II wa lefu la tswekere	Lenane lena la dipotso le mabapi le bohloko ba manonyeletso, monono o fetang tekano, kgathello e phahameng ya madi le mofuta wa II wa lefu la tswekere	
	Lenane lena la dipotso ke la **boithaopo bo phethahetseng.** O ka nka qeto ya ho se nke karolo kapa ho se arabe potso efe kapa efe e itseng	Lenane lena la dipotso ke la **boithaopo bo phethahetseng.** O ka nka qeto ya ho se nke karolo kapa ho se arabe potso efe kapa efe e itseng	
	Lenane lena la dipotso ke la **lekunutu bo phethahetseng.** Ka kopo o se etse matshwao a mofuta ofe kapa ofe a ka o supang ka bo mong.	Lenane lena la dipotso ke la **lekunutu bo phethahetseng.** Ka kopo o se etse matshwao a mofuta ofe kapa ofe a ka o supang ka bo mong.	Grammar: Wrong pronoun was used.
	Dintlha tse kopantsweng di tla sebediswa ho theha lenaneo la tsebisatso ya bophelo bo botle.	Dintlha tse kopantsweng di tla sebediswa ho theha lenaneo la tsebisatso ya bophelo bo botle.	Grammar: Wrong spelling format for term.

English version	Translated version	Moderated version	Comments
	DITAELO	**DITAELO**	
	Kgetha karabo e le nngwe feela, ntle leha o laetswe ka tsela e nngwe	Kgetha karabo e le nngwe feela, ntle leha o laetswe ka tsela e nngwe	
	➢ Ka kopo tshwaya karabo e nepahetseng mohl. □V kapa o e etse sedikadikwe karabong e le nngwe m ho bontshitsweng.	➢ Ka kopo tshwaya karabo e nepahetseng mohl. □V kapa o e etse sedikadikwe karabong e le nngwe m ho bontshitsweng.	
Thank you very much for your co-operation	**Re lebohela tshedisanommoho ya hao haholo**	**Re lebohela tshedisanommoho ya hao haholo**	
	Khoutu ya ID	**Khoutu ya ID**	
	Mohla:	**Mohla:**	
	Tleliniki:	**Tleliniki:**	
	MOKGAHLELO WA I:	**MOKGAHLELO WA I:**	
	DIPOTSO TSE LATELANG DI BOTSA KA DINTLHA TSA HAO TSA BOTHO LE NALANE LA BOPHELO BO BOTLE (DINTLHA TSE FAPANENG TSA DITJHABA)	**DIPOTSO TSE LATELANG DI BOTSA KA DINTLHA TSA HAO TSA BOTHO LE NALANE LA BOPHELO BO BOTLE (DINTLHA TSE FAPANENG TSA DITJHABA)**	Grammar: spelling error Grammar: Correction by using conventional plural translation of the term “demographics”.
	Q1 – Q7 hophethelwa ke mofuputsi ka ba/mothusi wa mofuputsi)	**Q1 – Q7 hophethelwa ke mofuputsi ka ba/mothusi wa mofuputsi)**	Wrong translation: Wrong sense of word used for translation. Intended sense of the source term “complete” is to “fill in”. The translation renders it as “finish off”. Correct format for showing plural alternative option. Without use of brackets for (ba) it would seem as if “ba/” is a word on its own, whereas if only indicates a plural form of the noun

English version	Translated version	Moderated version	Comments
Q1:	Dilemo tse Dilemo tse	Dilemo tse	
	KAPA Letsatsi la tswalo	**KAPA** Letsatsi la tswalo	
Q2:	**Boima:**	**Boima:**	
Q3:	**Bolelele:**	**Bolelele:**	
Q4:	**Indekse ya Boima ba Mmele:**	**Indekse ya Boima ba Mmele:**	
Q5:	**Teko ya Hemoglucose (ho bala ho tswa foldareng haeba e le teng):**	**Teko ya Hemoglucose (ho bala ho tswa foldareng haeba e le teng):**	"Reading" here has been corrected to its true meaning as a noun and not a verb.
Q6:	**Kgatello ya Madi:**	**Kgatello ya Madi:**	
Q 7:	**Mafu a tsamaellanang le a mang:(ka kopo bontsha tsohle tse amehang)**	**Mafu a tsamaellanang le a mang:(ka kopo bontsha tsohle tse amehang)**	
	Mofetshe	Kankere (Mofetshe)	Both terms acceptable but "mofetshe" is not a generally known term for cancer, unlike the localized Afrikaans term "kankere". Even the English term "cancer" is more widely known than the original Sesotho term "mofetshe".
	Tswekere (Mofuta wa I wa Lefu la Tswekere)	Tswekere (Mofuta wa I wa Lefu la Tswekere)	
	Mafu a Methapo ya pelo (Lefu la pelo)	Mafu a methapo ya madi yapelo (Lefu la pelo)	"Coronary" (**blood** (ya madi) vessels of the heart) was not properly conveyed in the translations.
	Tshithabelo ya maikutlo	Ho sithabela maikutlo	The adjective form as opposed to the adverb (now corrected to) is not wrong but might be too difficult to understand for the average Sesotho speaker.
	Seterouku	Seterouku	
	Lefu la nako e telele la ho hema	Lefu la nako e telele la ho hema	

English version	Translated version	Moderated version	Comments
Q8:	**Puo ya lapeng:**	**Puo ya lapeng:**	
	Afrikaans	Afrikanse	Now localised
	Senyesemane	Senyesemane	
	Sesotho	Sesotho	
	E nngwe (hlalosa ka kopo)	E nngwe (hlalosa ka kopo)	
Q9:	**Morabe / Botso**	**Morabe / Setso**	Wrong spelling corrected
	MoAforika/Motsho	MoAforika/Motsho	
	Mokhalate	Wa mmala	Better translation for “coloured” used
	Mosweu	E mosweu	Grammatical correction.
	MoIndia/MoAsia	MoIndia/MoAsia	
	E nngwe (hlalosa ka kopo)	E nngwe (hlalosa ka kopo)	
Q10:	**Boemo ba lenyalo:**	**Boemo ba tsalenyalo:**	Missing conjunction added
	Ha o so nyale/nyalwe	Ha o so nyale/nyalwe	
	O nyetse/nyetswe / Molekane wa lehae (molekane ya dulang le wena)	O nyetse/nyetswe / Molekane wa lapeng (molekane ya dulang le wena)	“lehae” is a noun would be used to mean “local” and not “domestic”, particularly in this context.
	Le arohane / le hlalane	Le arohane / le hlalane	
	O mohlolo/mohlohadi	O mohlolo/mohlolohadi	
Q11:	**Tsebo ya bala:**	**Tsebo ya hobala:**	Missing preposition added
	Bala feela	Ho bala feela	Preposition added for grammatical correctness
	Bala le ho ngola	Ho bala le ho ngola	
	Ha ho letho	Ha ho letho	

English version	Translated version	Moderated version	Comments
Q12:	Ha o wa kena sekolo	Ha o a kena sekolo	
	Sekolo sa mathomo	Sekolo sa mathomo	
	Ha o wa kena sekolo	Ha o a kena sekolo	
	Sekolo sa sekhondari	Sekolo sa sekhondari	
	Thuto ya theshari	Thuto e phahameng (ya theshari)	The simpler term “e phahameng” (higher) is more accessible to the reader than the localized “theshiari”
Q13:	**O dula kae boholo ba selemo?**	**O dula kae boholo ba selemo?**	
	Lehae / flete ya hao	Lapeng / foleteng ya hao	In this context, home is better translated as “lapeng”
	Lehaeng la motswalle / setho sa lelapa	Lapeng la motswalle / setho sa lelapa	In this context, home is better translated as “lapeng”
	E nngwe (hlalosa ka kopo)	Ho sele (hlalosa ka kopo)	Wrong translation of “other” corrected. Here “other” means “other place” not “other thing” as was translated.
Q14:	**Mofuta wa ntlo:**	**Mofuta wa ntlo:**	
	Ntlo ya setene	Ntlo ya setene	
	Ntlo e sa hlophiswang	Mokhukhu	There is no conventional Sesotho original term for the source term. However, “mokhukhu” is widely accepted as meaning “informal housing”. I recommend it for easy comprehension. Otherwise the translation was too literal and devoid of meaning.
Q15:	**O dula le batho ba bakae?**	**O dula le batho ba bakae?**	
	Ke dula ke le mong	Ke dula ke le mong	
	motho a le mong	motho a le mong	
	batho ba 2	atho ba 2	

English version	Translated version	Moderated version	Comments
	batho ba 3	batho ba 3	
	batho ba 4	batho ba 4	
	batho ba 5 kapa ho feta	batho ba 5 kapa ho feta	
Q16:	**Maemo a hao a hajwale a khiro:**	**Maemo a hao a hajwale a kgiro:**	Spelling corrected
	O sebetsa nako yohle (dihora tse 40 kapa ho feta ka beke)	O sebetsa nako yohle (dihora tse 40 kapa ho feta ka beke)	
	Ha o sebetse	Ha o sebetse	
	O sebetsa nakwana (ka tlase ho dihora tse 40 ka beke)	O sebetsa nakwana (ka tlase ho dihora tse 40 ka beke)	
	Mopenshenara	Mopenshenara	
	“Mosebetsi wa nako e nyane”	“Mosebetsi wa nako e nyane”	
	E nngwe (hlalosa ka kopo)	E nngwe (hlalosa ka kopo)	
Q17:	**Maemo a hao a hajwale a khiro (mosebetsi):**	**Maemo a hao a hajwale a kgiro (mosebetsi):**	Spelling corrected
	Mme wa lelapa	Mme wa lelapa	
	Titjhere	Titjhere	
	Mosebetsi wa tafoleng	Mosebetsi wa tafoleng	
	O sebetsa lebenkeleng kapa kgwebong	O sebetsa lebenkeleng kapa kgwebong	
	Mosebeletsi wa feme	Mosebetsi wa femeng	Spelling corrected.
	Mosebeletsi wa lapeng	Mosebeletsi wa lapeng	I prefer to keep one term “mosebetsi” (worker) as opposed to using also “mosebeletsi” (servant) as domestic workers have legislated rights as well. “Mosebeletsi” sound a little inferior” and might
	Sesole	Sesole	
	Sepolesa	Sepolesa	

English version	Translated version	Moderated version	Comments
	O beile meja fatshe	O beile meja fatshe	
	Ha o sebetse	Ha o sebetse	
	E nngwe (hlalosa ka kopo)	E nngwe (hlalosa ka kopo)	
Q18:	**Ho hloka mosebetsi ka lebaka la:**	**Ho hloka mosebetsi ka lebaka la:**	
	Ho hlokomela lelapa la hao	O hlokometse lelapa la hao	Better grammatical format
	Ha ke kgone ho fumana mosebetsi	Ha ke kgone ho fumana mosebetsi	
	Mathata a bophelo bo botle	Bothata ba bophelo bo botle	
	O na le bokowa	O na le bokudi	
	Monna ha a ntumelle ho sebetsa	Monna ha a ntumelle ho sebetsa	
	Ke moholo haholo	Ke moholo haholo	
	E nngwe (hlalosa ka kopo)	Le sele (hlalosa ka kopo)	Translation must be for “other reason” and not “other thing” (e nngwe)
Q19:	**Na o fumana penshene kapa grante ya mmuso:**	**Na o fumana penshene kapa keranteya mmuso:**	Spelling corrected
	Ee	Ee	
	Tjhe	Tjhe	
Q20:	**Haeba ke ee, na ke:**	**Haeba o re ee, na ke:**	Formulated for better understanding as “If you say yes”. English is able to read shorter because of its much more frequesnt use than Sesotho.
	Grante ya bokowa (ha o kgone ho sebetsa ka lebaka la bokudi)	Keante ya bokowa (ha o kgone ho sebetsa ka lebaka la bokudi)	Spelling corrected
	Penshene (o tsofetse)	Penshene (ya maqheku)	Incomplete translation. “tsofetse” just meas “old”
	Ka bobedi	Ka bobedi	
Q21:	**Ke eng e hlalosang hantle ho fetisisa nalane ya hao ya ho tsuba:**	**Ke eng e hlalosang hantle kaho fetisisa nalane ya hao ya ho tsuba:**	Conjunction added
	Ha o so tsube ho hang	Ha o so tsube ho hang	

English version	Translated version	Moderated version	Comments
	O tsuba hona jwale	O a tsuba hona jwale	
	O ne o tsuba nakong e fetileng	O ne o tsuba nakong e fetileng	
	Haebake ee, ke dikwae tse kae ka letsatsi?	Haebao re ee, ke kwae e kae ka letsatsi?	See previous dikwae" (cigarettes) is not grammatically correct. It is noun that is incapable of pluralizing for Sesotho. Rather "disikarete" could be used as in this case; I left the term in singular, which by implication means also plural, and this will be found in the "how many" part.
	Haeba ke ee, o qadile o le dilemo tse kae?	Haeba o re ee, o qadile o le dilemo tse kae?	See previous
Q22:	**Ke eng e hlalosang hantle ho fetisisa nalane ya hao ya ho tsuba senifi**	**Ke efe e hlalosang hantle ho fetisisa nalane ya hao ya ho tsuba seneifi**	Spelling corrected
	Ha ke so sebedise senifi ho hang	Ha ke so sebedise seneifi ho hang	
	O tsuba senifi hona jwale	O tsuba seneifi hona jwale	
	Ke ne ke sebedisa senifi nakong e fetileng	Ke ne ke sebedisa seneifi nakong e fetileng	Spelling corrected
	Haeba ke ee, o tsuba senifi makgetlo a makae ka letsatsi?	Haeba o re ee, o tsuba seneifi makgetlo a makae ka letsatsi?	See previous
	Haeba ke ee, o qadile o le dilemo tse kae?	Haeba o re ee, o qadile o le dilemo tse kae?	See previous
Q23:	**Ke eng e hlalosang hantle ho fetisisa nalane ya hao ya tshebediso ya jwala:**	**Ke efe e hlalosang hantle ka ho fetisisa nalane ya hao ya tshebediso ya jwala:**	See previous
	Ha ke so sebedise dihlahiswa tsa jwala ho hang	Ha ke so sebedise dihlahiswa tsa jwala ho hang	
	Ke sebedisa dihlahiswa tsa jwala a jwale	Ke sebedisa dihlahiswa tsa jwala a jwale	
	Ke ne ke sebedisa dihlahiswa tsa jwala nakong e fetileng	Ke ne ke sebedisa dihlahiswa tsa jwala nakong e fetileng	

English version	Translated version	Moderated version	Comments
	Haeba ke ee, o sebedisa jwala ka makgetlo a makae ka beke?	Haeba o re ee, o sebedisa jwala ka makgetlo a makae ka beke?	See previous
	Haeba ke ee, o qadile o le dilemo tse kae?	Haeba o re ee, o qadile o le dilemo tse kae?	See previous
	DIPOTSO TSE LATELANG DI MABAPI LE BOPHELO BA HAO BO BOTLE	**DIPOTSO TSE LATELANG DI MABAPI LE BOPHELO BA HAO BO BOTLE**	
Q24:	**Bophelo ba hao bo botle ka kakaretso bo**	**Bophelo ba hao bo botle ka kakaretso bo**	
	Bo tswa pele	Bo tswile matsoho	Correct form of the Sesotho saying.
	Bo botle haholo	Bo botle haholo	
	Bo botle	Bo botle	
	Bo mahareng	Bo mahareng	
	Bo a fokola	Bo a fokola	
	Na o kile wa bolellwa ke ngaka hore o na le?	**Na o kile wa bolellwa ke ngaka hore o na le?**	
	Kgatello e phahameng ya madi *(Hypertension)*	Kgatello e phahameng ya madi *(Hypertension)*	
	Tswekere (Mofuta wa II wa Lefu la Tswekere)	Tswekere (Mofuta wa II wa Lefu la Tswekere)	
	Botenya bo fetang tekano	Botenya bo fetang tekano	
	Kholesterole *(hyperlipidaemia)*	Kholesterole *(hyperlipidaemia)*	
	Bohloko ba manonyeletso (Bokudi ba mesifa le masapo a mmele)	Bohloko ba manonyeletso (Bokudi ba mesifa le masapo a mmele)	
	Lebaka la hao la sehlooho la ho etela tleliniki kajeno ke lefe?	**Lebaka la hao la sehlooho la ho etela tleliniki kajeno ke lefe?**	
	Ho tla bona sista / mooki	Ho tla bona sista / mooki	
	Ho tla bona ngaka	Ho tla bona ngaka	
	Ho fumana meriana	Ho fumana meriana	
	Bobedi sista le meriana	Bobedi sista le meriana	

English version	Translated version	Moderated version	Comments
	Bohloko ba manonyeletso (Bokudi ba mesifa le masapo a mmele)	Bohloko ba manonyeletso (Bokudi ba mesifa le masapo a mmele)	
	E nngwe (hlalosa ka kopo)	E nngwe (hlalosa ka kopo)	
	Ke efe ya mafu a latelang ao o bileng le ona dikgweding tse tharo tse fetileng?	**Ke afe a mafu a latelang ao o bileng le oona dikgweding tse tharo tse fetileng?**	Grammatical correction: The context is plural, "conditions". Translation was singular and asking as if only one could apply.
	Kgatello e phahameng ya madi *(Hypertension)*	Kgatello e phahameng ya madi *(Hypertension)*	
	Tswekere (Mofuta wa II wa Lefu la Tswekere)	Tswekere (Mofuta wa II wa Lefu la Tswekere)	
	Botenya bo fetang tekano	Botenya bo fetang tekano	
	Bohloko ba manonyeletso kapa mesifa	Bohloko ba manonyeletso kapa mesifa	
	Ho lemala kapa kotsi	Ho lemala kapa kotsi	
	Mathata a pelo	Mathata a pelo	
	Ditletlebo mabapi le mpa	Ditletlebo mabapi le mpa	
	Mathata a amanang lebong kapa ditho tsa mosese	Mathata a amanang leditho tsa bong kapa tsa mosese	Previous translation was saying "bong" which means "sex/gender" as opposed to the correction offered now "ditho tsa bong" (genito…")
	Mofetshe	Seso se sa foleng	A simpler translation as already mentioned above offered.
	Ditshwaetso (TB/e nngwe	Ditshwaetso (TB/e sele	See previous
	Kgolofalo	Kgolofalo	
	E nngwe (hlalosa ka kopo)	Le sele (hlalosa ka kopo)	See previous

English version	Translated version	Moderated version	Comments
	Na ngaka ya hao kapa sista / mooki o kile a o jweta hore o hloka ho latela lenaneo la boikwetliso?	**Na ngaka ya hao kapa sista / mooki o kile a o jwetsa hore o hloka ho latela lenaneo la boikwetliso?**	Spelling corrected.
	Ee	Ee	
	Tjhe	Tjhe	
	Ha ke na bonnete	Ha ke na bonnete	
	Nakong ya dikgwedi tse 3 tse fetileng na o bile le bohloko, ho opelwa, ho ruruha, ho satalla (ho tiya) kahare kapa ho potoloha manonyeletso a hao kapa mokokotlo bo sa amananeng le ho lemala / kotsi?	**Nakong ya dikgwedi tse 3 tse fetileng na o bile le bohloko, ho opelwa, ho ruruha, ho satalla (ho tiya) kahare kapa ho potoloha manonyeletso a hao kapa mokokotlo bo sa amananeng le ho lemala / kotsi?**	
	Ee	Ee	
	Tjhe	Tjhe	
	Ha ke na bonnete	Ha ke na bonnete	
	Nakong ya matsatsi a 7 a fetileng na o bile le bohloko, ho opelwa, ho ruruha, ho satalla (ho tiya) kahare kapa ho potoloha manonyeletso a hao kapa mokokotlo bo sa amananeng le ho lemana / kotsi?	**Nakong ya matsatsi a 7 a fetileng na o bile le bohloko, ho opelwa, ho ruruha, ho satalla (ho tiya) kahare kapa ho potoloha manonyeletso a hao kapa mokokotlo bo sa amananeng le ho lemana / kotsi?**	
	Ee	Ee	
	Tjhe	Tjhe	
	Ha ke na bonnete	Ha ke na bonnete	
	Khoutu ya ID	**Khoutu ya ID**	
	Mohla:	**Mohla:**	
	Tleliniki:	**Tleliniki:**	
	MOKGAHLELO WA II:	**MOKGAHLELO WA II:**	

English version	Translated version	Moderated version	Comments
	DIPOTSO TSE LATELANG DI BOTSA KA BOHLOKO KA MANONYELETSO KAPA MESIFA, HO SATALLA / HO TIYA KAPA HO RURUHA HO POTOLOHA MANONYELETSO A HAO, KAPA MOTSAMAO O FOKOTSEHILENG MANONYELETSONG AFE KAPA AFE	**DIPOTSO TSE LATELANG DI BOTSA KA BOHLOKO BA MANONYELETSO KAPA MESIFA, HO SATALLA / HO TIYA KAPA HO RURUHA HO POTOLOHA MANONYELETSO A HAO, KAPA MOTSAMAO O FOKOTSEHILENG MANONYELETSONG AFE KAPA AFE**	Spelling corrected
	Ka kopo bontsha sebopehong se ka tlase, ka ✓dibaka tsohle tseo o utlwileng bohloko ho tsona dikgweding tse 3 tse fetileng pele ho patlisiso mmele ka X dibakeng tsohle moo o bileng le ho ruruha	**Ka kopo bontsha setshwanshong se ka tlasemona, ka ✓dibaka tsohle tseo o utlwileng bohloko ho tsona dikgweding tse 3 tse fetileng pele ho patlisiso le ka X dibakeng tsohle moo o bileng le ho ruruha**	Wrong translation of "figure" corrected. Missing word added Unnecessary additional word deleted.
	Ka pele	**Ka pele**	
	Ka morao	**Ka morao**	
	Ka kopo bontsha sebopehong se ka tlase, ka ✓dibaka tsohle tseo o utlwileng bohloko ho tsona matsatsing a 7 a fetileng pele ho patlisiso mme le ka X dibakeng tsohle moo o bileng le ho ruruha	**Ka kopo bontsha setshwantshong se ka tlasemona, ka ✓dibaka tsohle tseo o utlwileng bohloko ho tsona matsatsing a 7 a fetileng pele ho patlisiso le ka X dibakeng tsohle moo o bileng le ho ruruha**	Wrong translation of "figure" corrected. Missing word added Unnecessary additional word deleted.
	Ka pele	**Ka pele**	
	Ka morao	**Ka morao**	
	Bohloko bo qadile neng?	**Bohloko bo qadile neng?**	
	Ka tlase ho matsatsi a 7 a fetileng	Ka tlase ho matsatsi a 7 a fetileng	
	Dikgweding tse 3 tse fetileng	Dikgweding tse 3 tse fetileng	

English version	Translated version	Moderated version	Comments
	Dikgwedi tse 3 – selemo se 1 se fetileng	Dikgwedi tse 3 ho isa selemong se 1 se fetileng	Not advisable to use hyphen if there is a mixture of a number and words. Preferable only when numerals a used. Spelling corrected
	Ho feta selemo se 1 se fetileng	Ho feta selemo se 1 se fetileng	
	Ke matsatsi a makae dikgweding tse 3 tse fetileng na o bile le bohloko bofe kapa bofe?	**Ke matsatsi a makae dikgweding tse 3 tse fetileng o bileng le bohloko bofe kapa bofe?**	Correct language format for a question used.
	Bontsha sekaleng matla a bohloko boo o bileng le bona nakong ya matsatsi a 7 a fetileng.	**Bontsha sekaleng matla a bohloko boo o bileng le bona nakong ya matsatsi a 7 a fetileng.**	
	Ha ho bohloko	Ha ho bohloko	
	Bo bobebe	Bo bobebe	
	Bo bobebe	Bo bobebe	
	Totile	Bo totileng	Preposition used and correct phrasing used. These terms are incapable of standing on their own without a preposition.
	Totile haholo	Bototileng haholo	Preposition used and correct phrasing used. These terms are incapable of standing on their own without a preposition.
	Totile haholo	Bototileng haholo	Preposition used and correct phrasing used. These terms are incapable of standing on their own without a preposition.

English version	Translated version	Moderated version	Comments
	Bontsha sekaleng matla a bohloko boo o bileng le bona nakong ya dikgwedi tse 3 tse fetileng.	**Bontsha sekaleng matla a bohloko boo o bileng le bona nakong ya dikgwedi tse 3 tse fetileng.**	
	Ha ho bohloko	Ha ho bohloko	
	Bo bobebe	Bo bobebe	
	Bo bobebe	Bo bobebe	
	Bo totileng	Bo totileng	Preposition used and correct phrasing used. These terms are incapable of standing on their own without a preposition.
	Bototileng haholo	Bototileng haholo	Preposition used and correct phrasing used. These terms are incapable of standing on their own without a preposition.
	Bototileng haholo	Bototileng haholo	Preposition used and correct phrasing used. These terms are incapable of standing on their own without a preposition.
	Ha ho bohloko	Ha ho bohloko	
	Bo bobebe	Bo bobebe	
	Haeba bohloko bo hlaha hape le hape, ketsahalo eo e nka nako e kae?	**Haeba bohloko bo hlaha kgafetsakgafetsa, ketsahalo eo e nka nako e kae?**	Proper translation term now used.
	Matsatsi a mmalwa	Matsatsi a mmalwa	
	dibeke tse 4 - 6	dibeke tse 4 - 6	
	dibeke tse 6 - 12	dibeke tse 6 - 12	
	Ho feta dikgwedi tse 3	Ho feta dikgwedi tse 3	
	Bohloko to matla haholo neng?	**Bohloko bo matla haholo neng?**	Spelling corrected

English version	Translated version	Moderated version	Comments
	Hoseng ha o tsoha	Hoseng ha o tsoha	
	Kamora tshebetso (ho etsa ho hong)	Kamora tshebetso (ho etsa ho hong)	
	Ha o phomotse bosiu	Ha o phomotse bosiu	
	E nngwe (hlalosa ka kopo)	E nngwe (hlalosa ka kopo)	
	Nakong ya selemo se fetileng na o bile le ho tiya / ho satalla manonyeletsong a hao hoseng kamora ho tswa dikobong kapa kamora phomolo e telele ntle le motsamao?	**Nakong ya selemo se fetileng na o bile le ho tiya / ho satalla manonyeletsong a hao hoseng kamora ho tswa dikobong kapa kamora phomolo e telele ntle le ho tsamaya?**	Grammatical correction: Adverb used instead of an adjective.
	Ee	Ee	
	Tjhe	Tjhe	
	Ha ke na bonnete	Ha ke na bonnete	
	Ho tiya / ho satalla ho bile teng nako e kae?	**Ho tiya / ho satalla ho bile teng nako e kae?**	
	metsotso e 30 kapa ka tlase	metsotso e 30 kapa ka tlase	
	Ho feta metsotso e 30	Ho feta metsotso e 30	
	Na ho tiya / ho satalla ho ile ha tsamaya kamora ho ikwetlisa kapa ho itsamaisa manonyeletso?	**Na ho tiya / ho satalla ho ile ha fela kamora ho ikwetlisa kapa ho itsamaisa manonyeletso?**	Literal translation corrected. “go away” here means “end” or “stop”
	Ee	Ee	
	Tjhe	Tjhe	
	Ha ke na bonnete	Ha ke na bonnete	
	Na o kile wa fumanwa kapa na motho o kile a o jwetsa hore o na le lefu la masapo kapa mafu a mang a manonyeletso jwalo ka ramatiki?	**Na o kile wa fumanwa kapa na motho o kile a o jwetsa hore o na le lefu la masapo kapa mafu a mang a manonyeletso jwalo ka ramatiki?**	
	Phumano ya lefu eo o e fuweng ke efe?	**Phumano ya lefu eo o e fuweng ke efe?**	
	Phumano ya lefu e entswe kae mme ke mang?	**Phumano ya lefu e entswe kae?**	

English version	Translated version	Moderated version	Comments
	Na o ntse o nwa moriana bakeng sa bohloko ba manonyeletso kapa mokokotlo, o sa amananeng le temalo, nakong ya dikgwedi tse 3?	**Na o ntse o nwa moriana bakeng sa bohloko ba manonyeletso kapa mokokotlo, o sa amananeng le temalo, nakong ya dikgwedi tse 3?**	"Addiction" needs further clarity in the English. Otherwise, wrongly translated in Sesotho
	Ee	Ee	
	Tjhe	Tjhe	
	Ha ke na bonnete	Ha ke na bonnete	
	Haeba ke ee, ho sebedisitswe meriana efe?	**Haeba o re ee, o sebedisitse meriana efe?**	See previous
	Dibolaya	bohloko tse ithekelwang	
	Meriana ya tlhaho, dimela, ditlatsetso	Meriana ya tlhaho, dimela, ditlatsetsotsa phepo	Incomplete translation made complete
	Meriana e ithekelwang e kgahlano le tlerefalo (NSAIDS's)	Meriana e ithekelwang e alafang tlerefalo (di-NSAIDS)	Literal wrong translation for "anti" (against) here. The purposive meaning here is "something that treats/works against"
	Meriana e laetsweng ke ngaka e kgahlano le tlerefalo (NSAIDS's)	Meriana e laetsweng ke ngaka e alafang tlerefalo (di-NSAIDS)	Literal wrong translation for "anti" (against) here. The purposive meaning here is "something that treats/works against"
	Meriana e meng e laetsweng ke ngaka	Meriana e meng e laetsweng ke ngaka	
	E nngwe (hlalosa ka kopo)	E meng (hlalosa ka kopo)	Spelling corrected
	Na o fumane mofuta ofe kapa ofe o mong wa kalafo, ntle le moriana wa bohloko?	**Na o fumane mofuta ofe kapa ofe o mong wa kalafo, ntle le moriana wa bohloko?**	
	Ee	Ee	
	Tjhe	Tjhe	

English version	Translated version	Moderated version	Comments
	Ha ke na bonnete	Ha ke na bonnete	
	Hlalosa ka kopo	Hlalosa ka kopo	
	Kameho ke efe, haeba e le teng, eo bohloko / lefu la masapo le bileng le yona bophelong ba hao jwalo ka ha ho bontshitswe ka tlase?	**Kameho ke efe, haeba e le teng, eo bohloko / lefu la masapo le bileng le yona bophelong ba hao jwalo ka ha ho bontshitswe ka tlasemoo?**	Left out word added.
	Ha ho letho	**Ha ho letho**	
	Bobebe	**Bobebe**	
	Mahareng	**Mahareng**	
	Totile	**Totile**	
	Dikamano tsa lelapa	Dikamano tsa lelapa	
	Dikamano tsa setjhaba	Dikamano tsa setjhaba	
	Dikamano tsa lenyalo (ho kenyeletswa mesebetsi yathobalano	Dikamano tsa lenyalo (ho kenyeletswa diketso tsathobalano	In Sesotho “thobalano” incorporates “activities” by implication. “Acts of/activities” (mesebetsi ya) is not necessary to translate.
	Maemo a ditjhelete	Maemo a ditjhelete	
	Bokgoni ba ho sebetsa	Bokgoni ba ho sebetsa	
	Mosebetsi wa boithabiso	Mosebetsi wa boithabiso	
	Dipapadi	Dipapadi	
	Tse ding, hlalosa ka kopo	Tse ding, hlalosa ka kopo	
	Na o emisitse ho sebetsa ka lebaka la bohloko / lefu la masapo nakong ya selemo se fetileng?	**Na o emisitse ho sebetsa ka lebaka la bohloko / lefu la masapo nakong ya selemo se fetileng?**	
	Ee	Ee	
	Tjhe	Tjhe	
	Ha ke na bonnete	Ha ke na bonnete	
	Na o fetotse mosebitsi wa hao ka lebaka la bohloko / lefu la masapo nakong ya selemo se fetileng?	**Na o fetotse mosebetsi wa hao ka lebaka la bohloko / lefu la masapo nakong ya selemo se fetileng?**	Spelling corrected
	Ee	Ee	

English version	Translated version	Moderated version	Comments
	Tjhe	Tjhe	
	Ha ke na bonnete	Ha ke na bonnete	
	Na o nyahama ha bonolo kapa o ngongorehe ka lebaka la bohloko / lefu la masapo?	**Na o nyahama ha bonolo kapa o ngongorehe ka lebaka la bohloko / lefu la masapo?**	
	a boroko ba hao bo etsahala ka tsela e sa tlwaelehang ka lebaka la bohloko / lefu la masapo?	**a boroko ba hao bo etsahala ka tsela e sa tlwaelehang ka lebaka la bohloko / lefu la masapo?**	
	Ee	Ee	
	Tjhe	Tjhe	
	Ha ke na bonnete	Ha ke na bonnete	
	Na o ikutlwa o khathetse mmeleng ka lebaka la bohloko / lefu la masapo (o sa kgone ho etsa mesebetsi ya letsatsi le letsatsi)?	**Na o ikutlwa o kgathetse mmeleng ka lebaka la bohloko / lefu la masapo (o sa kgone ho etsa mesebetsi ya letsatsi le letsatsi)?**	Spelling corrected
	RE A LEBOHA HA O NKILE NAKO YA HO PHETHELA LENANE LENA LA DIPOTSO	**RE A LEBOHA HA O NKILE NAKO YA HO PHETHA LENANE LENA LA DIPOTSO**	“phethela” means to finish off something that was left off. “Phetha” means complete.

APPENDIX 12

Comparison of translation: WHODAS 2.0

WHODAS 2.0 self-administered 12-item questionnaire

English version	Translated version	Moderated version	Comments
	Kgatiso ya dintho tse 12, tse tsamaiswang ke wena	**Kgatiso ya dintho tse 12, tse tsamaiswang ke wena**	Wrong translation. Translation of "version" is "kgatiso" and not "mofuta", which means "type of"
	Lenane lena la dipotso le botsa ka mathata a bakwang ke maemo a amangbophelo bo botle. Maemo a amangbophelo bo botle a kenyeletsa mafu kapa bokudi, mathata a mang a bophelo bo botle a ka bang makgutshwane kapa a nka nako e telele, ditemalo, mathata a kelello kapa maikutlo, le mathata ka jwala kapa dithethefatsi.	Lenane lena la dipotso le botsa ka mathata a bakwang ke maemo a amangbophelo bo botle. Maemo a amangbophelo bo botle a kenyeletsa mafu kapa bokudi, mathata a mang a bophelo bo botle a ka bang makgutshwane kapa a nka nako e telele, ditemalo, mathata a kelello kapa maikutlo, le mathata ka jwala kapa dithethefatsi.	Omission of conjunction corrected.
	Nahana ka matsatsi a 30 a fetileng mme o arabe dipotso tsena, o nahana ka boholo ba bothata bo o bileng le bona ho etsa mesebetsi e latelang Bakeng sa potso ka nngwe, ka kopo etsa sedikadikwe ho karabo e le nngwe feela.	Nahana ka matsatsi a 30 a fetileng mme o arabe dipotso tsena, o nahana ka boholo ba bothata bo o bileng le bona ho etsa mesebetsi e latelang Bakeng sa potso ka nngwe, ka kopo etsa sedikadikwe ho karabo e le nngwe feela.	
In the past 30 days, how much difficulty did you have in:	Nakong ya matsatsi a fetileng a 30, o bile le bothata bo bokae ba ho	Nakong ya matsatsi a fetileng a 30, o bile le bothata bo bokae ba ho	
None	Letho	Letho	
Mild	Bobebe	Bobebe	
Moderate	Mahareng	Mahareng	
Severe	Totileng	Totileng	Grammatical correction (participle form)
Extreme of cannot do	Totileng haholo kapa ha o kgone ho etsa	Totileng haholo kapa ha o kgone ho etsa	Grammatical correction (participle form)

English version	Translated version	Moderated version	Comments
S1: Standing for long periods such as 30 minutes?	Ho hlokomela boikarabello ba hao ba lapeng?	Ho hlokomela boikarabello ba hao ba lapeng?	
S2: Taking care of your household responsibilities?	Ho ithuta mosebetsi o motjha, mohlala, ho ithuta ho fihla sebakeng se sejtha?	Ho ithuta mosebetsi o motjha, mohlala, ho ithuta ho fihla sebakeng se sejtha?	
S3: Learning a new task, for example, learning how to get to a new place?	O bile le bothata bo bokae ka ho nka karolo mesebetsing ya setjhaba(mohlala, mesebetsi ya mekete, bodumedi kapa e meng) ka tsela e tshwanang le batho ba bang?	O bile le bothata bo bokae ka ho nka karolo mesebetsing ya setjhaba(mohlala, mesebetsi ya mekete, bodumedi kapa e meng) ka tsela e tshwanang le batho ba bang?	
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?	O amehile hakae maikutlong ke mathata a hao a bophelo bo botle?	O amehile hakae maikutlong ke mathata a hao a bophelo bo botle?	
S5: How much have you been emotionally affected by your health problems?	Matsatsing a 30 a fetileng,a bileng le bothata bo bokae ka:	Matsatsing a 30 a fetileng,a bileng le bothata bo bokae ka:	Translation was too verbose for a questionnaire question. I excised the redundant words “matsatsing a makae”
S6: Concentrating on doing something for ten minutes?	Ho tsepamisa maikutlo ho etseng ntho bakeng sa metsotso e 10	Ho tsepamisa maikutlo ho etseng ntho bakeng sa metsotso e 10	
S7: Walking a long distance such as a kilometre [or equivalent]?	Ho tsamaya sebaka se se lelele bakhilomitara[kapa ho lekana]?	Ho tsamaya sebaka se se lelele bakhilomitara[kapa ho lekana]?	Not part of source and unnecessary.
S8: Washing your whole body?	Ho hlapa mmele wa hao kaofela?	Ho hlapa mmele wa hao kaofela?	Spelling corrected
S9: Getting dressed?	Hoapara?	Hoapara?	
S10: Dealing with people you do not know?	Ho sebetsana le bathobao o sa ba tsebeng?	Ho sebetsana le bathobao o sa ba tsebeng?	
S11: Maintaining a friendship?	Ho boloka setswalle?	Ho boloka setswalle?	

English version	Translated version	Moderated version	Comments
S12: Your day-to-day work?	Mosebetsi / sekolo sa hao sa letsatsi le letsatsi?	Mosebetsi / sekolo sa hao sa letsatsi le letsatsi?	
H1: Overall, in the past 30 days, how many days were these difficulties present?	Ka kakaretso, matsatsing a 30 a fetileng, ke ka matsatsi a makae mathata ao a bileng teng?	Ka kakaretso, matsatsing a 30 a fetileng, ke ka matsatsi a makae mathata ao a bileng teng?	
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?	Matsatsing a 30 a fetileng, ke ka matsatsi a makae o neng o sa kgone ho hang ho etsa mesebetsi ya hao ya tlwaelo kapa ho sebetsa ka lebaka la boemo bofe kapa bofe bo amang bophelo bo botle?	Matsatsing a 30 a fetileng, ke ka matsatsi a makae o neng o sa kgone ho hang ho etsa mesebetsi ya hao ya tlwaelo kapa ho sebetsa ka lebaka la boemo bofe kapa bofe bo amang bophelo bo botle?	Necessary conjunction added
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	Matsatsing a 30 a fetileng, ho sa balwe matsatsi ao oneng o sa kgone kahohlehohle, ke ka matsatsi a makae o ileng wa fokotsakapa wa theola mesebetsi ya hao ya tlwaelo kapa mosebetsi ka lebaka la maemo a hao a amangbophelo bo botle?	Matsatsing a 30 a fetileng, ho sa balwe matsatsi ao oneng o sa kgone kahohlehohle, ke ka matsatsi a makae o ileng wa fokotsakapa wa theola mesebetsi ya hao ya tlwaelo kapa mosebetsi ka lebaka la maemo a hao a amangbophelo bo botle?	Omission corrected. Typing error corrected. Necessary conjunction added
This completes the questionnaire. Thank you.	Sena se phethela puisano ya rona Ke a lebohaha o nkile karolo	Sena se phethela puisano ya rona Ke a lebohaha o nkile karolo	Omitted words added.

APPENDIX 13

Comparison of translation: Self-efficacy for managing chronic disease Six-item scale

Self-efficacy for Managing Chronic Disease Six-Item Scale

English version	Translated version	Moderated version	Comments
Self-efficacy for Managing Chronic Disease six-Item	Bonna boikemetseng ka ho bookamedi ba **Chronic Disease** ka dintlha tse tseletseng	Bonna boikemetseng ka ho bookamedi ba **mafu a sa foleng** ka dintlha tse tseletseng	Chronic disease was not translated
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.	Re ka thabela ho tseba ka botshepo ba hao ka ho nka karolo ho dithebetso tsena. Ho tswa potsong engwe le engwe ho dipotsi tsena tse latelang. Ka kopa kgetha nomoro ka ho araba ka boitshepo ba hao ka ho ka etsa karolo motsotsong ona.	Re ka thabela ho tseba ka boitshepo ba hao ka ho nka karolo ho ditshebetso tsena. Ho tswa potsong engwe le engwe ho dipotsi tsena tse latelang. Ka kopa kgetha nomoro ka ho araba ka boitshepo ba hao ka ho ka etsa karolo motsotsong ona.	Typing error corrected
1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?	1. O ka hole hokae ka ho tshwarella mokgathala o etswang ke ho kula ha hao ka ho setiswa ke dintho tseo o batlang ho di etsa?	1. O ka **itshepa** hole hokae ka ho tshwarella mokgathala o etswang ke ho kula ha hao ka ho setiswa ke dintho tseo o batlang ho di etsa?	Word omitted
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?	2. O ka itshepa hole hokae ka ho tshwarela ha mmele osa tsitsang kapa bokloko ba ho kula ha hao ka ho setiswa ke dintho tseo o batlang ho di etsa?	2. O ka itshepa hole hokae ka ho tshwarella ha mmele osa tsitsang kapa bokloko ba ho kula ha hao ka ho setiswa ke dintho tseo o batlang ho di etsa?	Typing error corrected
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?	3. O ka itshepa hole hokae ka ho tshwarella bohloko ba maikutlo bo etswng ke ho kula ha hao ka ho setiswa ke dintho tseo o batlang ho di etsa?	3. O ka itshepa hole hokae ka ho tshwarella bohloko ba maikutlo bo etswng ke ho kula ha hao ka ho setiswa ke dintho tseo o batlang ho di etsa?	

English version	Translated version	Moderated version	Comments
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?	4. O ka itshepa hole ho kae ka ho tshwarella ke matshwao kappa bothata ba bophelo boo onang le bona bo setisehang ke dintho tseo o batlang ho di etsa?		
5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?	5. O ka itshepa hole ho kae ka hore o etse dikarolo tse fapaneng le ditshebetso tse hlokahlang ho hlkomela bophelo ba ha obo tlasa dipehelo ka ho theoloa dihloko tsa hao ka hore o bone ngaka?		
6. How confident are you that you can do things other than just taking medication to reduce how much your illness affects your everyday life?	6. O itshepa hole ho kae ka ho ka etsa dintho ho feta ka ho nka moriana hore o theole bongata ba ho kula ha hao boo bo etswang ka ho phela letsatsi le letsatsi?	6. O itshepa hole ho kae ka ho ka etsa dintho ho feta ka ho nka meriana hore o theole bongata ba ho kula ha hao boo bo etswang ka ho phela letsatsi le letsatsi?	Typing error corrected
Not at all confident	Ha ho bonnete haholo		
Totally confident	Bonnete bo boholo		

APPENDIX 14

Comparison of translation: International Physical Activity Questionnaire

International Physical Activity Questionnaire

English version	Translated version	Moderated version	Comments
	LENANE LA DIPOTSO LA MATJHABA LA DIKETSO TSA TSHEBEDISO YA MMELE	LENANE LA DIPOTSO LA MATJHABA LA DIKETSO TSA TSHEBEDISO YA MMELE	Lenaneo" means "programme". This is a list of questions, therefore the correct term is "lenane" I feel the use of "diketso" **(acts/actions/activities)** in the opening here will help provide better clarity on the broad meaning of "activity" which unfortunately in Sesotho has no unique translation equivalent. We use the generic term "work". Thankfully the context here is enough to clarify that activity can also mean sport or just about anything a person does. "Tshebetso" would be wrong as it means things that the body does, whether on its own or through a person's acts..
	Re lakatsa ho tseba mefuta ya mesebetsi ya mmele eo batho ba e etsang jwalo ka karolo ya maphelo a bona a letsatsi le letsatsi	Re lakatsa ho tseba mefuta ya mesebetsi ya mmele eo batho ba e etsang jwalo ka karolo ya maphelo a bona a letsatsi le letsatsi	"Re na le kgahleho" is not simply put (too verbose) as it should compare to "re lakatsa" (we want to …).
	Dipotso di tla o botsa ka nako eo o e qetileng o sebedisa mmele nakong ya **matsatsi a 7 a fetileng**	Dipotso di tla o botsa ka nako eo o e qetileng o sebedisa mmele nakong ya **matsatsi a 7 a fetileng**	

English version	Translated version	Moderated version	Comments
	Ka kopo araba potso ka nngwe le haeba o sa ipone jwalo ka motho ya sebedisang mmele	Ka kopo araba potso ka nngwe le haeba o sa ipone jwalo ka motho ya sebedisang mmele	
	Ka kopo nahana ka mesebetsi eo o e etsang mosebetsing, jwalo ka karolo ya mosebetsi wa hao wa ka tlung le jareteng, ho tloha sebakeng se seng ho ya ho se seng, le ka nako ya hao ya boithapollo, boikwetliso kapa dipapadi	Ka kopo nahana ka mesebetsi eo o e etsang mosebetsing, jwalo ka karolo ya mosebetsi wa hao wa ka tlung le jareteng, ho tloha sebakeng se seng ho ya ho se seng, le ka nako ya hao ya boithapollo, boikwetliso kapa dipapadi	Typing error corrected
	Nahana ka mesebetsi yohle e **matla** eo o e entseng **matsatsing a 7 a fetileng.**	Nahana ka mesebetsi yohle e **matla** eo o e entseng **matsatsing a 7 a fetileng.**	
	Mesebetsi e **matla** ya mmele e bua ka mesebetsi e hlokang matla a mangata a mmele mme e etsa hore o heme kamatla haholo ho feta tlwaelo.	Mesebetsi e **matla** ya mmele e bua ka mesebetsi e hlokang matla a mangata a mmele mme e etsa hore o heme kamatla haholo ho feta tlwaelo.	Typing error corrected.
	Nahana *feela* ka mesebetsi ya mmele eo o eentseng bakeng sa bonyane metsotso e 10 ka nako	Nahana *feela* ka mesebetsi ya mmele eo o eentseng bakeng sa bonyane metsotso e 10 ka nako	Omitted word added.
1.	Nakong ya **matsatsi a 7 a fetileng,** ke ka matsatsi a makae o entseng mesebetsi e **matla** ya mmele jwalo ka ho phahamisa dintho tse boima, ho tjheka, diaerobiki, kapa hopalama le ho potlakisabaesekele?	Nakong ya **matsatsi a 7 a fetileng,** ke ka matsatsi a makae o entseng mesebetsi e **matla** ya mmele jwalo ka ho phahamisa dintho tse boima, ho tjheka, diaerobiki, kapa hopalama le ho potlakisabaesekele?	Spelling corrected. “tsamaya” means “walk”. In oral language it would go un noticed, however, in written language it is nonsensical. The appropriate term is “ride” (palama).
	matsatsi a ka beke	**matsatsi a ka beke**	Omitted conjunction added.
	Ha ho mesebetsi e matla ya mmele	Ha ho mesebetsi e matla ya mmele	
	Tlolela ho potso ya 3	***Tlolela ho potso ya 3***	

English version	Translated version	Moderated version	Comments
2.	O ne o qeta nako e kae ka tlwaelo o etsa mesebetsi e **matla** ya mmele ka le le leng la matsatsi ao?	O ne o qeta nako e kae ka tlwaelo o etsa mesebetsi e **matla** ya mmele ka le le leng la matsatsi ao?	
	dihora tse ka letsatsi	**dihora tse ka letsatsi**	Omitted conjunction added.
	metsotso e ka letsatsi	**metsotso e ka letsatsi**	Omitted conjunction added.
	Ha ke tsebe/Ha ke na bonnete	Ha ke tsebe/Ha ke na bonnete	
	Nahana ka mesebetsi yohle e **mahareng** eo o e entseng **matsatsing a 7 a fetileng**	Nahana ka mesebetsi yohle e **mahareng** eo o e entseng **matsatsing a 7 a fetileng**	
	Mesebetsi e **mahareng** e bua ka mesebetsi e hlokang matla amahareng a mmele mme e etsa hore o heme haholwanyane ho feta tlwaelo.	Mesebetsi e **mahareng** e bua ka mesebetsi e hlokang matla amahareng a mmele mme e etsa hore o heme haholwanyane ho feta tlwaelo.	The term “physical effort” was not in the translation. Now added. Typo corrected. Harder” means “more faster/rapidly” and does not imply “pain” or “distress” as translated here.
	Nahana feela ka mesebetsi ya mmele eo o e entseng bakeng sa bonyane metsotso e 10 ka nako	Nahana feela ka mesebetsi ya mmele eo o e entseng bakeng sa bonyane metsotso e 10 ka nako	
3.	Nakong ya **matsatsi a 7 a fetileng,** ke ka matsatsi a makae o entseng mesebetsi e **mahareng** ya mmele jwalo ka ho phahamisa dintho tse bobebe, ho tsamaya ka baesekele ka sekgahla se tlwaelehileng, kapa ho bapala tenese ya batho ba bane?	Nakong ya **matsatsi a 7 a fetileng,** ke ka matsatsi a makae o entseng mesebetsi e **mahareng** ya mmele jwalo ka ho phahamisa dintho tse bobebe, ho tsamaya ka baesekele ka sekgahla se tlwaelehileng, kapa ho bapala tenese ya batho ba bane?	
	O se ke wa kenyeletsa ho tsamaya.	O se ke wa kenyeletsa ho tsamaya.	
	matsatsi a ka beke	**matsatsi a ka beke**	Omitted conjunction added.

English version	Translated version	Moderated version	Comments
	Ha ho mesebetsi e mahareng ya mmele	Ha ho mesebetsi e mahareng ya mmele	
	Tlolela ho potso ya 5	***Tlolela ho potso ya 5***	
4.	O ne o qeta nako e kae ka tlwaelo o etsa mesebetsi e **mahareng** ya mmele ka le le leng la matsatsi ao?	O ne o qeta nako e kae ka tlwaelo o etsa mesebetsi e **mahareng** ya mmele ka le le leng la matsatsi ao?	
	dihora tse ka letsatsi	**dihora tse ka letsatsi**	Omitted conjunction added.
	metsotso e ka letsatsi	**metsotso e ka letsatsi**	Omitted conjunction added.
	Nahana ka nako eo o eqetileng o **tsamaya matsatsing a 7 a fetileng**	Nahana ka nako eo o eqetileng o **tsamaya matsatsing a 7 a fetileng**	Typing omission corrected.
	Sena se kenyelletsa mosebetsing le hae, ho tsamaya ho tloha sebakeng ho ya ho se seng, le ho tsamaya hofe kapa hofe hoo o ho entseng bakeng sa boithapollo, dipapadi, boikwetliso, kapa phomolo feela	Sena se kenyelletsa mosebetsing le hae, ho tsamaya ho tloha sebakeng ho ya ho se seng, le ho tsamaya hofe kapa hofe hoo o ho entseng bakeng sa boithapollo, dipapadi, boikwetliso, kapa phomolo feela	This is too cluttered and ends up rendering the translation absurd. Now corrected.
5.	Nakong ya **matsatsi a 7 a fetileng,** ke ka matsatsi a makae o **tsamaileng** bakeng sa bonyane metsotso e 10 ka nako?	Nakong ya **matsatsi a 7 a fetileng,** ke ka matsatsi a makae o **tsamaileng** bakeng sa bonyane metsotso e 10 ka nako?	
	matsatsi a ka beke	**matsatsi a ka beke**	Omitted conjunction added.
	Ha ke a tsamaya	Ha ke a tsamaya	
	Tlolela ho potso ya 7	***Tlolela ho potso ya 7***	
6.	O ne o qeta nako e kae ka tlwaelo o **tsamaya** ka le le leng la matsatsi ao?	O ne o qeta nako e kae ka tlwaelo o **tsamaya** ka le le leng la matsatsi ao?	Unnecessary word deleted.
	Dihoratse ka letsatsi	**Dihoratse ka letsatsi**	Omitted conjunction added.
	metsotso e ka letsatsi	**metsotso e ka letsatsi**	Omitted conjunction added.

English version	Translated version	Moderated version	Comments
	Ha ke tsebe/Ha ke na bonnete	Ha ke tsebe/Ha ke na bonnete	
	Potso ya ho qetela e mabapi le nako eo o e qetileng**o dutse** hara beke nakong ya **matsatsi a 7 a fetileng**	Potso ya ho qetela e mabapi le nako eo o e qetileng**o dutse** hara beke nakong ya **matsatsi a 7 a fetileng**	This is corrected to past participle tense as it should
	Kenya nako eo o e qetang mosebetsing, hae, ha o etsa mosebetsi wa sekolo le ka nako ya boiketlo.	Kenya nako eo o e qetang mosebetsing, hae, ha o etsa mosebetsi wa sekolo le ka nako ya boiketlo.	phomolo" means "rest" but the term is "leisure" which does not mean doing nothing. It means doing things that are not work/study related and could even be inclusive of resting. Wrong pronoun here and now corrected.
	Ena e ka kenyeletsa nako eo o e qetang o dutse tafoleng, o etetse metswalle, o bala, kapa o dutse kapa o paqame fatshe ho shebella thelevishene	Ena e ka kenyeletsa nako eo o e qetang o dutse tafoleng, o etetse metswalle, o bala, kapa o dutse kapa o paqame fatshe ho shebella thelevishene	
7.	Nakong ya **matsatsi a 7 a fetileng,** o qetile nako e kae o **dutse**letsatsing**la hara beke**?	Nakong ya **matsatsi a 7 a fetileng,** o qetile nako e kae o **dutse**letsatsing**la hara beke**?	This is supposed to be past perfect tense, as is now corrected here. The corrected translation was present continuous tense.
	Dihoratse ka letsatsi	**Dihoratse ka letsatsi**	Omitted conjunction added.
	metsotso e ka letsatsi	**metsotso e ka letsatsi**	Omitted conjunction added.
	Ha ke tsebe/Ha ke na bonnete	Ha ke tsebe/Ha ke na bonnete	
	Ena ke pheletso ya lenane la dipotso, re a leboha ha o nkile karolo.	**Ena ke pheletso ya lenane la dipotso, re a leboha ha o nkile karolo.**	

APPENDIX 15

Comparison of translation: Acceptability Questionnaire

Acceptability Questionnaire

English version	Translated version	Moderated version	Comments
	LENANE LA DIPOTSO LA BOKUDI BA MESIFA LE SEKELETHONE *(MUSCULOSKELETAL)* LE MAFU A TSAMAELLANANG *(CO-MORBIDITY*	**LENANE LA DIPOTSO LA BOKUDI BA MESIFA LE SEKELETHONE *(MUSCULOSKELETAL)* LE MAFU A TSAMAELLANANG *(CO-MORBIDITY***	The term "lenane la dipotso" (questionnaire) must be at the beginning of the title because it applies to both the conditions.
	HO FUMANA KAMOHELEHO MABAPI LE LENANEO LA KENO-DIPAKENG	**HO FUMANA KAMOHELEHO MABAPI LE LENANEO LA KENO-DIPAKENG**	Mistranslation: "kamohelo" means "acceptance."It must be "kamoheleho"
	Lenane lena la dipotso ke la basadi ba pakeng tsa dilemo tse 40-64 ba tsamayang lenaneo la keno-dipakeng holong ya setjhaba ya MUCPP	Lenane lena la dipotso ke la basadi ba pakeng tsa dilemo tse 40-64 ba tsamayang lenaneo la keno-dipakeng holong ya setjhaba ya MUCPP	
	Lenane lena la dipotso le mabapi le hore na o fumane lenaneo la keno-dipakeng le le jwang.	Lenane lena la dipotso le mabapi le hore na o fumane lenaneo la keno-dipakeng le le jwang.	
	Lenane lena la dipotso ke la **boithaopo bo phethahetseng**	Lenane lena la dipotso ke la **boithaopo bo phethahetseng**	
	O ka nka qeto ya ho se nke karolo kapa ho se arabe potso efe kapa efe e itseng.	O ka nka qeto ya ho se nke karolo kapa ho se arabe potso efe kapa efe e itseng.	
	Lenane lena la dipotso ke la **sephirise phethahetseng(ha le hlahise lebitso la motho)**	Lenane lena la dipotso ke la **sephirise phethahetseng(ha le hlahise lebitso la motho)**	lekunutu"means "secret" as opposed to "confidentiality This is a further addition to clarify the actual result – does not reveal person's name

English version	Translated version	Moderated version	Comments
	Ka kopo o se etse matshwao a mofuta ofe kapa ofe lenaneng la dipotso a ka o tsebahatsang.	Ka kopo o se etse matshwao a mofuta ofe kapa ofe lenaneng la dipotso a ka o tsebahatsang.	Grammatical correction. This term must be in participle form. Mistranslation of “individually”. It has been translated in a literal sense here, whereas the purposive meaning is about revealing a person him/herself, and not “separate
	DITAELO	**DITAELO**	
	Ka kopo fana ka maikutlo a hao a nnete	Ka kopo fana ka maikutlo a hao a nnete	
	Ke leboha tshebedisanommoho ya hao haholo	**Ke leboha tshebedisanommoho ya hao haholo**	
	Khoutu ya ID	**Khoutu ya ID**	
	Mohla:	**Mohla:**	
	Dilemo:	**Dilemo:**	
	MOKGAHLELO WA III	**MOKGAHLELO WA III**	
	DIPOTSO TSE LATELANG DI BOTSA KA HORE NA O IKUTLWA JWANG KA LENANEO LEO O LE KENETSENG BAKENG SA DIBEKE TSE 6	**DIPOTSO TSE LATELANG DI BOTSA KA HORE NA O IKUTLWA JWANG KA LENANEO LEO O LE KENETSENG BAKENG SA DIBEKE TSE 6**	
Q1:	**O ratile eng kaho fetisisa ka lenaneo?**	**O ratile eng kaho fetisisa ka lenaneo?**	Omitted conjunction added.
Q2:	**Ke eng eo o e ratilenghanyane kaho fetisisa ka lenaneo?**	**Ke eng eo o e ratilenghanyane kaho fetisisa ka lenaneo?**	Mistranslation: This question must complement the previous one (Q1) as opposites. The previous translation was saying “what did you dislike most about the program?” It must be about “like” and not “dislike”. It might sound academic but the effect is clearly different.

English version	Translated version	Moderated version	Comments
Q3:	**O ka fetola eng lenaneong?**	**O ka fetola eng lenaneong?**	Correct to participle form.
Q4:	**O ka eketsa eng lenaneong?**	**O ka eketsa eng lenaneong?**	Mistranslation: the source term is “add” and not “introduce” or “put in”. The effect must be that it adds to something there already.
Q5:	**O ile wanahana eng ka buka ya boitsamaiso?**	**O ile wanahana eng ka buka ya boitsamaiso?**	Must be past tense, as corrected here.

APPENDIX 16

Qualifications of translators

Translators utilised in the translation project

Translator	**Sex**	**Occupation**
A	Female	Free-lance translator
B	Male	Lecturer in Interpreting at a university as well as a freelance translator and interpreter
C	Female	Professional translator at a provincial government department
D	Male	Free-lance translator and the only translator that was accredited
Moderator	**Sex**	**Occupation and qualifications**
	Male	Associate Professor in Department of Linguistics and Language Practice in the Faculty of the Humanities, teaching translation studies at under- and post-graduate level at the University of the Free State as well as editing at under-graduate level. MA in Translation Studies from the University of the Free State (cum laude). An Accredited Professional Translator with the South African Translators' Institute (SATI) with 13 years of experience as a professional translator. Since then has translated 23 full-length books. A member of the Linguistics Society of Southern Africa, the International Association for Translation and Intercultural Studies, the European Association of Translation Studies and the Association of Translation Studies in Africa. Have extensive experience in translating in various fields such as psychology, theology, education, development studies. Also have 15 years of experience as an editor. Edited hundreds of research reports (even for the International Labour Organisation) and academic articles in development studies, theology, education, psychology, literary studies, business managements, etc.

APPENDIX 17

Cognitive debriefing results – COPCORD questionnaire

COPCORD epidemiological survey questionnaire

English version	Moderated version	Changes after cognitive debriefing	Comments
	LENANE LA DIPOTSO LABOKUDI BA MESIFA LE MASAPO A MMELE*(MUSCULOSKELETAL)* LE LENANE LA DIPOTSO LA MAFU A TSAMAELLANANG *(CO-MORBIDITY)*		
	(E theilwe hodima Lenane la Dipotso la COPCORD)		
	Lenane lena la dipotso ke la basadi ba pakeng tsa dilemo tse 40-70 ba tsamayang Ditliniki tsa Tlhokomelo ya Motheo ya Bophelo bo Botle		
	Lenane lena la dipotso le mabapi le bohloko ba manonyeletso, monono o fetang tekano, kgathello e phahameng ya madi le mofuta wa II wa lefu la tswekere		
	Lenane lena la dipotso ke la **boithaopo bo phethahetseng.** O ka nka qeto ya ho se nke karolo kapa ho se arabe potso efe kapa efe e itseng		
	Lenane lena la dipotso ke la **lekunutu bo phethahetseng.** Ka kopo o se etse matshwao a mofuta ofe kapa ofe a ka o supang ka bo mong.		
	Dintlha tse kopantsweng di tla sebediswa ho theha lenaneo la tsebisatso ya bophelo bo botle.		
	<u>DITAELO</u>		

English version	Moderated version	Changes after cognitive debriefing	Comments
	Kgetha karabo e le nngwe feela, ntle leha o laetswe ka tsela e nngwe		
	Ka kopo tshwaya karabo e nepahetsen mohl. □V kapa o e etse sedikadikwe karabong e le nngwe moo ho bontshitsweng.		
Thank you very much for your co-operation	**Re lebohela tshedisanommoho ya hao haholo**		
	Khoutu ya ID		
	Mohla:		
	Tleliniki:		
	MOKGAHLELO WA I:		
	DIPOTSO TSE LATELANG DI BOTSA KA DINTLHA TSA HAO TSA BOTHO LE NALANE LA BOPHELO BO BOTLE (DINTLHA TSE FAPANENG TSA DITJHABA)		
	Q1 – Q7 hophethelwa ke mofuputsi ka ba/mothusi wa mofuputsi)		
Q1:	Dilemo tse		
	KAPA Letsatsi la tswalo		
Q2:	**Boima:**		
Q3:	**Bolelele:**		
Q4:	**Indekse ya Boima ba Mmele:**		
Q5:	**Teko ya Hemoglucose (ho bala ho tswa foldareng haeba e le teng):**		
Q6:	**Kgatello ya Madi:**		
Q 7:	**Mafu a tsamaellanang le a mang:(ka kopo bontsha tsohle tse amehang)**		

English version	Moderated version	Changes after cognitive debriefing	Comments
	Kankere (Mofetshe)		
	Tswekere (Mofuta wa I wa Lefu la Tswekere)		
	Mafu a methapo ya madi yapelo (Lefu la pelo)		
	Ho sithabela maikutlo		
	Seterouku		
	Lefu la nako e telele la ho hema	Lefu la nako e telele	“la ho hema” was omitted
Q8:	**Puo ya lapeng:**		
	Afrikanse		
	Senyesemane		
	Sesotho		
	E nngwe (hlalosa ka kopo)		
Q9:	**Morabe / Setso**	**Morabe**	“Setso” was omitted
	MoAforika/Motsho	MoAforika	“Motsho” was omitted
	Wa mmala		
	E mosweu		
	MoIndia/MoAsia		
	E nngwe (hlalosa ka kopo)		
Q10:	**Boemo ba tsalenyalo:**		
	Ha o so nyale/nyalwe		
	O nyetse/nyetswe / Molekane wa lapeng (molekane ya dulang le wena)		
	Le arohane / le hlalane	Le hlalane	“arohane” was ommitted
	O mohlolo/mohlolohadi	mohlolohadi	“O mohlolo” was ommitted
Q11:	**Tsebo ya hobala:**		
	Ho bala feela		
	Ho bala le ho ngola		
	Ha ho letho	Ha ke tsebe hoh bala le hongola	Wording was changed
Q12:			
	Ha o a kena sekolo		

English version	Moderated version	Changes after cognitive debriefing	Comments
	Sekolo sa mathomo	Sekolo sa pele	"mathomo" was changed to "sa pele"
	Sekolo sa sekhondari		
	Thuto e phahameng (ya theshari)		
Q13:	**O dula kae boholo ba selemo?**		
	Lapeng / foleteng ya hao		
	Lapeng la motswalle / setho sa lelapa		
	Ho sele (hlalosa ka kopo)		
Q14:	**Mofuta wa ntlo:**		
	Ntlo ya setene		
	Mokhukhu		
Q15:	**O dula le batho ba bakae?**	**O dula le batho ba bakae?**	Wording and sentence construction was changed
	Ke dula ke le mong		
	motho a le mong		
	atho ba 2	bedi	Numbers changed to words
	batho ba 3	bararo	Numbers changed to words
	batho ba 4	bane	Numbers changed to words
	batho ba 5 kapa ho feta	bahlano	Numbers changed to words
Q16:	**Maemo a hao a hajwale a kgiro:**	**Maemo a hao a hajwale a khiro:**	Spelling corrected
	O sebetsa nako yohle (dihora tse 40 kapa ho feta ka beke)	O sebetsa nako yohle (dihora tse mashome a mane kapa ho feta ka beke)	Wording changed
	Ha o sebetse		
	O sebetsa nakwana (ka tlase ho dihora tse 40 ka beke)		
	Mopenshenara		
	"Mosebetsi wa nako e nyane"	"Mosebetsi wa nako nakwana"	Wording changed
	E nngwe (hlalosa ka kopo)		

English version	Moderated version	Changes after cognitive debriefing	Comments
Q17:	**Maemo a hao a hajwale a kgiro (mosebetsi):**	**Maemo a hao a hajwale a khiro (mosebetsi):**	Spelling corrected
	Mme wa lelapa		
	Titjhere	Titjhere/marutabana	“morulatane” omitted
	Mosebetsi wa tafoleng		
	O sebetsa lebenkeleng kapa kgwebong		
	Mosebetsi wa femeng		
	Mosebeletsi wa lapeng		
	Sesole		
	Sepolesa		
	O beile meja fatshe		
	Ha o sebetse		
	E nngwe (hlalosa ka kopo)		
Q18:	**Ho hloka mosebetsi ka lebaka la:**		
	O hlokometse lelapa la hao		
	Ha ke kgone ho fumana mosebetsi		
	Bothata ba bophelo bo botle		
	O na le bokudi		
	Monna ha a ntumelle ho sebetsa		
	Ke moholo haholo		
	Le sele (hlalosa ka kopo)		
Q19:	**Na o fumana penshene kapa keranteya mmuso:**		
	Ee		
	Tjhe		
Q20:	**Haeba o re ee, na ke:**		
	Keante ya bokowa (ha o kgone ho sebetsa ka lebaka la bokudi)		
	Penshene (ya maqheku)		
	Ka bobedi		

English version	Moderated version	Changes after cognitive debriefing	Comments
Q21:	**Ke eng e hlalosang hantle kaho fetisisa nalane ya hao ya ho tsuba:**		
	Ha o so tsube ho hang		
	O a tsuba hona jwale		
	O ne o tsuba nakong e fetileng		
	Haebao re ee, ke kwae e kae ka letsatsi?	Haeba o re ee, ke kwae tse kae ka letsatsi?	Wording changed
	Haeba o re ee, o qadile o le dilemo tse kae?		
Q22:	**Ke efe e hlalosang hantle ho fetisisa nalane ya hao ya ho tsuba seneifi**		
	Ha ke so sebedise seneifi ho hang		
	O tsuba seneifi hona jwale		
	Ke ne ke sebedisa seneifi nakong e fetileng		
	Haeba o re ee, o tsuba seneifi makgetlo a makae ka letsatsi?		
	Haeba o re ee, o qadile o le dilemo tse kae?		
Q23:	**Ke efe e hlalosang hantle ka ho fetisisa nalane ya hao ya tshebediso ya jwala:**		
	Ha ke so sebedise dihlahiswa tsa jwala ho hang	Ha ke so sebedise dihlahiswa tsa nnotahi ho hang tsa jwala	Wording changed
	Ke sebedisa dihlahiswa tsa jwala a jwale		
	Ke ne ke sebedisa dihlahiswa tsa jwala nakong e fetileng		
	Haeba o re ee, o sebedisa jwala ka makgetlo a makae ka beke?		

English version	Moderated version	Changes after cognitive debriefing	Comments
	Haeba o re ee, o qadile o le dilemo tse kae?		
	DIPOTSO TSE LATELANG DI MABAPI LE BOPHELO BA HAO BO BOTLE		
Q24:	**Bophelo ba hao bo botle ka kakaretso bo**		
	Bo tswile matsoho		
	Bo botle haholo		
	Bo botle		
	Bo mahareng		
	Bo a fokola		
	Na o kile wa bolellwa ke ngaka hore o na le?		
	Kgatello e phahameng ya madi *(Hypertension)*		
	Tswekere (Mofuta wa II wa Lefu la Tswekere)		
	Botenya bo fetang tekano		
	Kholesterole *(hyperlipidaemia)*		
	Bohloko ba manonyeletso (Bokudi ba mesifa le masapo a mmele)		
	Lebaka la hao la sehlooho la ho etela tleliniki kajeno ke lefe?		
	Ho tla bona sista / mooki	Ho tla bona mooki	Wording changed “sista” not used commonly rather “mooki”
	Ho tla bona ngaka		
	Ho fumana meriana		
	Bobedi sista le meriana	Bobedi mooki le meriana	Wording changed “sista” not used commonly rather “mooki”
	Bohloko ba manonyeletso (Bokudi ba mesifa le masapo a mmele)		

English version	Moderated version	Changes after cognitive debriefing	Comments
	E nngwe (hlalosa ka kopo)		
	Ke afe a mafu a latelang ao o bileng le oona dikgweding tse tharo tse fetileng?		
	Kgatello e phahameng ya madi *(Hypertension)*		
	Tswekere (Mofuta wa II wa Lefu la Tswekere)		
	Botenya bo fetang tekano		
	Bohloko ba manonyeletso kapa mesifa		
	Ho lemala kapa kotsi		
	Mathata a pelo		
	Ditletlebo mabapi le mpa		
	Mathata a amanang leditho tsa bong kapa tsa mosese		
	Seso se sa foleng	Mofetshe	Wording changed
	Ditshwaetso (TB/e sele		
	Kgolofalo	Holofala	Wording changed
	Le sele (hlalosa ka kopo)		
	Na ngaka ya hao kapa sista / mooki o kile a o jwetsa hore o hloka ho latela lenaneo la boikwetliso?	**Na ngaka ya hao kapa mooki o kile a o jwetsa hore o hloka ho latela lenaneo l boikwetliso?**	Wording changed “sista” not used commonly rather “mooki”
	Ee		
	Tjhe		
	Ha ke na bonnete		

English version	Moderated version	Changes after cognitive debriefing	Comments
	Nakong ya dikgwedi tse 3 tse fetileng na o bile le bohloko, ho opelwa, ho ruruha, ho satalla (ho tiya) kahare kapa ho potoloha manonyeletso a hao kapa mokokotlo bo sa amananeng le ho lemala / kotsi?	**Nakong ya dikgwedi tse tharo tse fetileng na o bile le bohloko, ho opelwa ho ruruha, ho satalla (ho tiya) kahare kapa ho potoloha manonyeletso a hao kapa mokokotlo bo sa amananeng le ho lemala / kotsi?**	Wording changed
	Ee		
	Tjhe		
	Ha ke na bonnete		
	Nakong ya matsatsi a 7 a fetileng na o bile le bohloko, ho opelwa, ho ruruha, ho satalla (ho tiya) kahare kapa ho potoloha manonyeletso a hao kapa mokokotlo bo sa amananeng le ho lemana / kotsi?	**Nakong ya matsatsi a supilenga fetilen na o bile le bohloko, ho opelwa, ho ruruha, ho satalla (ho tiya) kahare kapa ho potoloha manonyeletso a hao kapa mokokotlo bo sa amananeng le ho lemaa / kotsi?**	Wording changed
	Ee		
	Tjhe		
	Ha ke na bonnete		
	Khoutu ya ID		
	Mohla:		
	Tleliniki:		

English version	Moderated version	Changes after cognitive debriefing	Comments
	MOKGAHLELO WA II:		
	DIPOTSO TSE LATELANG DI BOTSA KA BOHLOKO BA MANONYELETSO KAPA MESIFA, HO SATALLA / HO TIYA KAPA HO RURUHA HO POTOLOHA MANONYELETSO A HAO, KAPA MOTSAMAO O FOKOTSEHILENG MANONYELETSONG AFE KAPA AFE		
	Ka kopo bontsha setshwanshong se ka tlasemona, ka ✓dibaka tsohle tseo o utlwileng bohloko ho tsona dikgweding tse 3 tse fetileng pele ho patlisiso le ka X dibakeng tsohle moo o bileng le ho ruruha	**Ka kopo bontsha setshwanshong se ka tlase mona, ka ✓dibaka tsohle tseo o utlwileng bohloko ho tsonadikgweding tse tharo tse fetileng pele ho patlisiso l ka X dibakeng tsohle moo o bileng le ho ruruha.**	
	Ka pele		
	Ka morao		
	Ka kopo bontsha setshwantshong se ka tlasemona, ka ✓dibaka tsohle tseo o utlwileng bohloko ho tsona matsatsing a 7 a fetileng pele ho patlisiso le ka X dibakeng tsohle moo o bileng le ho ruruha		
	Ka pele		
	Ka morao		
	Bohloko bo qadile neng?		
	Ka tlase ho matsatsi a 7 a fetileng	Ka tlase ho matsatsi a supileng a fetileng	Wording instead of numbers
	Dikgweding tse 3 tse fetileng	Dikgweding tse tharo tse fetileng	Wording instead of numbers
	Dikgwedi tse 3 ho isa selemong se 1 se fetileng	Dikgwedi tse tharo ho isa selemong se le seng se fetileng	Wording instead of numbers

English version	Moderated version	Changes after cognitive debriefing	Comments
	Ho feta selemo se 1 se fetileng	Ho feta selemo se le seng se fetileng	Wording instead of numbers
	Ke matsatsi a makae dikgweding tse 3 tse fetileng o bileng le bohloko bofe kapa bofe?		
	Bontsha sekaleng matla a bohloko boo o bileng le bona nakong ya matsatsi a 7 a fetileng.	**Bontsha sekaleng matla a bohloko boo o bileng le bona nakong ya matsatsi a supileng a fetileng.**	Wording instead of numbers
	Ha ho bohloko		
	Bo bobebe		
	Bo bobebe		
	Bo totileng		
	Bototileng haholo		
	Bototileng haholo		
	Bontsha sekaleng matla a bohloko boo o bileng le bona nakong ya dikgwedi tse 3 tse fetileng.	**Bontsha sekaleng matla a bohloko boo o bileng le bona nakong ya dikgwedi ts tharo tse fetileng.**	Wording instead of numbers
	Ha ho bohloko		
	Bo bobebe		
	Bo bobebe		
	Bo totileng		
	Bototileng haholo		
	Bototileng haholo		
	Ha ho bohloko		
	Bo bobebe		
	Haeba bohloko bo hlaha kgafetsakgafetsa, ketsahalo eo e nka nako e kae?		

English version	Moderated version	Changes after cognitive debriefing	Comments
	Matsatsi a mmalwa		
	dibeke tse 4 - 6	nne ho isa hotse tsheletsheng	Wording changed
	dibeke tse 6 - 12	tsheletsheng ho isa ho tse leshone le metso e mmedi	Wording changed
	Ho feta dikgwedi tse 3	Ho feta dikgwedi tse tharo	Wording instead of numbers
	Bohloko bo matla haholo neng?		
	Hoseng ha o tsoha		
	Kamora tshebetso (ho etsa ho hong)		
	Ha o phomotse bosiu		
	E nngwe (hlalosa ka kopo)		
	Nakong ya selemo se fetileng na o bile le ho tiya / ho satalla manonyeletsong a hao hoseng kamora ho tswa dikobong kapa kamora phomolo e telele ntle le ho tsamaya?		
	Ee		
	Tjhe		
	Ha ke na bonnete		
	Ho tiya / ho satalla ho bile teng nako e kae?		
	metsotso e 30 kapa ka tlase	metsotso e mashome a mararo kapa ka tlase	Wording changed
	Ho feta metsotso e 30	Ho feta metsotso e mashome a mararo	Wording changed
	Na ho tiya / ho satalla ho ile ha fela kamora ho ikwetlisa kapa ho itsamaisa manonyeletso?		
	Ee		
	Tjhe		

English version	Moderated version	Changes after cognitive debriefing	Comments
	Ha ke na bonnete		
	Na o kile wa fumanwa kapa na motho o kile a o jwetsa hore o na le lefu la masapo kapa mafu a mang a manonyeletso jwalo ka ramatiki?		
	Phumano ya lefu eo o e fuweng ke efe?		
	Phumano ya lefu e entswe kae?		
	Na o ntse o nwa moriana bakeng sa bohloko ba manonyeletso kapa mokokotlo, o sa amananeng le temalo, nakong ya dikgwedi tse 3?	**Na o ntse o nwa moriana bakeng sa bohloko ba manonyeletso kapa mokokotlo, o sa amananeng le temalo, nakong ya dikgwedi tsetharo?**	Wording instead of numbers
	Ee		
	Tjhe		
	Ha ke na bonnete		
	Haeba o re ee, o sebedisitse meriana efe?		
	bohloko tse ithekelwang		
	Meriana ya tlhaho, dimela, ditlatsetsotsa phepo		
	Meriana e ithekelwang e alafang tlerefalo (di-NSAIDS)		
	Meriana e laetsweng ke ngaka e alafang tlerefalo (di-NSAIDS)		
	Meriana e meng e laetsweng ke ngaka		
	E meng (hlalosa ka kopo)		

English version	Moderated version	Changes after cognitive debriefing	Comments
	Na o fumane mofuta ofe kapa ofe o mong wa kalafo, ntle le moriana wa bohloko?		
	Ee		
	Tjhe		
	Ha ke na bonnete		
	Hlalosa ka kopo		
	Kameho ke efe, haeba e le teng, eo bohloko / lefu la masapo le bileng le yona bophelong ba hao jwalo ka ha ho bontshitswe ka tlasemoo?		
	Ha ho letho		
	Bobebe		
	Mahareng		
	Totile		
	Dikamano tsa lelapa		
	Dikamano tsa setjhaba		
	Dikamano tsa lenyalo (ho kenyeletswa diketso tsathobalano		
	Maemo a ditjhelete		
	Bokgoni ba ho sebetsa		
	Mosebetsi wa boithabiso	Mosebetsi wa boithabiso	Wording changed
	Dipapadi		
	Tse ding, hlalosa ka kopo		
	Na o emisitse ho sebetsa ka lebaka la bohloko / lefu la masapo nakong ya selemo se fetileng?		
	Ee		
	Tjhe		
	Ha ke na bonnete		

English version	Moderated version	Changes after cognitive debriefing	Comments
	Na o fetotse mosebetsi wa hao ka lebaka la bohloko / lefu la masapo nakong ya selemo se fetileng?		
	Ee		
	Tjhe		
	Ha ke na bonnete		
	Na o nyahama ha bonolo kapa o ngongorehe ka lebaka la bohloko / lefu la masapo?		
	a boroko ba hao bo etsahala ka tsela e sa tlwaelehang ka lebaka la bohloko / lefu la masapo?		
	Ee		
	Tjhe		
	Ha ke na bonnete		
	Na o ikutlwa o kgathetse mmeleng ka lebaka la bohloko / lefu la masapo (o sa kgone ho etsa mesebetsi ya letsatsi le letsatsi)?		
	RE A LEBOHA HA O NKILE NAKO YA HO PHETHA LENANE LENA LA DIPOTSO		

APPENDIX 18

Time to complete questionnaires

Demographic information regarding cognitive debriefing per questionnaire

1 Epidemiological survey

Language: Sesotho

Age of each participants:	Gender:	Profession:	Specify time taken by each participants to complete the survey, in minutes:
R1: 46	Female	Supervisor for cleaning company	R1: 20
R2: 52	Female	General worker	R2: 25
R3: 42	Female	Unemployed	R3: 22
R4: 54	Female	Cleaning lady	R4: 20
R5: 60	Female	Retired	R5: 27
Mean age: 50.8 years			Mean time: 16.8 minutes
Median age: 52 years			Median time: 17 minutes

2 WHODAS 2.0 (Self-administered)

Language: Sesotho

Age of each participants:	Gender:	Profession:	Specify time taken by each participants to complete the survey, in minutes:
R1: 46	Female	Supervisor for cleaning company	R1: 5
R2: 52	Female	General worker	R2: 7
R3: 42	Female	Self-employed	R3: 5
R4: 54	Female	Cleaning lady	R4: 8
R5: 60	Female	Manager	R5: 8
Mean age: 50.8 years			Mean time: 6.6 minutes
Median age: 52 years			Median time: 7 minutes

The median time for the participants to complete the WHODAS 2.0 is in accordance to Ustun et al's (2010) findings that the 12-item version can be completed in five to 10 minutes when self-administered.(1)

1. Ustun TB, Chatterji S, Kostanjsek N, Rehm J, Kennedy C, Epping-Jordan J, et al. Developing the World Health Organization Disability Assessment Schedule 2.0. *Bulletin of the World Health Organization*. 2010;88(11):815-23.

APPENDIX 19

Results of cognitive debriefing

Results of the cognitive debriefing session of the translation project

Only the questions that participants experienced difficulty with will be mentioned in the results. Only slight difficulty was experienced with the questions.

Phase I: Questions ask about your personal data and medical history (demographic characteristics)

Question 7: Co-morbidities (please indicate all applicable). Participants had to indicate present, not present or do not know.

Chronic respiratory disease: Two of the participants did not understand what was meant by chronic respiratory disease and thought it meant that you go shortness of breath when walking. The other three participants did understand that it is a specific disease and mentioned that it is something like asthma.

Question 12: Highest level of education: Participants were given the options of no schooling, primary school, secondary school and tertiary education.

Two of the participants wanted to change the word tertiary education to university – while the other three did understand that it included other institutions for example a university of technology or the word the participants used "technicon".

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.

Question 5: **If your pain is recurrent, how long does the episode last?** Participants had the option to choose few days, four to six weeks, six to 12 weeks and more than 3 months.

All the participants preferred that the 12 weeks were to be put into three months as they did not understand that the 12 weeks were the same time frame as three months.

Question 9: Did the tightness / stiffness go away after exercise or movement of the joint? Participants were given the options of yes, no and not sure.

One of the participants did not understand what was meant by movement of the joint. The other four participants could explain exactly what was meant by the wording. A note was made that the fieldworkers need to explain the concept to participants when asking the question during the survey to ensure that there is no misunderstanding of the concept.

Question 10: Have you ever been diagnosed or has anyone told you that you have arthritis or other joint diseases like rheumatism? Once again participants were given the options of yes, no or not sure.

Three of the participants did not understand what was meant by rheumatism. They understood that "rumatiki" meant older joints but they were not familiar with rheumatoid arthritis. When the facilitator explained the difference between the two diseases to them they acknowledge that they had seen people with the disease and understood the difference between the two diseases. A note was made that during the training of the fieldworkers they had to be made aware of the difference between the two diseases and that they must explain the two concepts to participants when completing the question during the survey.

Question 10a: What was the diagnosis given to you?

All the participants struggled with the concept of diagnosis given to you. Once the facilitator explained to them that the doctor after examination informs you what is wrong with you, therefore giving you a diagnosis, they laughed and said that the doctor normally just gives them medicine and does not tell them what is wrong with them. If they do tell them it is normally that they have "high blood" or "high sugar". They never say anything about their joint pain.

Question 14: What is the effect, if any, the pain / arthritis has had on your life as outlined below? A table was given indicating that participants should indicate if there was no effect, a mild, moderate or severe effect. The aspects of life that was included in the table was family, social, marital relations, financial position, ability to work, hobby, games and other.

All five the participants did not understand the word hobby in Sesotho. Once the facilitator explained the concept to them, they acknowledge that they were familiar with the concept, but then realized that there was a spelling error in the questionnaire and that is why they did not recognise the word.

Further minor changes were made to wording, typing errors or grammatical errors that participants felt would enhance the questionnaire.

APPENDIX 20

Results of cognitive debriefing of fieldworkers

Feedback from fieldworkers during translation project

The fieldworkers mentioned that older participants did not feel comfortable answering questions regarding difficulties experienced during their sexual activities and the researcher made it clear to the fieldworkers that participants had the right to refuse to answer questions that made them uncomfortable and that this would be noted as missing data. Please refer to Question 14 below.

Other questions that posed problems for the participants were:

Question 29a: 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? Participants had to indicate yes, no or not sure. There was uncertainty what to indicate when the joint pain was present a year ago or if they experienced joint pain for longer than three months. The fieldworkers were instructed after the pilot study to note the answer next to the question.

Question 12: If yes, what medication was used? Participants were given the options over the counter pain killers; natural remedies, herbs, supplements; over the counter anti-inflammatory drugs (NSAIDS's); prescribed anti-inflammatory drugs (NSAID's); other prescribed medication and other. The fieldworkers replaced the word "over the counter" with "which you can buy in a shop or pharmacy without a doctor's note" which the participants understood better.

Question 14: What is the effect, if any, the pain / arthritis has had on your life as outlined below? Participants could indicate none, mild, moderate and severe. Participant's especially older women did not feel comfortable to answer the question regarding their marital relations (including sexual activities).

APPENDIX 21

Human Research Ethics Committee Letter

University of Cape Town

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

02 October 2013

HREC REF: 605/2013

Prof J Jelsma
Health & Rehab
F-Floor
OMB

Dear Prof Jelsma

PROJECT TITLE: AN INVESTIGATION INTO THE PREVALENCE AND NATURE OF MUSCULOSKELETAL CONDITIONS AMONGST WOMEN ATTENDING PRIMARY HEALTH CARE CLINICS, AND THE EFFECTIVENESS OF AN INTERVENTION PROGRAM FOR THESE PATIENTS

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 October 2014

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)

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

APPENDIX 22

Ethics Committee Letter

University of the Free State

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS UV

Research Division
Internal Post Box G40
☎(051) 4052812
Fax (051) 4444359

E-mail address: StraussHS@ufs.ac.za

Ms H Strauss/jdpl

2014-06-26

REC Reference nr 230408-011
IRB nr 00006240

MS RY BARNES
DEPARTMENT OF PHYSIOTHERAPY
FACULTY OF HEALTH SCIENCES
CR DE WET BUILDING
UFS

Dear Ms Barnes

ECUFS NR 185/2013
PROJECT TITLE: AN INVESTIGATION INTO THE PREVALENCE AND NATURE OF MUSCULOSKELETAL CONDITIONS AMONGST WOMEN ATTENDING MUCPP AND THE EFFECTIVENESS OF AN INTERVENTION PROGRAM FOR THESE PATIENTS.

- You are hereby kindly informed that the Ethics Committee approved the above study after all conditions have been met when the following signed permission letters were submitted. It will be condoned at the meeting scheduled for 22 July 2014:
  - ***Head of the Dept of Health, Free State Province***
  - ***Head of MUCCP***
- The Ethics Committee also approved the following:
  - ***Project title of the study changed from "An investigation into the prevalence and nature of musculoskeletal conditions amongst women attending Primary Health Care Clinics, and the effectiveness of an intervention program for these patients to "An investigation into the prevalence and nature of musculoskeletal conditions amongst women attending MUCPP and the effectiveness of an intervention program for these patients".***
  - ***Amendments to the protocol***
- Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.

- Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.
- The Committee must be informed of any serious adverse event and/or termination of the study.
- A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies
- Kindly refer to the ECUFS reference number in correspondence to the Ethics Committee secretariat.

PROF WH KRUGER
CHAIR: ETHICS COMMITTEE

Cc

APPENDIX 23

Free State Department of Health Permission Letter

health
Department of
Health
FREE STATE PROVINCE

27 November 2013

Ms RY Barnes
Department of Physiotherapy
Faculty of Health Sciences (UFS)
BLOEMFONTEIN
9300

Dear Ms RY Barnes

Subject: An investigation into the prevalence and nature of musculoskeletal conditions amongst women attending primary health care clinics, and the effectiveness of an intervention program for these patients

The above mentioned correspondence bears reference.

- Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation must be voluntary.
- Written consent by each participants.
- Ascertain that your data collection exercise neither interferes with the day to day running of the health facilities nor the performance of duties by the respondents.
- Serious Adverse events to be reported and/ or termination of the study.
- Confidentiality of information will be ensured and no names will be used.
- Research results and a complete report should be made available to the Free State Department of Health on completion of the study.
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Free State and to Free State Department of Health
- Please indicate by name the "Other" clinics which you going to conduct research from and send the list to the department of Health
- Signed permission letter from the Head of MUCPP and The sister in charge at Primary Health Care Clinics have to be submitted to the Ethics committee of the University of Free State
- Research may not be conducted before the above conditions has/have been met.
- Department of Health to be fully indemnified from any harm that patients and staff experiences in the study

Head : Health
PO Box 227, Bloemfotein, 9300
4th Floor, Executive Suite, Bophelo House, cnr Maitland and, Harvey Road, Bloemfotein
Tel: (051) 408 1646 Fax: (051) 408 1556 e-mail:khusemj@fshealth.gov.za/fshealth.gov.za/chikobvup@fshealth.gov.za

APPENDIX 24

Community clinic permission letter

PERMISSION LETTER

EPIDEMIOLOGICAL STUDY

20 May 2014

Dear Sister

Re: Permission for research study in women between the ages of 40 – 64 years attending Primary Health Care Clinics in the Bloemfontein area and MUCPP.

Research title: An investigation in the prevalence and nature of musculoskeletal conditions amongst women attending Primary Health Care Clinics, and the effectiveness of an intervention program for these patients.

I am a PhD student in physiotherapy at the University of Cape Town and a lecturer in physiotherapy at the University of the Free State (UFS). My field of interest is neuromusculoskeletal conditions and co-morbidities, therefore I would like to examine the nature and prevalence of non-traumatic joint pain and the relationship between joint pain and other co-morbid conditions in women attending Primary Health Care Clinics in Bloemfontein. I have randomly selected9 clinics for the study and MUCPP of which your clinic is one. I will need 135 women from this clinic to meet my sample size of 1 353.

My hypothesis is that there will be a high incidence of co-morbidities and musculoskeletal conditions amongst women between the ages of 40 – 64 years attending Primary Health Care Clinics.

Participants will be recruited while waiting in the queue at the clinic. Participation in the survey will take approximately 20 minutes. Participants will not forfeit their place in the queue at the clinic and completing the questionnaire will not affect their scheduled visit to the clinic. The rest of their treatment at the clinic will stay the same, thus there will be no impact on the service delivery of the clinic during the survey. Taking part in the survey is voluntary and participants may decide to stop taking part in the survey at any time without being penalised in any way. There is no risk involved in taking part in the survey as participants will only be answering questions or completing the questionnaires by themselves.

Blood pressure measurements and glucose readings of the participants will be required and a finger prick test will be performed to determine the glucose readings of each participant after informed consent has been obtained. Participants will also be weighed and their height will be measured to determine their body max index. The researcher will provide electronic scales that will be available at each clinic. The researcher will also provide blood pressure monitors as well as Accu check monitors for the finger prick test. This will ensure that there is no impact on the service delivery and no extra costs will be incurred by the clinic.

The information of the participants will be strictly confidential. Each participant will receive a unique, arbitrary code and any written documents will be labelled with that number to keep the nature and quality of the participants' information strictly confidential. The result of the study may be published in an accredited journal and presented at a congress.

This letter is to ask permission to perform the survey at the Clinic. No responsibilities are expected of you or your staff.

Ethical approval has been obtained from the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town and the Ethical committee at the Medical Faculty of the University of the Free State. Numbers: HREC Ref 605/2013 and ECUFS nr 185/2013.

For any questions regarding the study, you can contact me at 082 740 1069 or e-mail me at BarnesRY@ufs.ac.za or contact the secretariat of the ethics committee of the University of Free State's Faculty of Health Science at 051-4052812 or the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town (contact number: 021 – 406 6411).

I have also received permission from the Head of the Department of Health from the Free State. Please see attached signed letter.

If permission is granted for the study, please sign the attached slip.

Yours faithfully

Roline Barnes
(Researcher)(Physiotherapist

To: Roline Barnes

I, Pulane Juliet Miningwa.

sister in charge at MUCPP CHC

have read the information document and understand the nature of the study as well as the benefits and risks involved. I give my permission for the survey into musculoskeletal conditions and co-morbidity, amongst women attending Primary Health Care Clinics and MUCPP to take place at the clinic. I wish to be kept informed of any changes to the survey if deemed necessary.

Date: 2014-05-21

0823781369
0514356430

APPENDIX 25

Epidemiological study

Participant information leaflet

INFORMATION LEAFLET

EPIDEMIOLOGICAL STUDY

University of Cape Town: *An investigation into musculoskeletal conditions and co-morbidity amongst women attending Primary Health Care Clinics and the effectiveness of an intervention programme for patients with these conditions.*

Dear Participant

Introduction

I, Roline Barnes, am currently a student in Physiotherapy at the University of Cape Town and a lecturer at the University of the Free State. I need to do a research project in order to get my degree. Research is simply the process to learn the answer to a question.

Title of the research project

The title of the survey is *"An investigation into musculoskeletal conditions and co-morbidity amongst women attending Primary Health Care Clinics and the effectiveness of an intervention programme for patients with these conditions."*

Purpose of the survey

I am interested in knowing how many women attending the clinics have pain in their joints and also 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 their lifestyle and how the pain in their joint and illnesses prevent them from doing things in their lives (e.g. climbing stairs, walking to the shop). Telling me this can help me to inform people in the Local Government and the Department of Health to help people in the community to cope better with the joint pain and other illnesses. The government can also place people at the clinics that are trained to give patients at the clinics exercises and information to handle the pain and illnesses better.

Selection of participants

All women at the clinic on the day of the research, between the ages of 40 – 64 years will be asked to take part in the survey (answering questions).

Description of research

They will be answering a few questions regarding their age, weight, where they live, their general health and when they experience pain in their joints (if any). It will take more or less 20 minutes to answer all the questions. They will not lose their place in the queue (line) and answering the questions will not affect their visit to the clinic. The rest of their treatment at the clinic will stay the same. They are taking part in the survey as a volunteer / of their own free will and they may decide to stop taking part in the survey (answering the questions) at any time without being punished in any way. There is no danger involved in taking part in the survey as they will only be answering questions that will be completed on paper. Their weight and height will be measured and their finger will be pricked to get a drop of blood to test their sugar levels. This will not be painful. They will see that there is a number in the top corner of the questionnaire and their 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 they have given - this will protect who they are (their identity). They will receive no money to take part in the survey.

There are no direct benefits for them taking part in the survey, but the results of the survey will help me, the researcher, to use the information to develop a programme that might help women with high blood, high sugar and being overweight to live healthier. The women taking part in the study will not receive any money for taking part and the study will also not cost them any money to take part.

The results of the survey might be put in a magazine for doctors, nurses and other people working with health, so that they can know how many people like themselves, have problems with joint pain and other illnesses in the community.

The person in charge of the clinics and the sister told me that I may do the study at the clinic and that I may give women the form to fill in, if they want to help me.

If they want to ask anything before we start with the questions, or later on, they can phone me, Roline Barnes, at 082 740 1069, or the person supervising me, Prof Jelsma, at 021 – 406 6595. They may also contact the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee (contact number: 021 – 406 6411) or the University of the Free State Ethics Committee (contact number:

051 – 405 2812) if they have any queries/questions or concerns regarding their rights or welfare as research participant.

Thank you

Roline Barnes

APPENDIX 26

Epidemiological study

Participant informed consent document

CONSENT TO PARTICIPATE IN RESEARCH

EPIDEMIOLOGICAL STUDY

University of Cape Town: *An investigation into musculoskeletal conditions and co-morbidity amongst women attending Primary Health Care Clinics.*

I _____ have read (or had read to me by)
_____ the information sheet.

I understand what is required of me and I have had all my questions answered. I do not feel that I am forced to take part in this study and I am doing so of my own free will. I know that I can withdraw at any time if I so wish and that it will have no consequences for me.

Signed:

_____ _____

Participant Date and place

_____ _____

Researcher Date and place

_____ _____

Witness *(if necessary)* Date and place

APPENDIX 27

Epidemiological Study

STROBE checklist

STROBE guidelines for observational studies in epidemiology and indication of section where items were addressed

Section/Topic	Item No	Checklist item	Reported in
Title and abstract	1 (a) 1 (b)	Identification of the study design Abstract	Section 6.2.1 Abstract
Introduction			
Background/objectives	2 (a)	Scientific background and rationale	Section 1.1.1 - 1.1.2 and 1.3 and 6.1
	2 (b)	Specific objectives	Section 1.2 and 6.1.1
Methods			
Study design	4	Study design	Section 6.2.1
Setting	5	Setting, locations and relevant dates, including periods of recruitment and data collection	Section 1.4 and 6.7
Participants			
Cross-sectional study	6	Eligibility criteria, source and methods of selection of participants	Section 6.2.2 - 6.2.3 and 6.2.3.1
Variables	7	Define outcomes, exposures, predictors, potential confounders and effect modifiers	Section 5.2.1 – 5.2.3 and 6.3

Section/Topic	Item No	Checklist item	Reported in
Data sources/ measurement	8	Details of methods of measurement	Section 5.2.1 – 5.2.3 and 6.3 and 6.7
Bias	9	Efforts to address potential sources of bias	
Study size	10	Study size arrived at	Section 6.2.3.2
Quantitative variables	11	Quantitative variables handled in analysis	Section 6.9
Statistical methods	12	Describe all statistical methods	Section 6.8 and 6.9
	(b)	Methods used to examine subgroups and interactions	Sections 6.8 and 6.9
	(c)	Missing data	Section 6.9
	(d)	Cross-sectionals study – analytical methods of sampling strategy	Section 6.8 and 6.9
	(e)	Sensitivity analyses	Section 6.9
Results	13	Numbers of individuals at each stage of study	Section 6.9 and Figure 7

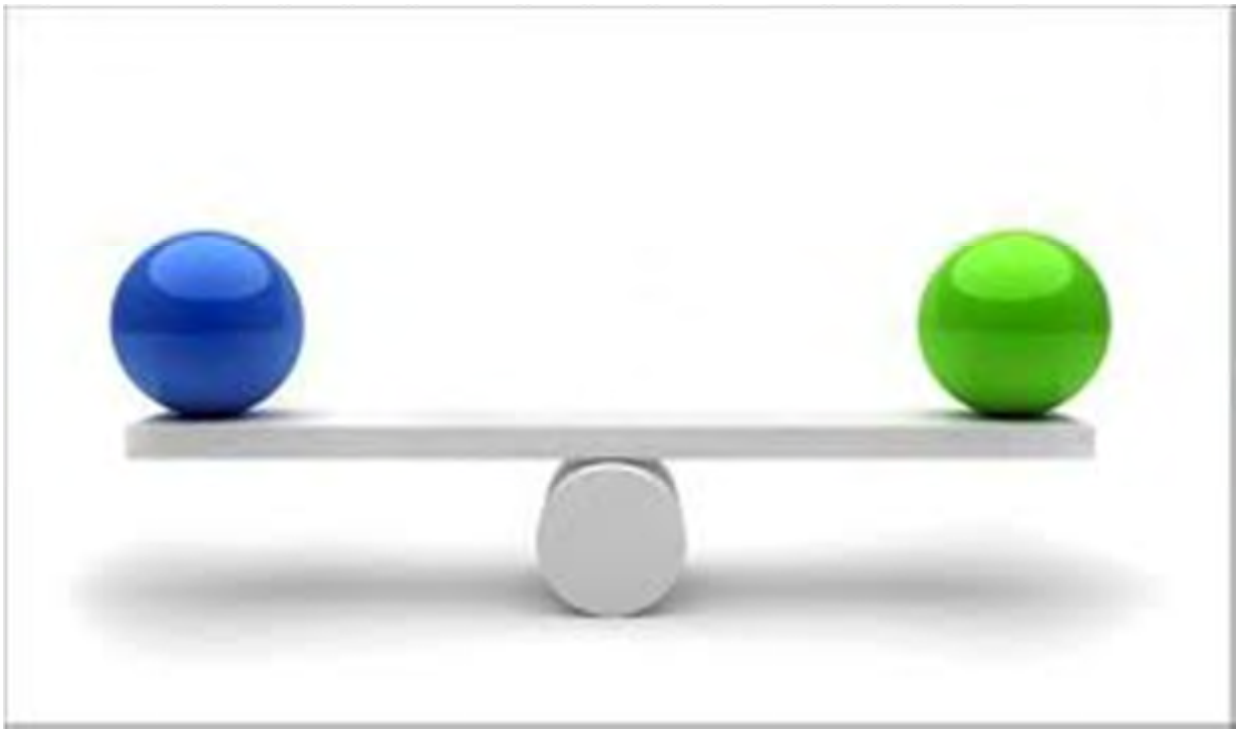
Section/Topic	Item No	Checklist item	Reported in
	(b)	Reasons for non-participation	Section 6.9.1 and Figure 7
	(c)	Flow diagram	Figure 7
Descriptive data	14	Characteristics of study participants	Section 6.9.1 and 6.9.2
	(b)	Number of participants with missing data	Section 6.9.1 and Figure 7
Outcome data	15	Numbers of outcome events (Objectives) or summary measures	Section 6.9
Main results	16	Unadjusted estimates and if applicable confounder-adjusted estimates and precision (95% confidence interval)	Section 6.9
	(b)	Category boundaries when continuous variables were categorized	Section 6.9.3 – 6.9.9
	(c)	Consider translating estimates of relative risk into absolute risk for a meaningful time period	Section 6.9.6
Other analyses	17	Other analyses done	N/A

Section/Topic	Item No	Checklist item	Reported in
Discussion			
Key results	18	Summary of key results	Section 6.9.10 and Section 6.10
Limitations	19	Discussion of limitations of the study	Section 6.10.7
Interpretation	20	Cautious overall interpretation of results	Section 6.10.8
Generalisability	21	Discussion of generalisability (external validity)	Section 6.10.7 and 6.10.8
Other information			
Funding	22	Sources of funding and role of the funders	N/A

APPENDIX 28

Balanced Lifestyle workbook

Balanced lifestyle



Name: _____

Balanced Lifestyle

This a workbook designed to be used over 6 weeks which aims to help people develop self-management skills for living with musculoskeletal pain, diabetes mellitus type II, hypertension and being overweight. Using this workbook is not about sitting and reading or listening to your group leader. In order to get the most out of this workbook and group you will be asked to share your experiences, set goals and share these goals with other members in the group and you will need to take part in exercises and activities. This workbook is NOT a substitute for any other medical care that has been recommended for the treatment of your condition(s). Throughout the workbook and group session we will refer to musculoskeletal pain (joint pain), diabetes (sugar); hypertension (high blood pressure) and being overweight. You may suffer from one, two or even more than two of the conditions mentioned at the same time. Please only use the information in the workbook and group sessions that is applicable to your condition(s).

You will benefit most from this workbook if you commit yourself to completing all the sessions within the 6 week period of time. Research tells us that these group sessions are of great benefit to people living with chronic diseases such as diabetes, high blood pressure and arthritis. But to benefit from the group session, it is essential to use the workbook regularly over 6 weeks and to participate in the exercises and group activities. The workbook is divided into six sections:

1. Week 1: What is Hypertension, Diabetes Mellitus Type II and being overweight
   Self-management
2. Week 2: Exercise
3. Week 3: Stress Management
4. Week 4: Pain (Musculoskeletal pain – joint pain)
5. Week 5: Eating Well
6. Week 6: Continuing as a successful self-manager

Your group leader is…….. . She has been trained to give you all the exercises as well as the information you need to manage your chronic disease. She has been trained by a physiotherapist lecturer who specializes in musculoskeletal conditions/diabetes, high blood pressure and being overweight.

Week 1: High Blood Pressure (Hypertension)

Blood pressure is a measurement of the amount of pressure in a type of blood vessel called an artery. The measurement is given as two numbers. A normal blood pressure is 120/80 mmHg. Both numbers are important because a high reading for either type of pressure can cause damage. Most people who have high blood pressure have no symptoms and cannot tell if their blood pressure is high and the cause is unknown. People, whose blood pressure is high, can feel well. Over years untreated high blood pressure can damage blood vessels and in some people this damage can cause strokes, heart attack or damage to the eyes or kidneys. That is why it is important to control your blood pressure. Blood pressure can be lowered by a combination of a low salt diet, exercise, maintaining a healthy weight, limiting alcohol and using your medication properly (if you have any).

Get help immediately if:

Heart attack warning signs:

♥If you feel a severe, crushing or squeezing chest pain

♥Pain or discomfort in one or both arms, the back, neck, jaw or stomach

♥Chest pain lasting longer than 5 minutes when there is no apparent cause and it is not relieved by rest.

♥Chest pain and any of the following at the same time: irregular heartbeat, sweating, nausea or vomiting, shortness of breath, light-headedness, or unusual weakness. For women chest pain may not be present with these symptoms

♥Stop immediately what you are doing

♥Sit down

♥Call 051 – 405 8911 or 051 - 407 6000

♥If you are not allergic to aspirin, take one tablet of 325 mg. (Disprin)

Stroke warning signs:

- Sudden numbness or weakness of the face, arms or leg especially on one side of the body
- Sudden confusion, trouble speaking or trouble understanding
- Sudden trouble seeing in one or both eyes that does not clear with blinking
- Sudden trouble walking, dizziness, loss of balance or coordination
- Sudden severe headache with no known cause
- Don't wait more than 5 minutes to call for help

Diabetes Mellitus Type II (Sugar)

Diabetes is a disease that makes it difficult for the body to use the sugar in the blood. The body normally produces a hormone called insulin. People with diabetes either don't have enough insulin in their body or the insulin in their body is not working properly. This means that the body cannot move the sugar out of the blood so the sugar levels remain high. The extra sugar in the blood causes problems for the body's functions. Type II diabetes may start as a result of being overweight, lack of exercise, eating and other lifestyle habits. It is more common among people who are overweight. Increased fat makes it hard for the body to use the insulin in the correct way. Diabetes does not happen overnight, it happens slowly over time. There are many people whose blood sugar levels are higher than normal but not high enough to be diagnosed with diabetes. Most people with type II diabetes can manage their blood glucose (that is the amount of sugar in the blood) with medication, controlling their exercise, diet and weight, sometimes by losing between 4-6 kg. The general rule is that if you can lose 7% of your body weight you can bring blood glucose into a healthy range. So if you weigh 80kg, if you lose 6kg and get down to 74kg you have a good chance of getting your blood glucose under control.

Early symptoms of diabetes mellitus type II may include:

- Fatigue (very tired all the time)
- Hunger
- Increased thirst
- Going to the toilet more often (urinating)
- Blurred vision
- Pain or numbness in the feet or hands
- Skin or other infections that heal slowly or occur often

Get help immediately if:

- If you feel chest pain or pressure
- If you have fainted or find someone unconscious
- If you have a seizure
- If you feel that you can't breathe and are short of breath
- Call 051 – 405 8911 or 051 - 407 6000

Go to the clinic if you have:

- Numbness, tingling, or pain in your feet or legs
- Problems with your eyesight
- Sores or infections on your feet
- Symptoms of high blood sugar (being very thirsty, having blurry vision, having dry skin, feeling weak or tired, needing to urinate a lot)
- Symptoms of low blood sugar (feeling weak or tired, trembling, sweating, feeling irritable, having trouble thinking clearly, fast heartbeat, double or blurry vision, feeling uneasy)

Being overweight

Being overweight is a disease in itself and is also a risk for other chronic diseases. Being overweight makes your life shorter; increases the risk of heart disease, and stroke; increases the risk for type II diabetes and hypertension. It is also associated with problems with breathing when you are asleep (this is called obstructive sleep apnea) and being overweight reduces the quality of life. Losing weight can lower your blood pressure, cholesterol and decrease the risk of dying earlier. Weight loss may improve your quality of life and your self-esteem. Losing weight is not easy but it can be done and has many benefits for your health.

Musculoskeletal conditions (Joint pain)

Musculoskeletal conditions are a large group of conditions that affect the joints and muscles over a long period of time. This happens when the joint is worker harder or stretching further than what it is prepared for. How serious the condition is may vary from person to person. Pain and discomfort may interfere with everyday tasks such as walking. Go to the clinic if you feel recurrent pain, if your joints are stiff and painful and there is swelling around your joints.

Self-Management

What is self-management? Self-management does not mean that you are expected to look after your health on your own. Someone who is a successful self-manager takes responsibility for their own well-being and health. They choose to work with the health team, with their medicine (if applicable) and with themselves to live a healthy, balanced life (just like a manager in a business – who doesn't have to do everything themselves, they work with a team to reach a specific goal).

There are lots of things you can learn to do which will help you to become a successful self-manager. The first thing is to understand your conditions which might be joint pain; diabetes mellitus type II, hypertension and being overweight. You need to understand about the condition(s), how they can affect your life and, if you have been given any, about the medication(s) given to you to treat the condition(s).

The second thing about being a self-manager is being able to think about the information and how it affects you and your life. The last thing is to think what you would like 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 read and learn about and practice every day during the group sessions and when using the workbook include exercising, relaxation techniques and healthy eating.

During the group sessions and using this workbook you will learn about exercises and its benefits, in the second week you will learn about the common symptoms of joint pain, diabetes, high blood pressure and being overweight; and how to manage these. The third week will focus on stress management, and the final weeks will focus on managing pain, and eating well. Some of you may already know a lot about these topics, while others may not know much. It is important to share information in the group sessions 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 worthwhile going through the workbook and attending the group session to make sure you have not missed out

on any information. Research tells us that people, who are well informed and understand about their health, manage their condition(s) better and have a better quality of life. Using this workbook, you will also learn and discuss the steps that you need to become a good self-manager. The steps are discussed below.

Self-management steps

Step 1:

To be a good self-manager you need to learn about and practice several skills during the group sessions and use the workbook. The first step is to decide *what* it is you would like to be able to do. This can be the hardest step. For example you might feel that you are overweight. First you need to think why you are overweight. Perhaps one of the reasons you are overweight is that you have not been eating the right types of food. Your first step might be to decide that you would start eating the right types of food. This will help you to feel better.

Write down three things that you would like to be able to do:

1) _____

_____

2) _____

_____

3) _____

_____

Step 2:

But deciding that you are going to lose weight doesn't mean it will happen. You will 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 lose weight you need to think about the different options you have. For example you could eat smaller portions of food, or you could decide you would decide you would make better choices about the types of food you are going to eat or by joining an exercise group. Never think that what you would like to be able to do is impossible. Always look at every available option and look at it from every angle.

Write down three different ways that you could try to achieve what you would like to do:

1) _____

2) _____

3) _____

Now that you have decided on *how* you are going to do things you need to compile an action plan. It is important that this plan is realistic otherwise it is likely that you will not succeed.

- First decide what you are going to do *this week*
- Now make a *specific plan*

Saying that this week I'm going to try to meet some new people or you are going to eat healthier food is NOT a specific plan. To be specific, the plan must have different parts. It is useful to ask yourself some questions to make ea specific plan. Questions like:

- *What?*

  Exactly what are you going to do? For example you could decide that in order to lose weight you are going to eat smaller portions of food.

- *How much?*

  Then you must decide how much you are going to do. For example are you going to dish up your food on a smaller plate and change the way you are cooking food all at once. Changing two things at once is going to be more challenging than only changing one thing at a time. So you have to decide how much you will be able to do.

- *When will you do it?*

  Then you must decide on exactly on which day you are going to start changing the portion size of your food and what meal. Maybe it is better to start off with your main meal of the day because that is when you eat the biggest plate of food. Or you can start by changing the portions size of your breakfast to ease you into a new routine.

- *How often?*

  This is always the hardest part. We would all 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 not possible and if we then miss a day we feel that we have failed and we give up. How often will you exercise? Not every day, but maybe three times a week. You know that you won't become fit 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 a 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 myself 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? Can you change the plan or solve the problems to make you feel more confident?

Step 3:

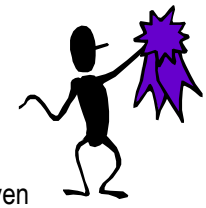
Now, write down your plan and put it somewhere you will see it every day. There is an action planning form at the end of this section and 5 more at the back of this workbook book. Use one for every week you are goingtotake part in the group sessions. You are welcome to draw up more of the action planning forms and keep on 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
- Specific
- Answers the questions: What? How much? When? How often?
- One I am confident that I can achieve this with a score of at least 7 out of 10.

Now you need to start carrying 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. During the group sessions you are going to make a plan every week and record how you are doing. It helps to report back to the group because then you can 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 with the group which might give you ideas about how to change or make plans to cope better.

Step 4:



Always check if you have achieved your plan and give yourself a reward. Also think about how achieving your plan makes you feel. Is the plan helping you to achieve what you want? ***What about problems?***

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 with plans. The steps are the following:

1. Deciding what the problem is (you might need friends and family to help you here)
2. List ideas to solve the problem
3. Select one idea to try and solve the problem
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.

A successful self-manager is someone who:

- Sets goals
- Makes a list of ways to achieve the goals
- Makes action plans to achieve the goals
- Carries out the action plans
- Checks progress every week
- Is able to change the action plan if there are problems
- Gives themselves a reward for achieving their goals

At the end of each section and at the end of the workbook there are "Action Planning Forms". Please use these forms to plan what you would like to do and how you are going to do it. Exercise is one of the most important aspects of the group sessions and workbook for all the conditions this workbook is used for. Please use the "Action Planning Form" at the end of this section to plan what exercise you are going to do this week.

Week 2: Exercise

Exercise is an 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 heart to be stronger and healthier and keeps our lungs working. Exercise makes our muscles and bones strong and our joints flexible so that we can keep moving. Exercise also helps us feel happy, improves our memory, helps us sleep better and lessens the effects of high blood pressure and diabetes. Exercise might also help us lose weight.

In the past, when people became ill with a chronic disease like high blood pressure or diabetes, medical care focused on helping them when their symptoms became worse. Treatment focused on using drugs and people were often advised to rest or decrease their activity. Today we know that if we teach people who develop chronic diseases about their disease and encourage them to do 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.

One of the biggest benefits of exercise is that exercising regularly makes you feel more in control of your life.

Exercise is good for:

- Improving mood
- Strength
- Improving sleep
- Concentration and memory
- Heart and lung health
- Decreasing body fat
- Digestion
- Increasing confidence to self-manage chronic diseases.

Although exercise is good for you and safe for you to do, sometimes your body will give you clues that you must not exercise today.

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.

What kind of exercise should you do?

You do not have to join a gym or a club to exercise. There are lots of ways of exercising from formal sports like running, playing netball or swimming. But, walking is a very good way to exercise for all ages. 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 and even cleaning the house is exercise. There are lots of ways that you 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/grandchildren!

There are three general kinds of exercises:

1. Endurance exercises like walking or dancing. Endurance exercise is sometimes called aerobic exercise which means that you will be breathing faster and your heart will be beating faster. 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 or we can do 150 minutes of exercise over the weekend. If we need to lose weight we have to do 45 – 60 minutes of exercises. You don't have to start with this amount straight away, start of slowly, set goals and build up the amount of time.
2. The second kind of exercise is strengthening exercises. This kind of exercise focuses on making us stronger. To make muscles stronger we have to do exercises which make the muscles work harder against a resistance, like weight training but you can also strengthen your muscles by working with heavy bags of shopping!
3. The last kind of exercise is stretching exercise. Stretching exercises focus 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

Endurance

Strengthening

Flexibility

We know one of the hardest things about exercise is not doing it once, but to keep on doing it. There are several steps we can follow to make sure that when we start to exercise we stick to it. We usually have lots of excuses why we can't exercise. Here are some of the 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. Exercise is as important as medicine to help us remain healthy (remember it doesn't mean you should stop using your medicine). If we know that it is that important we can make time for it.

"I'm too tired"

When people feel tired they become less active. As you become less active, your body loses fitness and you become weaker, you may feel stiffer and you will become tired more easily. This means that exercising might feel harder and so you exercise less. This often results in a downward spiral and people often get to the point where even walking down the street to the taxi rank can feel like too much. Being active or doing exercise, when you are feeling tired will give you more energy and you will feel less tired.

"I'm too sick"

You may be too sick to undertake vigorous exercise but you can still try and 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. .

"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 up this time, it still isn't enough exercise to keep us healthy and 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 you find them 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 4: Pain. 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, or I'm too old"

We can always find reasons not to exercise. Remember that exercise can be done anywhere, anytime. You can put on music and dance, if it's too dangerous find a group of people to exercise with which 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 it is important to reward yourself for achieving your goals; this makes it easier to move on to your next goal. We will now look at the important steps 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 exercises or activities that you want to do and that are fun
- Set a specific time and place to do your exercises
- 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)
- Keep an exercise diary to keep track of how you are doing (there is one at the back of this workbook, so please make use of it)
- Start now – don't wait. Begin gradually and progress slowly
- Revise your program At the end of the 6 – 8 weeks make a new plan for the next 6 weeks
- Reward yourself. It is already a reward to feel better and healthier but also give yourself a reward for achieving your goal, like eating a favourite meal or going to visit a friend.

Your exercise program:

An exercise program should include the three different types of exercise: endurance, flexibility and strength exercises. Following the steps in the box "Steps to success with exercise", you need to decide on what you would like 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 different things. If you have not done any exercise for a long time, have not been feeling well, if you have had stiffness or pain 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 this 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 this will make your muscles shorter and tighter.
- Stretch to the point of *tension* in a muscle and hold for 30 seconds to a minute before you relax.
- Don't push until it hurts, *stretch to tension not pain.*
- Start off with 5 repetitions of each exercise. After 1 week increase it to 7, after another week increase to 10.
- Always do the *same number* of exercises on both sides 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 for more than two hours after you exercise you have probably done too much. Don't stop doing the exercises but decrease the number of 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 and try and 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 include flexibility exercises at least once a week.

Strengthening Exercises:

You do not need to go to a gym to do strengthening exercises; most exercises can be done at home. To make muscles stronger you must make them work against a resistance or a force – the muscles have to push or pull. You should not do strengthening exercises every day, 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 start off doing each exercise 5 times. 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 (heavier shopping bags for example) to get stronger.

Endurance Exercises:

The difficult thing is deciding how much exercise to start with. The easiest starting point is to ask: "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 gradually. It is better to start off by doing less than you think you can and increase from there.

There are three things you need to think about when you do endurance exercises. The three things are *frequency* (how often am I going to do this exercise); *duration* (how long am I going to do this exercise) and *intensity* (how hard am I going to work when I exercise).

1. Frequency:

Endurance exercise must be done 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 that you have to lie in bed all day, it means that you do not do exercise.

2.Duration:

How much can I do without suffering for it tomorrow? That is your starting point. If you start with 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 fast for 3 minutes, then walk slowly for 2 minutes; then walk fast again for another 3 minutes. Slowly over time cut down the slow walking and increase the fast 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. You can also walk the total of 150 minutes in one day over the weekend. The effect on your body will be the same, but you will find it difficult and will have to be fit to be able to do this.

3. Intensity:

How will you know that you are exercising hard enough? How will you know if you are exercising too hard? When doing endurance exercises 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 try to sing it would be difficult and you would have to stop singing to take deeper breaths. Moderate intensity means you should feel that you are breathing a little faster and a little deeper but you can still talk. It may take you a while to find the right intensity for you during your exercise session. This is normal; take your time to get to know how your body responds. You can also increase your walking exercise by increasing your arm work. Bend your elbow a bit and swing your arms more vigorously, or you can hold a tin of food in each hand, or put sand, or dried beans in two small plastic

bottles or socks. The extra work you do with your arms increases your intensity of exercise without forcing you to walk faster than you find comfortable.

How will you know that you are improving in your exercises? For the flexibility and strength exercises it is easy to feel the improvement as you will be able to move easier and you will feel stronger and be able to lift heavier items. For some people it is harder to know if they are improving with the endurance exercises. One way to see improvement is to do a test. One of the easiest tests 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 a little 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 easier).

Please use the exercise diary at the end of each section to record your goals and your progress in achieving them.

Exercise Routine

This is a 20 minute exercise routine which is safe for people with musculoskeletal conditions, diabetes type II, hypertension and being overweight. 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.

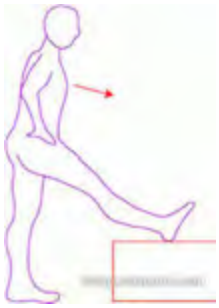
   You can also dance for 2 minutes.

3. Stretch your neck – keep your shoulders relaxed and turn to look over your right shoulder, hold for 30 seconds. Bring your head back to the middle, then turn to look over your left shoulder – hold for 30 seconds and then bring your head back to the middle. Now put your left ear on your left shoulder - hold for 30 seconds and then bring your head back to the middle. Repeat to the right. Now put your chin on your chest - hold for 30 seconds and then bring your head back to the middle. Roll shoulders forwards 5 times, then roll your shoulders backwards 5 times.

4. 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.

5. 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 30 seconds and then do the same on the left.

6. Stretch your hamstring muscle by putting your right heel on the ground and pulling your toes upward, put your hands above your knee and lean forward to feel the stretch behind your knee. Repeat on the left for 30 seconds.



7. Sit on a chair – make both your knees straight and then bend again. Do this 30 times. This works the front thigh muscles.

8. Sit on a chair – now stand up, keep sitting down and standing up for 2 minutes. Stand up and sit down 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.

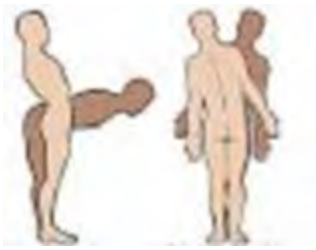
9. Then with your arms folded on your chest, stand up from the chair and sit down again. Keep sitting down and standing up for 2 minutes. Do this at a steady pace – that is a pace which you can maintain for 2 minutes.

10. 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.

11. Stand up straight. Take one big step forward with your right foot and bend your knees So that your left knee almost touches the ground (lunge) or as far as you can go. Push Back with your right leg to bring your feet back together again. Repeat on the left. Do 10 lunges on each leg.

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. Stretch your body – with your feet shoulder width apart, slide your right hand down your right leg so that you bend sideways. Bend as far as you can - hold for 30 seconds and then stand up straight again. Repeat this to the left. Put your hands on your bottom; bend your body backwards as far as you can. Now bend forward and try to touch your toes.



14. 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 Planning Form - *Exercise*

Use this form to develop an action plan for exercise. What exercise would you like to do?

Be sure your action plan includes:

What you would like 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 10confident

Keep a record of how you did:

	I Plan to…..	**I did…..**
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Week 3: Managing Common Symptoms of Musculoskeletal Disorders

Musculoskeletal conditions may and can affect a person's quality of life, with pain being the most common reason for seeing a doctor, clinic sister or physiotherapist. Other symptoms may be:

- 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

What is pain?

It is important for you to understand what pain is and what type of pain you may experience with musculoskeletal conditions (MSC) in order to manage your symptoms. 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 protects the part of the body while it heals. Once the body is healed, there is no more pain. Musculoskeletal conditions usually begin as acute pain, which means that pain starts suddenly and lasts for a short time. The pain usually comes on when the joint is moved or used and then the pain subsides.

MSC don'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 why this happens is not yet known. Chronic pain 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. This is not possible with MSC as the joint pain is not something new, so we can't damage it anymore by moving and exercise.

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 on-going damage
- Chronic pain cannot be "switched off."
- An increase in your pain (with or without exercise) does not mean a new injury.

Flare ups of pain:

Although a person with MSC 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 changed to reduce the flare up of pain again. If your pain is being caused by tense muscles then heat can help to decrease the pain. You can warm up the muscles by having a warm bath or shower. If you cannot have a hot bath or shower, then keeping the muscles warm with clothes or a blanket can also help. If you touch the painful area and it is already hot, this means it is inflamed and you should not make it hotter by applying heat to it.

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. Don't rest TOO much as your joints can get stiff. It is helpful to take painkillers as prescribed by your doctor if your pain gets worse. Putting ice onto the joint for not more than 10-20 minutes at a time on the painful area can also help. You can use a small bag of ice wrapped in a towel or wrap a towel around a bag of frozen vegetables. Don't put ice directly onto bare skin. If you do not have a freezer then putting a damp cloth on your skin (if you have a fridge then use water from the fridge) will also work.

Medicine

If you have medicine to help your pain it is important that you take it regularly. Do not wait for the pain to start before you take the medicine, if you wait it will not work as well. If the doctor or nurse has told you to take the medicine several times a day then it is important that you do this, even if you are not feeling any pain at the time; not feeling pain means that the medicine is working. Do not wait for the pain to come back again before taking another pill, it won't work as well.

If your medicines are not helping the pain then you must go back to the nurse or doctor. You might need stronger medicine or you might need to take two different kinds of medicine at the same time.

Common medicines used to treat pain are:

- Paracetomol (panado, dolorol, painamol, painstop) is a very good, very effective and safe medicine for pain. It is important not to take more than 10 tablets per day.
- Aspirin (disprin) is also very good but some people need to be careful with this medicine. If you use it for a long time you need to be careful of side-effects like ulcers, asthma or kidney problems.
- Anti-inflammatories like indomethacin (indocid), dicolfenac (voltaren or panamor) or ibuprofen (brufen or inza) are good if your pain is being caused by inflamed muscles or joints. These must be taken with food. These can also cause side-effects like ulcers.
- Paracetomol and Codeine is stronger than paracetomol on its own. If you have been using paracetomol on its own and taking it as the nurse or doctor told you but your pain is not getting better they may give you paracetomol with codeine.

Remember that the most important thing about the pain medicines is to take them before the pain starts or as soon as the pain starts. Don't wait for the pain to become severe before you take the pain medicine. It won't work nearly as well.

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).

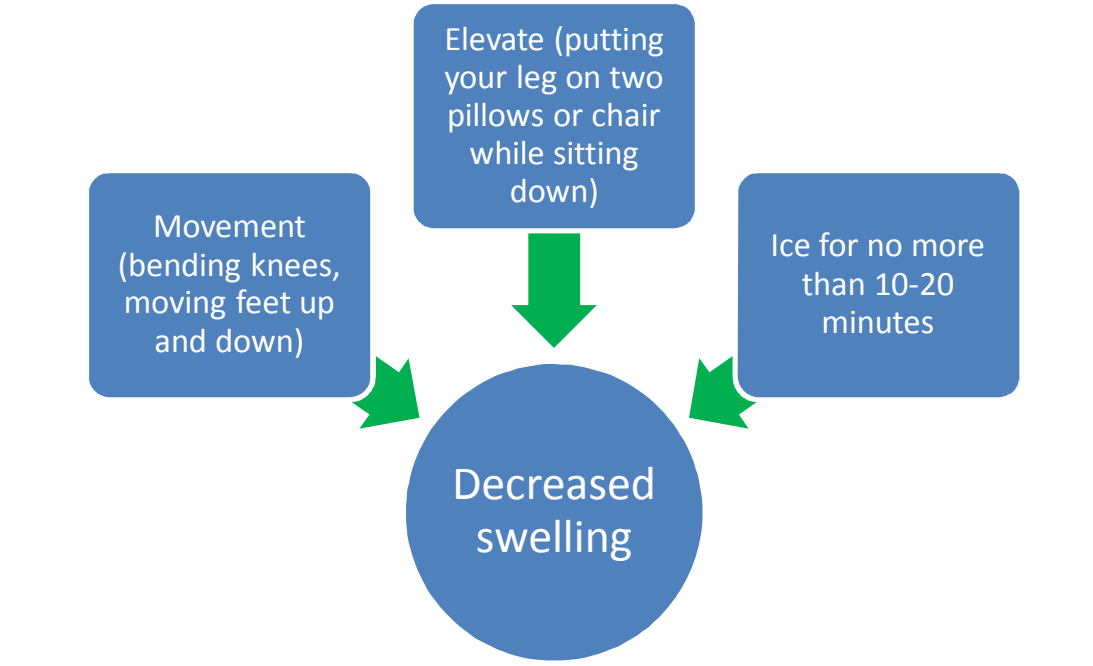
What can I do about stiffness?

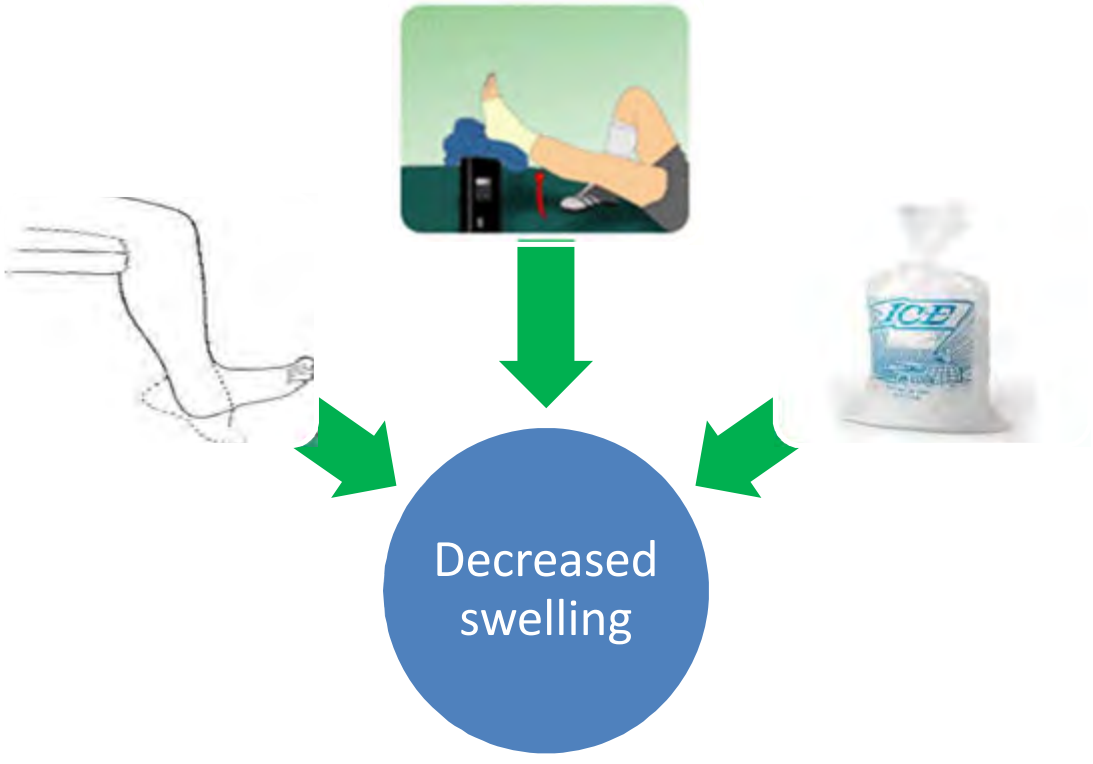
After a period of rest/sleep or limited movement the joints need to slowly get moving in order to get used to moving again. So before getting out of bed in the morning move your feet up and down 20 times. Then bend each knee up and down 20 times and open and close your legs 20 times to get the joints warmed up.

What is swelling?

Swelling is a common symptom of a flare up or may be a regular symptom experienced during MSC. 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 to do about swelling?





Difficulties doing certain activities?

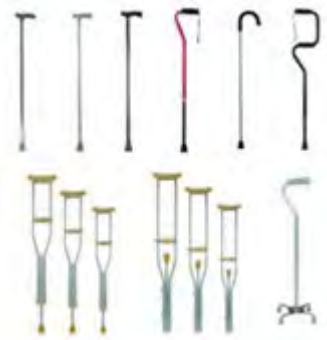
Sometimes you may feel that you are unable to do a specific task at home or outside of the house. You may feel too stiff, weak or sore to do a certain activity. You may just need to "warm up" in the morning before trying something or you may be having a flare up and then you should follow the management tips as given above..

What to do when you are struggling when doing an activity?

First try and think 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 going through a joint, an assistive device such as a walking stick, crutch or walker can be very helpful to protect your joints. This allows your arms to take 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. Two crutches or a walking frame uses both arms 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 need to use something like this.



Activity modifications:

Can change the way you do activities to protect joints.

- Avoiding certain activities that put a lot of strain on the joint, like kneeling or climbing steps.
- Use a padded pillow under your knee if you must kneel.
- 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 up.

- 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 is better than struggling to climb steps if this is available.

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. 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 to be able to do more.

How to pace?

- Pace your activities during the day so that they are spread out with enough 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. Start exercising or walking 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.

Tiredness

If you do too many activities at one time or in a short time without break periods of rest, your body will feel extremely tired and you will be tired. It is important to slowly start small activities and short times of exercise to allow your body to adjust. If you are tired it is wise to stop the activity and rest for a short while (1-2 days) until you feel better. This does not mean you need to lie in bed; you can continue with your daily tasks 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, your legs shaky.

Action Planning Form – Managing Symptoms

Think about a common symptom which you experience. Use this form to draw up an action plan of how you plan to manage this symptom the next time it occurs.

Be sure your action plan includes:

What you would like 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		
Sunday		

Exercise Diary

Use this exercise diary to keep track of the exercise goals and plan you drew up in week one.

Start by writing down your goal.

Write down here what you would like to be able to do: _____

Now, what would you like to be able to do *this week* which will help you to reach your goal?

Remember from your action plan to include:

What you would like 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 minutes in the morning after breakfast and in the evening after supper*		*Very tired by the second session, I'm going to cut down to morning only for this week.*
Monday			
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Week 4: Stress Management

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 families, about money or worrying about getting a job or coping with my job. 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 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. 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.

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 removal!

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 taxi to work but you knew the day before that taxi would be late, this would be less stressful than finding out after you have got onto the taxi 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, you are likely to feel less stressed about it. If you are on a taxi 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 taxi 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 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 feeling like you have no support will probably make you feel more stressed. But, we 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. Support does not mean doing everything for you.

Stress is not just the things that happen to us. There are many different things we can do to manage stress every day.

Managing Stress:

1.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.

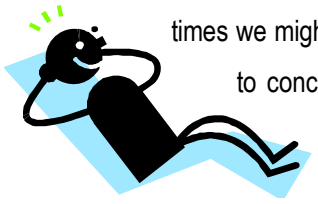
The second step is to look at the problem in a different way. Think about how you are feeling. Are your thoughts and feelings about the problem inaccurate? Maybe you are very worried about your health, this is stressing you. Are you worried that you will be unable to work? Are these thoughts and feelings 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?

Step three is - 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 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.

The last step to deal with stress is to get help. Family and friends and support groups 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 FAMSA who specialise in family and relationship counselling.

1. Relaxation



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. 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

2. Sleep

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. *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.

3. *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.

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
- Have a morning routine

3. 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

5. Communicating with your health carer

Anyone living with a long term health problem, whether it a MSC, high blood pressure or diabetes will have to visit the clinic regularly. Visiting the clinic regularly can be stressful because it takes time, you have to plan ahead, and you might not be sure how long you are going to have to wait. 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. 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. 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, and when the doctor or nurse asks if there is anything you want to ask, you can use your list.

If there are particular symptoms you want to discuss, write down the specific information the doctor or nurse will want to know. Helpful things are: when did it start, how long do the symptoms last, what makes you feel better or worse, have you changed anything like 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? 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!

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

Action Planning Form – Stress Management

Think about one thing that is causing you stress. Use this action plan form to come up with a plan of how to manage your stress this week.

Be sure your action plan includes:

What you would like 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		
Sunday		

Exercise Diary

Use this exercise diary to keep track of your exercise goals and activities.

Start by writing down your goal.

Write down here what you would like to be able to do: _____

Now, what would you like to be able to do *this week* which will help you to reach your goal?

Remember from your action plan to include:

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	Exercise Planned	**Exercise I did...**	**How did I feel? Do you need to change anything?**
e.g.	*20 minutes in the morning after breakfast and in the evening after supper*		*Very tired by the second session, I'm going to cut down to morning only for this week.*
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Week 5: Eating Well

In our current daily life, healthy and freshly prepared food is often replaced by foods high in fat and energy, containing insufficient vitamins and minerals. Healthy eating is necessary to get a healthy body weight and to have enough energy for daily activities. A healthy, nutritious diet can help you look and feel your best.

It is also important to control your cholesterol levels. Cholesterol is a waxy substance produced by the liver and found in certain foods. A high cholesterol level may speed up the hardening of your arteries and increase the risk of a heart attack. A healthy low-fat diet with plenty of high-fibre starch helps to control cholesterol levels.

1. Enjoy a variety of foods

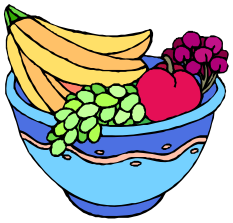
Different foods provide different nutrients. Eating different types of food gives your body all the nutrients it needs. It is important to remember that there is not one food that provides all the nutrients that our body needs. To make sure that your diet is balanced, try to eat one food from each of the following three food groups at every meal.

Protective foods

Foods in this group have enough vitamins and minerals that can help protect you against diseases.

Protective foods are:

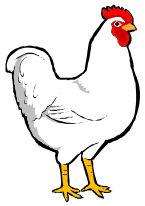
* All fruits
* All vegetables



Building foods

Foods in the building group are rich in protein, which is necessary to build muscle and new body tissues. Building foods are:

* Meat, fish and poultry (chicken, duck, turkey) You may have one or two portions of protein per day.
* Eggs
* Milk/maas/yoghurt
* Dried beans/lentils
* Nuts



Portion size:

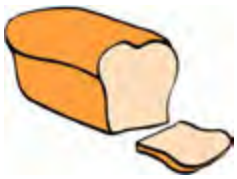
FOODS	UNIT
Fish, white	1 large piece
Fish, high fat flesh	1 small piece
Chicken, no skin	1 medium breast
Meat, lean	palm size, sliced 10mm
Eggs, hens	2
Liver, chicken	3
Cheese, yellow cube 30mm	3

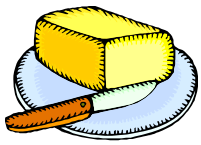
Energy foods

Energy foods give the body the energy to do every day activities like going to work.

Energy foods are:

* Bread
* Rice
* Porridge
* Potatoes
* Samp
* Mealies
* Butter / margarine
* Oil





Be active

Both exercise and healthy eating must be part of a healthy lifestyle. Many people spend a lot of time sitting in chairs. Remember…your body has been built to be active!

Balanced DietExercise + Healthy Lifestyle =

Drink lots of clean, safe water

Often when we feel hungry, it is our 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! Water makes up 50-55% of your body weight and water and oxygen are the most needed elements for life. Water carries nutrients to, and waste away from cells; cools the body and is important for the body and organs to work properly. Water comes from the fluid you drink; the food you eat and chemical reactions inside your body.

Adults should 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 drink a whole 8 glasses. If it is very hot or you are doing exercise you need to drink more than 8 glasses.

Hints:

* Drink when you are thirsty and in between.
* Drink at least one glass of water/juice every morning with breakfast.
* Drink 2 glasses one hour before exercise and another after exercise.
* Caffeine (coffee, tea & Coke) and Alcohol make you lose water.
* In general, juices from supermarkets have a lot of sugar in even when labels say 100% fruit juice. If you have juice, one glass a day is more than enough – and when possible, rather have a piece of fruit and then a glass of water.

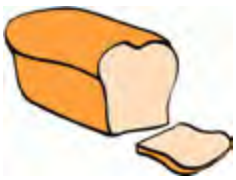
Make starchy foods part of most meals

Starch is the fuel for your body that gives most of the energy in food for your organs to function. It is important to eat 5-8portions of bread, porridge, rice, pasta and potatoes every day. These foods are usually the staple food in the diet.

Portion size:

FOODS	UNIT
Bread, brown / white	1 slice
Porridge, soft	½ cup
Maize meal, dry powder	3 heaped tablespoons
Potato	1 medium
Rice/ pasta/ whole grains, cooked	½ cup
Breakfast cereal Varies	
Cut corn, mealie	½ cup
Popcorn, popped, no salt or fat	2 cups

Starchy foods are:



* rich in carbohydrates (main source of energy for the body)
* low in fat
* contains important vitamins such as B-complex
* vitamins, fibre and minerals

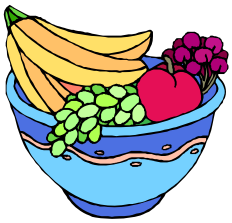
* unrefined / whole grain starch lets us feel fuller for longer
* starchy vegetables like sweet potatoes provide useful amounts of vitamin A and C

There are two kinds of carbohydrates – refined and unrefined. They both provide the body with energy. The refined carbohydrates give you a lot of energy very quickly, but also a high rise in blood sugar, followed by a quick drop which makes you feel tired and hungry again quickly. The unrefined carbohydrates raise your blood sugar slowly, so you have energy for longer. We need more of the unrefined carbohydrates than the refined carbohydrates.

Unrefined carbohydrates are also called whole grains. Examples are whole grain breakfast cereal, mealies on the cob and cut corn, popcorn, rolled oats, barley, brown rice, cracked wheat, and sorghum.

Examples of unrefined carbohydrates

Examples of refined carbohydrates



Eat plenty of vegetables and fruit every day

Vegetables give the body small amounts of carbohydrates, sugars, and lots of fibre if we eat the skins. Pure fruit juices also belong to this group, but have less fibre and a lot more sugar than fresh fruit.

Vegetables and fruit contain lots of vitamins and minerals and form part of the protective food group. Eat 3 -5 portions of vegetables and fruit every day.Eat vegetables and fruit from the different colour groups (red, green, yellow and orange). Fruit and vegetables can be eaten as part of a snack and/or main meal.

Portion size:

FOODS	UNIT
Fresh / frozen vegetables	½ cup cooked
Raw leafy vegetables	1 cup raw
All fresh fruits e.g. apple, banana.	1 piece medium sized
Small fruit e.g. apricots, plums	2 pieces
Large fruit e.g. grapefruit	½ piece
Chopped fruit	½ cup
Fruit juice	½ cup
Raisins	2 tablespoons

Dry beans, peas, lentils and soya gives energy and are a good source of protein, high in fibre and low in fat.We can eat these foods in the place of meat in some meals. These foods can help you to lose weight because they help you feel full for longer and can also help you to maintain healthy blood glucose levels.

Eat one portion from this group at least 2 -3 times per week.

Portion size:

FOODS	UNIT
Dry beans, cooked	½ cup
Lentils, split peas, cooked	½ cup
Soya mince, dry	30g (½ cup)
Raisins	2 tablespoons

Small portions of one of these foods may be eaten every day. These foods come from animals, gives protein and important minerals, but they also have fat which is not healthy when you have high blood pressure.Choose lean or lower fat options with less bad (saturated) fats.Some types of fish contain good fat. Try to eat tinned or fresh fish at least twice a week.

Drink milk, maas or yoghurt every day

Dairy products are a good source of calciumwhich helps to protect bones and prevent high blood pressure and diabetes. Low-fat or fat-free dairy products are good options.Have one portion of low-fat milk, maas or low-fat sugar free yoghurt per day.

Using coffee or tea whitener (e. g. Cremora) instead of milk is not good. It does not have the nutrients that milk has, and is high in fat.

Portion size:

FOODS	UNIT
Milk, low fat or skim	1 cup
Maas, low fat	1 cup
Yoghurt, low fat or fat free	1 tub, 100ml

Don't use fat too much and choose vegetable oils rather than hard fats

Choose vegetable oils rather than hard fats. Some fat is necessary, and is important for your body. Use only small amounts of food that has the right types of fat. Nuts, seeds, peanut butter (sugar free) and avocados are all good fats. It is better to eat/use fats and oils from plants sources, and not fats and oils from animal sources. Try not to eat food that is cooked by deep frying. You may use four portions of fat or oils per day.

* Avoid hard fats such as butter, margarine and animal fats.

* Use plant oils, nuts and seeds.

* Don't fry or roast food, rather, steam or microwave the food or eat it raw.

* Rather grill or roast meat, than fry it.

* Use non-stick pans instead of oil.

Portion size:

FOODS	UNIT
Oil; sunflower, canola, olive or other plant oil	1 teaspoon
Tub margarine	1 teaspoon
Peanut butter	1 heaped teaspoon

Don't use salt and foods high in salt

Food high in salt or eating too much salt can raise your blood pressure. Instead of using salt use herbs and spices like garlic, ginger or curry, and use plenty of vegetables when you make stews and bean dishes. Don't use too much salt when cooking. Foods with lots of salt in are stock cubes, soup powders, and salty snacks like chips and meats like polony. Do not use more than 1 teaspoon of salt a day from all sources.

Don't use too much sugar

Too much sugar can make you gain weight.Sugar gives energy, but doesn't have any other nutrients.

You can eat sugar, food and drinks that have sugar in as part of a healthy eating plan, but only two portions per day. There is lots of sugar in cakes, biscuits, doughnuts, sweets, chocolates and sweetened cold drinks (a can of fizzy drink has 3 tablespoons of sugar in it). You can use alittle bit of sugar with foods and drinks like soft porridge or tea. Foods made with sugar, like jam, can be used to make a mixed meal or a snack. It is better to eat foods that have sugar in with a meal, than to eat it in between meals, especially if you have high sugar (diabetes). Sweets and cold drinks may be eaten sometimes but should not be eaten in the place of a balanced meal.

Portion size:

FOODS	UNIT
Sugar, brown or white	1 teaspoon
Jam	1 heaped teaspoon

Information about the use of alcohol

Alcohol has a lot of energy and no other nutrients. Alcohol can make you gain weight. Women can have one drink per day.One drink is the same as ½ a glass of wine or one dumpie of beer or one tot of spirits.

Alcohol used with medications can be very dangerous to a persons' health.

Losing weight

When you first came to the clinic we measured your height and weight and we made a sum to determine your BMI (Body Mass Index). If you have a BMI of more than 25 this is not healthy, you should focus on what you are eating and how much you are exercising.

BMI Class	Range
Underweight	<18
Normal	18-25
Overweight	25-30
Obese 1	31-35
Obese 2	35-40
Obese 3	>40

From research we know that joint pain, high blood pressure and blood sugar are closely linked to being 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, especially 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. If you are overweight losing weight will improve your health by decreasing the loading on your joints and it will feel a lot easier for you to move around, do exercise and daily activities.

Action Planning 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 would like 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		
Sunday		

Exercise Diary

Keep using the exercise diary to keep track of your exercise goals from week one. You may want to start increasing your exercise plan.

Start by writing down your goal.

Write down here what you would like to be able to do: _____

Now, what would you like to be able to do *this week* which will help you to reach your goal?

Remember from your action plan to include:

What you would like 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 minutes in the morning after breakfast and in the evening after supper*		*Very tired by the second session, I'm going to cut down to mornings only for this week.*
Monday			
Tuesday			
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Friday			

Week 6: Continuing as a Successful Self-Manager

Over the last six weeks you have learnt many skills which will help you to live a balanced lifestyle with your condition. Research tells us that people living with any chronic disease who follow these steps have better a quality of life. This is true for people living with high blood pressure, diabetes or MSC. 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, and what exercises you should do! You have learnt about the common symptoms that trouble people living with MSC, high blood pressure and diabetes 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. 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 chronic conditions often worry about how they will manage their lives; how they will look after their families. Worrying about these things can also make people feel sad, angry or depressed. 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. Once you have identified what it is that worries you and makes you feel sad, depressed or afraid then you can start to make a plan to deal with it. This will help you to feel less sad, depressed 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, start to think about different ways to manage these things. If you were worried about not being able to look after your family, make 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 friends, social workers and counsellors. 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) _____

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

Moving forward:

Over the last 6 weeks you have learnt many things about how to live with a chronic illness like high blood pressure and diabetes. 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 a balanced life. 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. 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.

Useful Organisations:

MUCPP (Mangaung-University of the Free State Community Partnership Program)

119057 Singozo Street

Heidedal, Bloemfontein

Tel: 051 – 435 6430

Family and Marriage Society of South Africa (FAMSA) (http://www.famsa.org.za)

10 Strauss Street

Universitas, Bloemfontein

Tel: 051 – 525 2395

Pelonomi Regional Hosiptal

Dr Belcher Road

Heidedal, Bloemfontein

Tel: 051 – 405 1911

National District Hospital

Roth Avenue

Willows, Bloemfontein

Tel: 051 – 403 9600

Additional Reading

The information is this workbook is based on several sources of information. If you would like to read more on any of these topics we suggest you explore these:

Living Well with HIV & AIDS; Gifford A.L.; Lorig K; Laurent D; Gonzalez V (3rd edition) Bull Publishing Company, Boulder Colorado2005

Self-management of Long-term Health Conditions: A handbook for people with chronic disease. Expert Patients Programme Community Interest Company. Bull Publishing Company, Boulder Colorado 2007

Manage your pain. Nicholas M, Molloy A, Tonkin L, Beeston L ABC Books, Sydney 2000

Department of Health. 2012. Guidelines for Healthy Eating Information for Nutrition Educators. Department of Health. Directorate: Nutrition: Pretoria.

ACSM's Exercise Management for Persons with Chronic Diseases and Disabilities. Durstine JL; Moore GE; Painter PL; Roberts SD. Third Edition. ACSM Group Publishing. United States of America.

Action Planning Form

Be sure your action plan includes:

What you would like 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…..**
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Exercise Diary

Start by writing down your goal.

Write down what you would like to be able to do: _____

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Remember from your action plan to include:

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	Exercise Planned	**Exercise I did...**	**How did I feel? Do you need to change anything?**
e.g.	*20 minutes in the morning after breakfast and in the evening after supper*		*Very tired by the second session, I'm going to cut down to morning only for this week.*
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Acknowledgements:

Dr Romy Parker: Positive Living Course Booklet

Melissa Saw and Tina Kruger-Jakins: Living with Osteoarthritis workbook

Department of Dietetics, University of the Free Sate

APPENDIX 29

Non-pharmacological six weeks intervention programme

EXERCISE PRESCRIPTION – Week 1
Motivational Factor of Exercise Programme: To lower blood pressure To lower blood glucose levels To lose weight To increase physical activity levels
Client (group) specifications/risks/precautions: Vital signs of each participant- recently measured and available Correct use of medication Use of beta-blockers Participants may use assistive devices Additional pathologies/lifestyle diseases Attention to safety of the environment Participant should be able to take own heart rate/pulse (teach participants) Research assistant available during exercise class to monitor heart rate Calculate the target heart rate for each participant
Beginning of programme: Organise area: Sufficient chairs and water available. Obstacles in hall removed. Music available. All equipment available and ready for use: balls, bags etc. Sphygmomanometer available. Information to participants: Should not feel out of breath, light headed, nauseas. Each participant should take their resting heart rate or research assistants should take heart rates of each participant. Para-medic available in hall for emergencies.

Exercises:

Functional outcome	*Purpose of exercise (muscles and joints) (Type of exercise)*	*Description of exercise*	*Frequency, Intensity & Time*	*Biomechanical safety/risks*	*Objective measure of progress*
Warm-up	Dynamic warm-up	Dance: • 3 x steps left & clap • 3 x steps right & clap • 3 x steps forward & clap • 3 x steps in place (alternating trunk flexion/extension & clap with each step) • Turn 90˚ left Repeat	• 5 minutes	• Participants may rest as they feel necessary.	• Not applicable
Improve quality of life General mobility and increase flexibility	Stretching and warming up of muscles	• Neck rotation to Left and hold • Neck rotation to Right and hold • Neck flexion and hold • Lateral neck flexion to Left and hold • Lateral neck flexion to Right and hold • Shoulder elevation and roll shoulder anterior	• 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 repetitions	• Participants may rest as they feel necessary. • Participants are instructed that they should only feel a slight stretch and no pain. • If participant's heart rate or blood pressure is	• Participant should maintain normal neck range of motion. • Participants should maintain normal gleno-humeral range of motion. • Participant should maintain normal trunk range of movement. • Participants should maintain functional hip and trunk

		• Shoulder elevation and roll shoulder posterior	• 3 x 10 repetitions	unstable they should not perform bilateral shoulder flexion activities. • Participants are allowed to sit and perform activities if they feel unstable. • Research assistants should correct performing of stretches and should ensure that participants do not over stretch the muscles.	movements.
		• Arm circles of increasing circumference (with bilateral upper limbs in 90˚Abduction)	• 3 x 10 repetitions • Make circles in the air with outstretched arms, make the circles bigger as time goes on/on command.		
		• Posterior Deltoid stretch bilaterally	• 3 x 10 second hold • Pull arm across body, provide overpressure with opposite arm. Should feel stretch in back of the shoulder.		
		• Triceps stretch bilaterally	• 3 x 10 second hold • Try to touch hand to back of shoulder on same side, provide overpressure with opposite arm in a posterior direction. Should feel stretch in back of the arm.		
		• Trunk Rotations to Left & Right	• Rotate as far as possible to left and right, while keeping hips still. • 3 x 10 repetitions		
		• Standing bilateral hamstring stretch –	• Rounding of the lower back is not		

		keep legs straight whilst flexing at the hips to try and touch the toes	allowed. • 3 x 10 second hold		
1 minute water break					
Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Muscle Strengthening and Cardiovascular training	• Walking on the spot	• 2 minutes	• Participants are allowed to hold onto chair for balance/assistance. • Participants may rest as they feel necessary.	• Participant should be able to individually train at their own target heart rate or decrease the number of resting periods that they chose to take. • Participants should maintain their muscle strength in the upper and lower limbs.
		• Half Squats	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 4 x 10 repetitions		
		• Walking on the spot	• Increase speed every minute. • 2 minutes		
		• Half squat with isometric hold	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 5 x 10 second holds		
		• Marching	• 2 x steps forward,2 steps backward, Total 4		

			min		
		• Step and punch(Left & Right)	• Step forward with one leg and punch the air with the arm on the same side. • Total 5 minutes		
		• Lateral stepping(Left & Right)*	• 20 x repetitions each		
		• Alternating High knees to elbow*	• Flex the hip and knee in standing, then raise the knee until it can be touched by the elbow on the same side of the body without bending over. • 3 x 10 repetitions		
		• Walking on the spot	• 2 minutes		
1 minute water break					
Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Functional strengthening and cardiovascular training	• Ball transfer over obstacle course	• Challenge ends when each participant has completed the course. • Participants are divided into 3 equal teams. One by one, participants have to fill a material shopping bag with	• Participants are warned that they must not fall over the cones, but must rather do the activity slower to prevent any injuries. • Material shopping bags are used in the place of plastic shopping bags as	• The first team to have every member complete the course wins the challenge.

			10 hockey balls and transfer the balls into a crate 10 m away whilst walking around and over various cones acting as obstacles along the way. Participants should then race back to their team at the starting position.	plastic shopping bags may tear and the material shopping bags are also more environmental friendly.	

Ending off for programme:

Educational session - participants were briefed regarding the definition of hypertension; diabetes mellitus type II, joint pain being obese and what self management means. The steps of self management were discussed in detail with the participants. Workbook pages 2-9.

Provide home advice:

Need to complete their goals as set out in the workbook and must try and achieve their goals**.**
Drink plenty of water.
Reduce daily salt and fat intake**.**
Increase physical activity levels.
Wear the pedometer all the time.

Variety of exercises included:

Target heart rate, mobility, muscle strengthening, muscle stretches, balance

EXERCISE PRESCRIPTION – Week 2
Motivational Factor of Exercise Programme: To lower blood pressure To lower blood glucose levels To lose weight To increase physical activity levels
Client (group) specifications/risks/precautions: Vital signs of each participant- recently measured and available Correct use of medication Use of beta-blockers Participants may use assistive devices Additional pathologies/lifestyle diseases Attention to safety of the environment Participant should be able to take own heart rate/pulse (teach participants) Research assistant available during exercise class to monitor heart rate Calculate the target heart rate for each participant
Beginning of programme: Organise area: Sufficient chairs and water available. Obstacles in hall removed. Music available. All equipment available and ready for use: balls, bags etc. Sphygmomanometer available. Information to participants: Should not feel out of breath, light headed, nauseas. Each participant should take their resting heart rate or research assistants should take heart rates of each participant. Para-medic available in hall for emergencies.

Exercises:

Functional outcome	***Purpose of exercise (muscles and joints) (Type of exercise)***	***Description of exercise***	***Frequency, Intensity & Time***	***Biomechanical safety/risks***	***Objective measure of progress***
Warm-up	Dynamic warm-up	Dance: • 3 x steps left & clap • 3 x steps right & clap • 3 x steps forward & clap • 3 x steps in place (alternating trunk flexion/extension & clap with each step) • Turn 90˚ left Repeat	• 5 minutes	• Participants may rest as they feel necessary.	• Not applicable
Improve quality of life General mobility and increase flexibility	Stretching and warming up of muscles	• Neck rotation to Left and hold • Neck rotation to Right and hold • Neck flexion and hold • Lateral neck flexion to Left and hold • Lateral neck flexion to Right and hold • Shoulder elevation and roll shoulder anterior	• 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 repetitions	• Participants may rest as they feel necessary. • Participants are instructed that they should only feel a slight stretch and no pain. • If participant's heart rate or blood pressure is	• Participant should maintain normal neck range of motion. • Participants should maintain normal gleno-humeral range of motion. • Participant should maintain normal trunk range of movement. • Participants should maintain functional hip and trunk

		• Shoulder elevation and roll shoulder posterior	• 3 x 10 repetitions	unstable they should not perform bilateral shoulder flexion activities. • Participants are allowed to sit and perform activities if they feel unstable. • Research assistants should correct performing of stretches and should ensure that participants do not over stretch the muscles.	movements
		• Arm circles of increasing circumference (with bilateral upper limbs in 90˚Abduction)	• 3 x 10 repetitions • Make circles in the air with outstretched arms, make the circles bigger as time goes on/on command.		
		• Posterior Deltoid stretch bilaterally	• 3 x 10 second hold • Pull arm across body, provide overpressure with opposite arm. Should feel stretch in back of the shoulder.		
		• Triceps stretch bilaterally	• 3 x 10 second hold • Try to touch hand to back of shoulder on same side, provide overpressure with opposite arm in a posterior direction. Should feel stretch in back of the arm.		
		• Trunk Rotations to Left & Right	• Rotate as far as possible to left and right, while keeping hips still. • 3 x 10 repetitions		
		• Standing bilateral hamstring stretch –	• Rounding of the lower back is not		

		keep legs straight whilst flexing at the hips to try and touch the toes.	allowed. • 3 x 10 second hold		
1 minute water break					
Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Muscle Strengthening and Cardiovascular training	• Walking on the spot	• 2 minutes	• Participants are allowed to hold onto chair for balance/assistance. • Participants may rest as they feel necessary.	• Participant should be able to individually train at their own target heart rate or decrease the number of resting periods that they chose to take. • Participants should maintain their muscle strength in the upper and lower limbs.
		• Half Squats	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 4 x 10 repetitions		
		• Walking on the spot	• Increase speed every minute. • 2 minutes		
		• Half squat with isometric hold	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 5 x 10 second holds		
		• Marching	• 2 x steps forward,2 steps backward, Total 4		

			min		
		• Step and punch(Left & Right)	• Step forward with one leg and punch the air with the arm on the same side. • Total 5 minutes		
		• Lateral stepping(Left & Right)*	• 20 x repetitions each		
		• Alternating High knees to elbow*	• Flex the hip and knee in standing, then raise the knee until it can be touched by the elbow on the same side of the body without bending over. • 3 x 10 repetitions		
		• Walking on the spot	• 2 minutes		
1 minute water break					
Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Functional strengthening and cardiovascular training	• Ball transfer over obstacle course	• Challenge ends when each participant has completed the course. • Participants are divided into 3 equal teams. One by one, participants have to fill a material shopping bag with	• Participants are warned that they must not fall over the cones, but must rather do the activity slower to prevent any injuries. • Material shopping bags are used in the place of plastic shopping bags as	• The first team to have every member complete the course wins the challenge.

			10 hockey balls and transfer the balls into a crate 10 m away whilst walking around and over various cones acting as obstacles along the way. Participants should then race back to their team at the starting position.	plastic shopping bags may tear and the material shopping bags are also more environmental friendly.	

Ending off for programme:

Educational session **–** The importance of exercise and the type of exercises were discussed. Examples of exercises performed correctly were given to participants by the group leader. Workbook pages 10 – 20.

Provide home advice:

Need to complete their goals as set out in the workbook and must try and achieve their goals**.**
Drink plenty of water.
Reduce daily salt and fat intake**.**
Increase physical activity levels.

Variety of exercises included:

Target heart rate, mobility, muscle strengthening, muscle stretches, balance

EXERCISE PRESCRIPTION – Week 3
Motivational Factor of Exercise Programme: To lower blood pressure To lower blood glucose levels To lose weight To increase physical activity levels
Client (group) specifications/risks/precautions: Vital signs of each participant- recently measured and available Correct use of medication Use of beta-blockers Participants may use assistive devices Additional pathologies/lifestyle diseases Attention to safety of the environment Participant should be able to take own heart rate/pulse (teach participants) Research assistant available during exercise class to monitor heart rate Calculate the target heart rate for each participant
Beginning of programme: Organise area: Sufficient chairs and water available. Obstacles in hall removed. Music available. All equipment available and ready for use: balls, bags etc. Sphygmomanometer available. Information to participants: Should not feel out of breath, light headed, nauseas. Each participant should take their resting heart rate or research assistants should take heart rates of each participant. Para-medic available in hall for emergencies. **Note:** ***One participant who fell at home and had an ulcer on her right lower leg were encouraged to sit while performing stretches and walk on the spot while in the sitting position to relieve some of the discomfort she experienced.***

Exercises:

Functional outcome	*Purpose of exercise (muscles and joints) (Type of exercise)*	*Description of exercise*	*Frequency, Intensity & Time*	*Biomechanical safety/risks*	*Objective measure of progress*
Warm-up	Dynamic warm-up	Dance: • 3 x steps left & clap • 3 x steps right & clap • 3 x steps forward & clap • 3 x steps in place (alternating trunk flexion/extension & clap with each step) • Turn 90˚ left Repeat	• 5 minutes	• Participants may rest as they feel necessary.	• Not applicable
Improve quality of life General mobility and increase flexibility	Stretching and warming up of muscles	• Neck rotation to Left and hold • Neck rotation to Right and hold • Neck flexion and hold • Lateral neck flexion to Left and hold • Lateral neck flexion to Right and hold • Shoulder elevation and roll shoulder anterior	• 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 repetitions	• Participants may rest as they feel necessary. • Participants are instructed that they should only feel a slight stretch and no pain. • If participant's heart rate or blood pressure is	• Participant should maintain normal neck range of motion. • Participants should maintain normal gleno-humeral range of motion. • Participant should maintain normal trunk range of movement. • Participants should maintain functional hip and trunk

		• Shoulder elevation and roll shoulder posterior	• 3 x 10 repetitions	unstable they should not perform bilateral shoulder flexion activities. • Participants are allowed to sit and perform activities if they feel unstable. • Research assistants should correct performing of stretches and should ensure that participants do not over stretch the muscles.	movements.
		• Arm circles of increasing circumference (with bilateral upper limbs in 90˚Abduction)	• 3 x 10 repetitions • Make circles in the air with outstretched arms, make the circles bigger as time goes on/on command.		
		• Posterior Deltoid stretch bilaterally	• 3 x 10 second hold • Pull arm across body, provide overpressure with opposite arm. Should feel stretch in back of the shoulder.		
		• Triceps stretch bilaterally	• 3 x 10 second hold • Try to touch hand to back of shoulder on same side, provide overpressure with opposite arm in a posterior direction. Should feel stretch in back of the arm.		
		• Trunk Rotations to Left & Right	• Rotate as far as possible to left and right, while keeping hips still. • 3 x 10 repetitions		
		• Standing bilateral	• Rounding of the		

		hamstring stretch – keep legs straight whilst flexing at the hips to try and touch the toes	lower back is not allowed. • 3 x 10 second hold		
1 minute water break					
Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Muscle Strengthening and Cardiovascular training	• Walking on the spot	• 2 minutes	• Participants are allowed to hold onto chair for balance/assistance. • Participants may rest as they feel necessary.	• Participant should be able to individually train at their own target heart rate or decrease the number of resting periods that they chose to take. • Participants should maintain their muscle strength in the upper and lower limbs.
		• Half Squats	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 4 x 10 repetitions		
		• Walking on the spot	• Increase speed every minute. • 2 minutes		
		• Half squat with isometric hold	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 5 x 10 second holds		
		• Marching	• 2 x steps forward,2 steps		

			backward, Total 4 min		
		• Step and punch(Left & Right)	• Step forward with one leg and punch the air with the arm on the same side. • Total 5 minutes		
		• Lateral stepping(Left & Right)*	• 20 x repetitions each		
		• Alternating High knees to elbow*	• Flex the hip and knee in standing, then raise the knee until it can be touched by the elbow on the same side of the body without bending over. • 3 x 10 repetitions		
		• Walking on the spot	• 2 minutes		
1 minute water break					

Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Functional strengthening and cardiovascular training	• Ball throwing and catching "Over and under" ball game	• 1 x 10 rounds • Each participant should stand facing their partner. They should then throw a netball ball to each other, taking 1 step backward every time the ball is returned to the initial participant. This was repeated until both participants retreated for at least 20 m. • 10 x 20 m • Groups of 5 participants were formed, with participants standing behind one another. The first participant then passes the ball down the line either going above their head or sideways. The second participant passes the ball on to the next participant through their legs and move to the back	• Participants with uncontrolled hypertension were to pass the ball sideways and not over their head during the ball activity.	• The first team to have every member complete the course wins the challenge.

			of the line. This sequence is repeated until the line moves back a total of 20 m. The first team to have every member across the 20 m mark wins the challenge.		

Ending off for programme:

Educational session **–** Managing the common symptoms of musculoskeletal disorders were discussed. Joint pain, swelling and stiffness were discussed as well as management of the condition. The management included the use of medication for pain, elevation of limbs for decreasing possible swelling. Exercises were explained to increase flexibility and mobility and to decrease joint pain and stiffness. Participants were briefed how to manage their pain as well as swelling in their joints. Examples of assistive devices were shown to patients. Workbook pages 21-28.

Provide home advice:

Need to complete their goals as set out in the workbook and must try and achieve their goals**.**
Drink plenty of water.
Reduce daily salt and fat intake**.**
Increase physical activity levels.

Variety of exercises included:

Target heart rate, mobility, muscle strengthening, muscle stretches, balance

EXERCISE PRESCRIPTION – Week 4
Motivational Factor of Exercise Programme: To lower blood pressure To lower blood glucose levels To lose weight To increase physical activity levels
Client (group) specifications/risks/precautions: Vital signs of each patient- recently measured and available Correct use of medication Use of beta-blockers Patients may use assistive devices Additional pathologies/lifestyle diseases Attention to safety of the environment Patient should be able to take own heart rate/pulse (teach patients) Research assistant available during exercise class to monitor heart rate Calculate the target heart rate for each patient
Beginning of programme: Organise area: Sufficient chairs and water available. Obstacles in hall removed. Music available. All equipment available and ready for use: balls, bags etc. Sphygmomanometer available. Information to patients: Should not feel out of breath, light headed, nauseas. Each participant should take their resting heart rate or research assistants should take heart rates of each participant. Para-medic available in hall for emergencies. **Note:** ***One participant complained of feeling dizzy and experiencing blurred vision – the researcher took her to the nearby clinic for assessment.***

Exercises:

Functional outcome	***Purpose of exercise (muscles and joints) (Type of exercise)***	***Description of exercise***	***Frequency, Intensity & Time***	***Biomechanical safety/risks***	***Objective measure of progress***
Warm-up	Dynamic warm-up	Dance: • 3 x steps left & clap • 3 x steps right & clap • 3 x steps forward & clap • 3 x steps in place (alternating trunk flexion/extension & clap with each step) • Turn 90˚ left Repeat	• 5 minutes	• Participants may rest as they feel necessary.	• Not applicable
Improve quality of life General mobility and increase flexibility	Stretching and warming up of muscles	• Neck rotation to Left and hold • Neck rotation to Right and hold • Neck flexion and hold • Lateral neck flexion to Left and hold • Lateral neck flexion to Right and hold • Shoulder elevation and roll shoulder anterior	• 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 second hold • 3 x 10 repetitions	• Participants may rest as they feel necessary. • Participants are instructed that they should only feel a slight stretch and no pain.	• Participant should maintain normal neck range of motion. • Participants should maintain normal gleno-humeral range of motion. • Patient should maintain normal trunk range of movement. • Participants should maintain functional hip and trunk movements.

		• Shoulder elevation and roll shoulder posterior	• 3 x 10 repetitions		
		• Arm circles of increasing circumference (with bilateral upper limbs in 90˚Abduction)	• 3 x 10 repetitions • Make circles in the air with outstretched arms, make the circles bigger as time goes on/on command.	• If participant's heart rate or blood pressure is unstable they should not perform bilateral shoulder flexion activities. • Participants are allowed to sit and perform activities if they feel unstable. • Research assistants should correct performing of stretches and should ensure that participants do not over stretch the muscles.	
		• Posterior Deltoid stretch bilaterally	• 3 x 10 second hold • Pull arm across body, provide overpressure with opposite arm. Should feel stretch in back of the shoulder.		
		• Triceps stretch bilaterally	• 3 x 10 second hold • Try to touch hand to back of shoulder on same side, provide overpressure with opposite arm in a posterior direction. Should feel stretch in back of the arm.		
		• Trunk Rotations to Left & Right	• Rotate as far as possible to left and right, while keeping hips still. • 3 x 10 repetitions		
		• Standing bilateral hamstring stretch –	• Rounding of the lower back is not		

		keep legs straight whilst flexing at the hips to try and touch the toes	allowed. • 3 x 10 second hold		
1 minute water break					
Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Muscle Strengthening and Cardiovascular training	• Walking on the spot	• 2 minutes	• Participants are allowed to hold onto chair for balance/assistance. • Participants may rest as they feel necessary.	• Participant should be able to individually train at their own target heart rate or decrease the number of resting periods that they chose to take. • Participants should maintain their muscle strength in the upper and lower limbs.
		• Half Squats	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 4 x 10 repetitions		
		• Walking on the spot	• Increase speed every minute. • 2 minutes		
		• Half squat with isometric hold	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 5 x 10 second holds		
		• Marching	• 2 x steps forward,2 steps backward, Total 4		

			min		
		• Step and punch(Left & Right)	• Step forward with one leg and punch the air with the arm on the same side. • Total 5 minutes		
		• Lateral stepping(Left & Right)*	• 20 x repetitions each		
		• Alternating High knees to elbow*	• Flex the hip and knee in standing, then raise the knee until it can be touched by the elbow on the same side of the body without bending over. • 3 x 10 repetitions		
		• Walking on the spot	• 2 minutes		
1 minute water break					
Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Functional strengthening and cardiovascular training	• Ball throwing and catching	• 1 x 10 rounds • Each participant should stand facing their partner. They should then throw a netball ball to each other, taking 1 step backward every time the ball is returned to the initial participant. This was repeated		• The first team to have every member complete the course wins the challenge.

		• "Over and under" ball game	until both participants retreated for at least 20 m. • 10 x 20 m Groups of 5 participants were formed, with participants standing behind one another. The first participant then passes the ball down the line either going above their head or sideways. The second participant passes the ball on to the next participant through their legs and move to the back of the line. This sequence is repeated until the line moves back a total of 20 m. The first team to have every member across the 20 m mark wins the challenge.	• Participants with uncontrolled hypertension were to pass the ball sideways and not over their head during the ball activity.	

Ending off for programme:

Educational session **–** Stress and stress full situations was discussed as it was found that stress was a contributing factor to majority of the participants health conditions.

How to deal with stress effectively was also discussed in the group. A relaxation technique was taught to participants. Workbook pages 29 – 37.

Provide home advice: Need to complete their goals as set out in the workbook and must try and achieve their goals**.** Drink plenty of water. Reduce daily salt and fat intake**.** Increase physical activity levels.
Variety of exercises included: Target heart rate, mobility, muscle strengthening, muscle stretches, balance

EXERCISE PRESCRIPTION – Week 5
Motivational Factor of Exercise Programme: To lower blood pressure To lower blood glucose levels To lose weight To increase physical activity levels
Client (group) specifications/risks/precautions: Vital signs of each patient- recently measured and available Correct use of medication Use of beta-blockers Patients may use assistive devices Additional pathologies/lifestyle diseases Attention to safety of the environment Patient should be able to take own heart rate/pulse (teach patients) Research assistant available during exercise class to monitor heart rate Calculate the target heart rate for each patient
Beginning of programme: Organise area: Sufficient chairs and water available. Obstacles in hall removed. Music available. All equipment available and ready for use: balls, bags etc. Sphygmomanometer available. Information to patients: Should not feel out of breath, light headed, nauseas. Each participant should take their resting heart rate or research assistants should take heart rates of each participant. Para-medic available in hall for emergencies. **Note:** ***The participants who did not feel well the previous week returned and informed the researcher that she was admitted to hospital for two days for tests. She received different medication for her blood pressure and is doing well.*** ***One participant fell on her knee while walking to the shop and complained that her knee was painful (3/10). Both the researcher and the paramedic assessed the knee. There was no swelling, all ranges***

and muscle strength were normal. Upon assessment it was found that her patella was removed during previous knee surgery. She was given a support bandage, did not engage in activities of the lower limb and was referred to physiotherapy services for treatment.

Exercises:

Functional outcome	***Purpose of exercise (muscles and joints) (Type of exercise)***	***Description of exercise***	***Frequency, Intensity & Time***	***Biomechanical safety/risks***	***Objective measure of progress***
Warm-up	Dynamic warm-up	Dance:	• 5 minutes	• Participants may rest as they feel necessary. • Alternate squats and lunges each round • Alternate one repetition of overhead reaches with one repetition of knee touches. • Participants with unstable hypertension must not do the overhead activities.	• Not applicable
		• 3 x steps left & clap			
		• 3 x steps right & clap			
		• 3 x steps forward & clap			
		• 3 x steps in place (alternating trunk flexion/extension & clap with each step)			
		• Squats/lunges to the Left side and the Right side.	• 1 x 10 repetitions		
		• Bilateral overhead reach with arms	• 1 x 5 repetitions		
		• Bilateral knee touch with arms	• 1 x 5 repetitions		
		• Turn 90˚ left			
		Repeat			
Improve quality of life General mobility and increase flexibility	Stretching and warming up of muscles	• Neck rotation to Left and hold	• 3 x 20 second hold	• Participants may rest as they feel necessary. • Participants are instructed that	• Participant should maintain normal neck range of motion. • Participants should maintain normal gleno-humeral range of motion.
		• Neck rotation to Right and hold	• 3 x 20 second hold		
		• Neck flexion and hold	• 3 x 20 second hold		
		• Lateral neck flexion	• 3 x 20 second hold		

		to Left and hold		they should only feel a slight stretch and no pain. • If participant's heart rate or blood pressure is unstable they should not perform bilateral shoulder flexion activities. • Participants are allowed to sit and perform activities if they feel unstable. • Research assistants should correct performing of stretches and should ensure that participants do not over stretch the muscles.	• Patient should maintain normal trunk range of movement. • Participants should maintain functional hip and trunk movements.
		• Lateral neck flexion to Right and hold	• 3 x 20 second hold		
		• Shoulder elevation and roll shoulder anterior	• 3 x 20 repetitions		
		• Shoulder elevation and roll shoulder posterior	• 3 x 20 repetitions		
		• Arm circles of increasing circumference (with bilateral upper limbs in 90˚Abduction)	• 3 x 20 repetitions • Make circles in the air with outstretched arms, make the circles bigger as time goes on/on command.		
		• Posterior Deltoid stretch bilaterally	• 3 x 20 second hold • Pull arm across body, provide overpressure with opposite arm. Should feel stretch in back of the shoulder.		
		• Triceps stretch bilaterally	• 3 x 20 second hold • Try to touch hand to back of shoulder on same side, provide overpressure with opposite arm in a posterior direction. Should feel stretch in back of the arm.		

		• Trunk Rotations to Left & Right	• Rotate as far as possible to left and right, while keeping hips still. • 3 x 20 repetitions		
		• Standing bilateral hamstring stretch – keep legs straight whilst flexing at the hips to try and touch the toes	• Rounding of the lower back is not allowed. • 3 x 20 second hold		
1 minute water break					
Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Muscle Strengthening and Cardiovascular training	• Walking on the spot	• 5 minutes	• Participants are allowed to hold onto chair for balance/assistance. • Participants may rest as they feel necessary.	• Participant should be able to individually train at their own target heart rate or decrease the number of resting periods that they chose to take. • Participants should maintain their muscle strength in the
		• Half Squats	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 5 x 10 repetitions		
		• Walking on the spot	• Increase speed every minute. • 5 minutes		
		• Half squat with isometric hold	• Perform a squat without moving into pain or extreme stiffness/approxim		

			ately half of active range of movement. • 7 x 10 second holds		upper and lower limbs.
		• Marching	• 2 x steps forward,2 steps backward, Total 8 min		
		• Step and punch(Left & Right)	• Step forward with one leg and punch the air with the arm on the same side. • Total 8 minutes		
		• Lateral stepping(Left & Right)*	• 20 x repetitions each		
		• Alternating High knees to elbow*	• Flex the hip and knee in standing, then raise the knee until it can be touched by the elbow on the same side of the body without bending over. • 5 x 10 repetitions		
		• Walking on the spot	• 5 minutes		
1 minute water break					

Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Functional strengthening and cardiovascular training	• Ball throwing and catching • "Over and under" ball game	• 1 x 10 rounds • Each participant should stand facing their partner. They should then throw a netball ball to each other, taking 1 step backward every time the ball is returned to the initial participant. This was repeated until both participants retreated for at least 20 m. • 10 x 20 m Groups of 5 participants were formed, with participants standing behind one another. The first participant then passes the ball down the line either going above their head or sideways. The second participant passes the ball on to the next participant through their legs and move to the back of the line. This sequence is repeated until the line moves back a total of	• Participants with uncontrolled hypertension were to pass the ball sideways and not over their head during the ball activity.	• The first team to have every member complete the course wins the challenge.

			20 m. The first team to have every member across the 20 m mark wins the challenge.		

Ending off for programme:

Educational session **–** The importance of a healthy diet and the roles of different types of food in the body. The protective mechanism of certain foods was discussed, as well as the energy provided by certain foods. Food that builds up in the body was also discussed. Participants were also educated on portion size as well as the recommended daily allowance of carbohydrates, protein and fat. Workbook pages 38 – 46.

Provide home advice:

Need to complete their goals as set out in the workbook and must try and achieve their goals**.**
Drink plenty of water.
Reduce daily salt and fat intake**.**
Increase the physical activity levels.

Variety of exercises included:

Target heart rate, mobility, muscle strengthening, muscle stretches, balance

EXERCISE PRESCRIPTION – Week 6
Motivational Factor of Exercise Programme: To lower blood pressure To lower blood glucose levels To lose weight To increase physical activity levels
Client (group) specifications/risks/precautions: Vital signs of each patient- recently measured and available Correct use of medication Use of beta-blockers Patients may use assistive devices Additional pathologies/lifestyle diseases Attention to safety of the environment Patient should be able to take own heart rate/pulse (teach patients) Research assistant available during exercise class to monitor heart rate Calculate the target heart rate for each patient
Beginning of programme: Organise area: Sufficient chairs and water available. Obstacles in hall removed. Music available. All equipment available and ready for use: balls, bags etc. Sphygmomanometer available. Information to patients: Should not feel out of breath, light headed, nauseas. Each participant should take their resting heart rate or research assistants should take heart rates of each participant. Para-medic available in hall for emergencies. **Note:** ***The patient with the knee injury returned without the support bandage, informed the researcher that she received treatment from physiotherapy and was not experiencing any pain or discomfort. She continued with the exercise programme after being instructed to exercise within limits and inform the researcher immediately if she experienced any discomfort or pain.***

Exercises:

Functional outcome	***Purpose of exercise (muscles and joints) (Type of exercise)***	***Description of exercise***	***Frequency, Intensity & Time***	***Biomechanical safety/risks***	***Objective measure of progress***
Warm-up	Dynamic warm-up	Dance:	• 5 minutes	• Participants may rest as they feel necessary. • Alternate squats and lunges each round • Alternate one repetition of overhead reaches with one repetition of knee touches. • Participants with unstable hypertension must not do the overhead activities.	• Not applicable
		• 3 x steps left & clap			
		• 3 x steps right & clap			
		• 3 x steps forward & clap			
		• 3 x steps in place (alternating trunk flexion/extension & clap with each step)			
		• Squats/lunges to the Left side and the Right side.	• 1 x 10 repetitions		
		• Bilateral overhead reach with arms	• 1 x 5 repetitions		
		• Bilateral knee touch with arms	• 1 x 5 repetitions		
		• Turn 90˚ left			
		Repeat			
Improve quality of life General mobility and increase flexibility	Stretching and warming up of muscles	• Neck rotation to Left and hold	• 3 x 20 second hold	• Participants may rest as they feel necessary. • Participants are	• Participant should maintain normal neck range of motion. • Participants should maintain normal gleno-humeral range
		• Neck rotation to Right and hold	• 3 x 20 second hold		
		• Neck flexion and hold	• 3 x 20 second hold		

		• Lateral neck flexion to Left and hold	• 3 x 20 second hold	instructed that they should only feel a slight stretch and no pain. • If participant's heart rate or blood pressure is unstable they should not perform bilateral shoulder flexion activities. • Participants are allowed to sit and perform activities if they feel unstable. • Research assistants should correct performing of stretches and should ensure that participants do not over stretch the muscles.	of motion. • Patient should maintain normal trunk range of movement. • Participants should maintain functional hip and trunk movements.
		• Lateral neck flexion to Right and hold	• 3 x 20 second hold		
		• Shoulder elevation and roll shoulder anterior	• 3 x 20 repetitions		
		• Shoulder elevation and roll shoulder posterior	• 3 x 20 repetitions		
		• Arm circles of increasing circumference (with bilateral upper limbs in 90˚Abduction)	• 3 x 20 repetitions • Make circles in the air with outstretched arms, make the circles bigger as time goes on/on command.		
		• Posterior Deltoid stretch bilaterally	• 3 x 20 second hold • Pull arm across body, provide overpressure with opposite arm. Should feel stretch in back of the shoulder.		
		• Triceps stretch bilaterally	• 3 x 20 second hold • Try to touch hand to back of shoulder on same side, provide overpressure with opposite arm in a posterior direction. Should feel stretch in back of the arm.		

		• Trunk Rotations to Left & Right	• Rotate as far as possible to left and right, while keeping hips still. • 3 x 20 repetitions		
		• Standing bilateral hamstring stretch – keep legs straight whilst flexing at the hips to try and touch the toes	• Rounding of the lower back is not allowed. • 3 x 20 second hold		
1 minute water break					
Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Muscle Strengthening and Cardiovascular training	• Walking on the spot	• 5 minutes	• Participants are allowed to hold onto chair for balance/assistance. • Participants may rest as they feel necessary.	• Participant should be able to individually train at their own target heart rate or decrease the number of resting periods that they chose to take. • Participants should maintain their muscle strength in the
		• Half Squats	• Perform a squat without moving into pain or extreme stiffness/approximately half of active range of movement. • 5 x 10 repetitions		
		• Walking on the spot	• Increase speed every minute. • 5 minutes		
		• Half squat with isometric hold	• Perform a squat without moving into pain or extreme stiffness/approxim		

			ately half of active range of movement. • 7 x 10 second holds		upper and lower limbs.
		• Marching	• 2 x steps forward,2 steps backward, Total 8 min		
		• Step and punch(Left & Right)	• Step forward with one leg and punch the air with the arm on the same side. • Total 8 minutes		
		• Lateral stepping(Left & Right)*	• 20 x repetitions each		
		• Alternating High knees to elbow*	• Flex the hip and knee in standing, then raise the knee until it can be touched by the elbow on the same side of the body without bending over. • 5 x 10 repetitions		
		• Walking on the spot	• 5 minutes		
1 minute water break					

Improve quality of life Improved cardio-vascular function (endurance and fitness) Improved functionality	Functional strengthening and cardiovascular training	• Ball throwing and catching • "Over and under" ball game	• 1 x 10 rounds • Each participant should stand facing their partner. They should then throw a netball ball to each other, taking 1 step backward every time the ball is returned to the initial participant. This was repeated until both participants retreated for at least 20 m. • 10 x 20 m • Groups of 5 participants were formed, with participants standing behind one another. The first participant then passes the ball down the line either going above their head or sideways. The second participant passes the ball on to the next participant through their legs and	• Participants with uncontrolled hypertension were to pass the ball sideways and not over their head during the ball activity.	• The first team to have every member complete the course wins the challenge.

			move to the back of the line. • This sequence is repeated until the line moves back a total of 20 m. The first team to have every member across the 20 m mark wins the challenge.		

Ending off for programme:

Educational session **–** Time was spent on planning the way forward. Participant received information on how to continue to be a successful self manager of their conditions and of their life. Workbook pages 47 – 50.

Provide home advice:

Need to complete their goals as set out in the workbook and must try and achieve their goals**.**
Drink plenty of water.
Reduce daily salt and fat intake**.**
Increase the physical activity levels.

Variety of exercises included:

Target heart rate, mobility, muscle strengthening, muscle stretches, balance

APPENDIX 30

Borg Scale

Rating of Perceived Exertion
Borg CR10 Scale

Borg-CR-10 Scale™ © Gunnar Borg

0	Nothing at all	
1		How you feel sitting or simply standing
2	Weak	
3	Moderate	Exercise goal: How you feel when you walk or exercise
4		
5	Strong	
6		
7	Very Strong	How you feel when you really push yourself
8		
9		
10	Extremely Strong	
•	All-out effort	You're unable to go on

Borg Scale of Perceived Exertion

Borg-RPE Scale® © Gunnar Borg

6	No activity at all	
7		How you feel sitting or simply standing
8	Light activity	
9		
10		

11		
12	Moderate activity	Exercise goal: How you feel when you walk or exercise
13		

14	Hard	
15		
16	Very hard	How you feel when you really push yourself
17		
18	Very, very hard	
19		
20	All-out effort	You're unable to go on

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APPENDIX 31

Intervention study

Participant data form

SIMMONDS BATTERY OF FUNCTIONAL TESTS

Date: _ _ _ _ _ __ _ __ _ _ _ _ __ _ __ _ _ _ _ _ **Age:** _ _ _ _ _ __ _ **ID code** _ _ _ _ _ __ _

Activity	Description	Baseline reading			After 6 weeks		
15 m walking at preferred speed	Walk 7.5 m turn around and walk back to the starting position at preferred walking speed.						
15 m walking at fastest speed	Walk 8 m turn around and walk back to the start as fast as you can.						
Unloaded forward reach (cm)	Stand adjacent to a wall on which a tape measure is positioned horizontally at shoulder height. Reach forward as far as you can.						
Timed, repeated sit-to-stand	Sit in a standard chair – stand up and then sit back down. Repeat after a brief rest.	1st	2nd	AVG	1st	2nd	AVG
Sock test	Sit in a standard chair. Put on one loose-fitting sock.						
Loaded forward reach (cm)	Stand adjacent to a wall on which a tape measure is positioned horizontally at shoulder height. Hold a weighted 4.46 kg bar with both hands close to your body and at shoulder height. Reach forward as far as you can with the bar in a horizontal position, maintaining hands at shoulder height.						
Timed, repeated reach-up	Stand facing a wall and reach up as high as you can with both hands. A mark is placed on the wall at the reached distance. You must reach up and return your hands to your side 3 times as fast as you can.						
Distance walked in 6 minutes	Walk as far and as fast as you can for 6 minutes. You are allowed to rest if necessary during the 6 minutes.						
Timed belt tie	Sit in a standard chair and wrap a standard wrap bandage (approximately 1 m) around your waist and tie it in from of you.						

BASELINE INFORMATION

Date: _ _ _ _ _ __ _ __ _ _ _ _ __ _ __ _ _ _ _ __ _ _

ID code _ _ _ _ _ __ _

Description	Baseline reading		After 6 weeks	
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 reading (mmHg)				
Venous plasma glucose concentration (mmol/L)				
Kasch Pulse Recovery test: pulse rate per minute (3 minute step test)	Resting pulse rate	Pulse rate 1 min after step test	Resting pulse rate	Pulse rate 1 min after step test
Cholesterol (lipid metabolism) (mmol/L or mg/dL)				
Medication used	Name		Dosage	

PEDOMETER READINGS

Date: _ _ _ _ _ __ _ __ _ _ _ _ __ _ __ _ _ _ _ __ _ _

ID code _ _ _ _ _ __ _

Description	Baseline reading	After 6 weeks
Step length in cm		
Weight (kg) – accurate to 0.05 kg		
Pedometer reading		

APPENDIX 32

Pan African Clinical Trial Registry letter

19 November 2015

To Whom It May Concern:

RE: An investigation into the prevalence and nature of musculoskeletal conditions amongst women attending Primary Health Care Clinics, and the effectiveness of an intervention program for these patients.

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201511000689333**

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email, post or fax) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835

THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL
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APPENDIX 33

Intervention study

Participant information leaflet

INFORMATION LEAFLET

INTERVENTION STUDY

University of Cape Town: *An investigation into musculoskeletal conditions and co-morbidity amongst women attending a community clinic and the effectiveness of an intervention programme for patients with these conditions.*

Dear Participant

Introduction

I, Roline Barnes, am currently a student in Physiotherapy at the University of Cape Town and a lecturer at the University of the Free State. I need to do a research project in order to get my degree. Research is simply the process to learn the answer to a question.

Title of the research project

The title of the survey is *"An investigation into musculoskeletal conditions and co-morbidity amongst women attending a community clinic and the effectiveness of an intervention programme for patients with these conditions"*.

Purpose of the survey

I am interested in knowing what the changes would be in women between the ages of 40 – 64 years with joint pain and illnesses (high blood, sugar or overweight), if they receive a workbook with information and exercise for six weeks or go about what they normally do. This can help women to change their lifestyles by doing more exercises and looking at what they eat. It is possible that they may lose weight, that their sugar and high blood will be lower, that they will have less pain in their joints and that they may move easier. They will help me to tell people in the community that they should exercise more often. They will also help me to inform the local government and Department of Health about the exercises and how it helped them. The local government and Department of Health may then place people at the clinics that are trained to give patients at the clinics exercises and information when they have joint pain and other illnesses.

Selection of participants

All women between the ages of 40 – 64 years, who showed with the first questionnaire that they have joint pain, sugar, high blood and being overweight and who are willing to come once a week to MUCPP for two hours to exercise and receive information for the next six weeks.

Description of research

All the women who tell me that they want to take part in the study and have joint pain, sugar, high blood and are overweight will be put into two groups. I will choose 121 women and they will help me to choose exercises that they would like and that they think they will enjoy doing. After the exercises have been chosen I will make a workbook that will be used for six weeks.

The 121 women will then be put into three groups of 37 in each group. But ten will only be used for the test study (pilot study). This means that five will exercise with me for only three weeks and five will not exercise but fill in the forms and have the tests done as explained. The test study is very important as this will show me how I must change things to make them better, before I start with the big study that the 111 other women will be in.

Unfortunately I cannot tell them at this stage in which group they will be. This will only be done after the book has been completed and I use a computer to divide the names for myself. I will then phone them to tell them in what group they are and when we will start with the tests in the MUCPP hall. Please remember that they must have a cell phone number and that they must fill their number in on the form that I give them to ask if they want to be part of the study.

The 111 women will also be put into three groups. Two groups will receive the exercise and information workbook. One group will have 37 participants and they will do exercises and receive information given by a physiotherapist or a physiotherapy student in the hall of MUCPP once a week for two hours. This they will have to do for six weeks. The other group, which will also have 37 participants, will go about their lives as usual. All three groups' sugar readings and cholesterol readings (pricking their finger for a drop of blood and getting a reading of a portable machine), blood pressure readings (the same way the sister and the clinic always takes the blood pressure reading), weight (standing on a scale) and height (standing against a wall, and looking how tall they are) will be taken at the beginning of the programme, and at the end of the six weeks. They will complete forms that will ask them certain questions about things that they do during the day, about their health and about their pain.

Both the workbook and the exercise groups will receive a monitor that they will have to wear all the time during the day. This will measure how much they move each day. The monitor is the property of the researcher and must be given back to me after the six weeks. They must please take care of the monitor and make sure that it does not get lost or damaged.

If a participant is chosen to be in the exercise group a doctor will ask them certain questions, about the medication that they are taking, listen to their heart and lungs, take their blood pressure and see how fit they are, to make sure that they are healthy enough to exercise in the group. During the exercise session a paramedic will also be in the hall to help me if someone does not feel well or gets ill.

There is little chance for the participants to hurt themselves while doing the exercises, but a little bit of pain or the muscles feeling tight after the exercises is normal and should go away after a day or two. The more they exercise, the less pain and muscle tightness they will feel. I will do everything I can to make sure that they do not hurt themselves, but in the unfortunate case this does happen, the physiotherapist or physiotherapy student will refer them to National district hospital's physiotherapy department for treatment free of charge. They are taking part in the exercises as a volunteer / of their own free will and they may decide to stop taking part at any time without being punished in any way.

They will see that there is a number in the top corner of the paper that I will use to write their readings (blood sugar, weight and blood pressure) on. Their name and telephone number will be put on a separate paper with the number that only I will have. Nobody will know their readings (blood sugar, weight, and blood pressure readings) - this will protect who the participant is. They will receive no money to do the exercises. All 111 women will receive R20 to come to the allocated times for the test and the filling in of the forms, so that the study does not cost the participants any money. The women taking part in the study will not receive any money for taking part and the study will also not cost them any money to take part.

The women doing the exercises will be given R20 for taxi/bus fees to make sure that they can come to the exercise classes once a week for the six weeks. There might not be direct benefit for the women in the group that does not exercise with the physiotherapist for six weeks, or receive the workbook, but the information that they will give me is very important so that I can see if the exercises work if I compare the information from the three groups. The women in the group that exercises with the physiotherapist or get the workbook might lose some weight, their sugar and high blood can become lower and the pain in the joints can also be less. But this is not for sure. That is why we are doing the study to see if this will make a difference.

The results of the study might be put in a magazine for doctors, nurses and other people working with health, so that they can know that exercises help people with similar pain in the joint and other diseases just like the participants.

If they want to ask anything before we start with the questions, or later on, they can phone me, Roline Barnes, at 082 740 1069, or the person supervising me, Prof Jelsma, at 021 – 406 6595.They may also contact the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee (contact number: 021 – 406 6411) or the University of the Free State Ethics Committee (contact number: 051 – 405 2812) if they have any queries/questions or concerns regarding their rights or welfare as research participant.

Thank you

APPENDIX 34

Intervention study

Participant informed consent document

CONSENT TO PARTICIPATE IN RESEARCH

INTERVENTION STUDY

University of Cape Town: *An investigation into the effectiveness of an intervention programme for patients with co-morbidities attending community clinics.*

I _____ have read (or had read to me by)

_____ the information sheet.

I understand what is required of me and I have had all my questions answered. I do not feel that I am force to take part in this study and I am doing so of my own free will. I know that I can withdraw at any time if I so wish and that it will not have consequences for me.

Signed:

_____ _____

Participant Date and place

_____ _____

Researcher Date and place

_____ _____

Witness *(if necessary)* Date and place

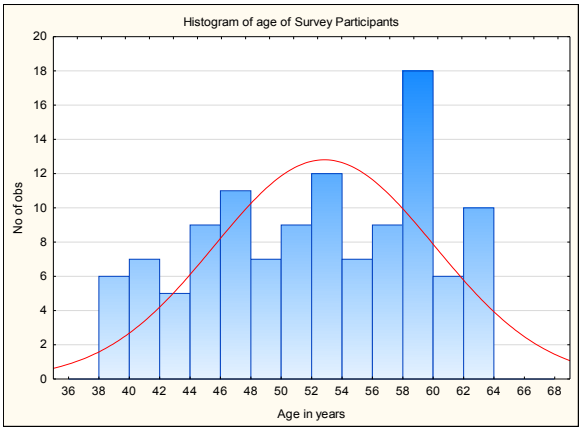
APPENDIX 35

Intervention study

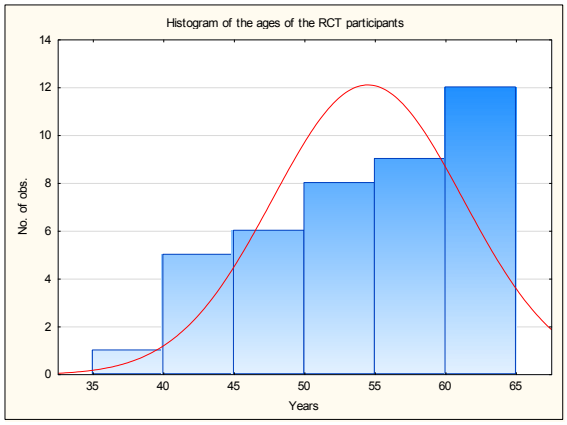
Comparison of demographic information and health variables survey group (with and with out joint pain) compared to the randomised, control trial group at baseline

1.1 Comparison of demographic information of survey participants and randomised, control trial participants at baseline

According to the Shapiro-Wilk test of normality the distribution of the age of the participants for both the survey and the randomised, control trial groups did not follow a normal distribution (W = 0.956; p < 0.0001 and W= 0.956; p = 0.013 respectively). Figure 1 Histogram of the age distribution of the survey and randomised, control trial groupbelow shows the age distribution of the survey and randomised, control trial groups.



(n=1376)



(n=41)

*Note that each category includes the upper bounds of that category.

Figure 1 Histogram of the age distribution of the survey and randomised, control trial groups

The median age of the participants in the survey group was 52 years (inter-quartile range (IQR): 46-58 years, and range of 40-65 years). The median age of the participants of the randomised, control trial group was 56 years (IQR: 50-61 years and range of 40-64 years) and was significantly higher (p = 0.014) than the median age of the survey group as seen in Figure 1 Histogram of the age distribution of the survey and randomised, control trial groups

below.

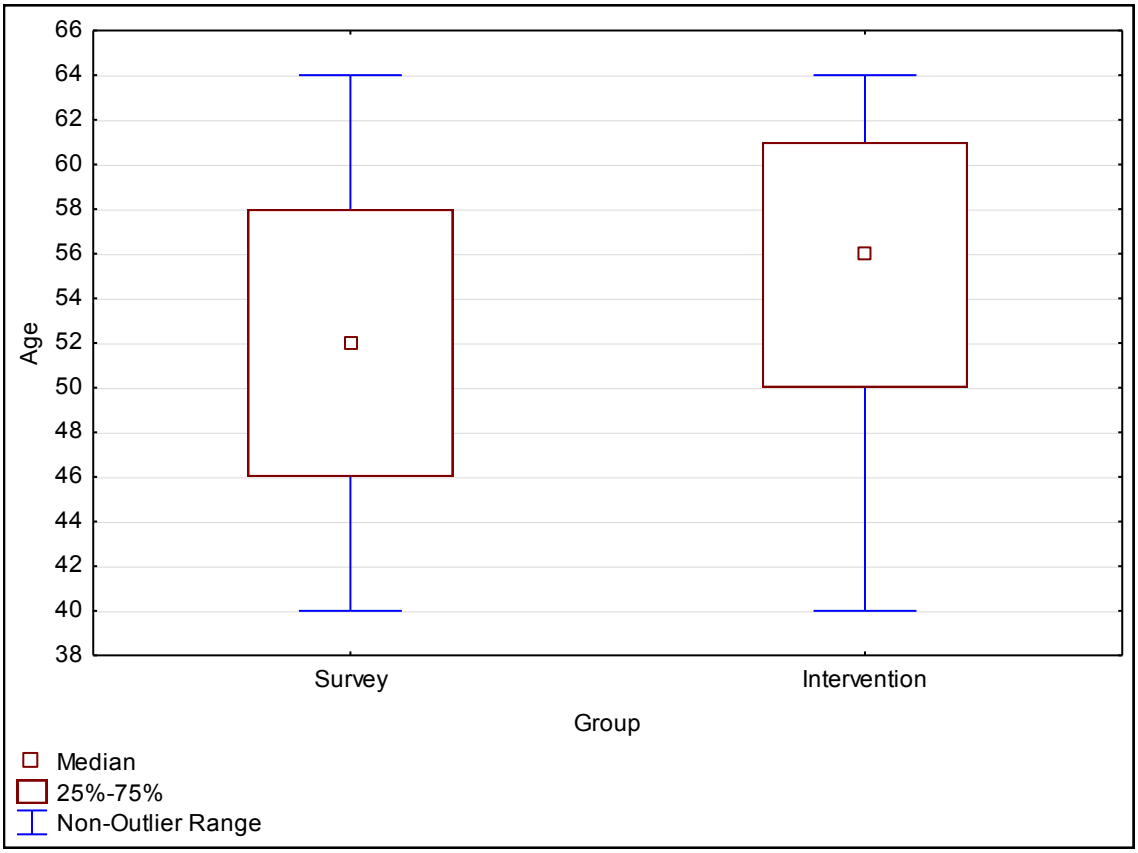


Figure 2 Descriptive statistics regarding the age of the participants in the survey and randomised, control trial groups

In the survey group 68% of the participants and in the randomised, control trial group 62% of the participants were Sesotho speaking, while Isixhosa was the next most spoken language with 18% of participants speaking Isixhosa in the survey group and 19% in the randomised, control trial group (Table 1 Demographic and living conditions of the participants in the survey and randomised, control trial group The marital status of the survey group was slightly different compared to the randomised, control trial group with 36% of the participants in the survey group never being married and 46% being married, while in the randomised, control trial group the majority of the participants (36%) were never married and 33% being married. The majority of the participants in both the groups owned their own brick homes. The median number of residents per household in the survey was 5 people (IQR: 4-6 people) which was significantly different ($p < 0.000$) from the median number of four people (IQR: 3-5 people) in the randomised, control trial group.

Table 1 Demographic and living conditions of the participants in the survey and randomised, control trial group

Variable	Categories	Survey (n = 1376)	Survey percentage	RCT (n = 42)	RCT percentage	Between Groups (Chi-Square test)
Language	Sesotho	935	67.95%	26	62%	Chi-square=1.45* p = 0.484
	Isixhosa	246	17.87%	8	19%	
	Setswana	176	12.79%	8	19%	
	English	11	0.8%	0	0%	
	Afrikaans	2	0.15%	0	0%	
	Zulu	4	0.29%	0	0%	
	Missing	2	0.15%	0	0%	
Race	African	1371	99.64%	42	100%	-
	Coloured	3	0.22%	0	0%	
	White	1	0.07%	0	0%	
	Missing	1	0.07%	0	0%	
Marital Status	Married	638	46.37%	14	33%	Chi-square=5.55 p =0.062
	Never married	494	35.89%	15	36%	
	Widowed/Separated/Divorced	242	17.59%	13	31%	
	Missing	2	0.15%	0	0%	
House ownership	Own	1024	74.42%	35	83%	Chi-square=1.08* p = 0.299
	Friend/family	340	24.71%	7	17%	
	Other	7	0.51%	0	0%	
	Missing	5	0.36%	0	0%	
Type of dwelling	Brick	1145	83.21%	34	81%	Chi-square=0.06* p = 0.807
	Informal	225	16.35%	8	19%	
	Missing	6	0.44%	0	0%	

Number of residents per household	Three or less	283	20.56%	21	50%	Chi-square=19.16 p <.001
	Four or more	1090	79.22%	21	50%	
	Missing	3	0.22%	0	0%	

Note that frequency of missing data was not included in Chi-Square analysis.

*Calculation only included cells greater than 5.

Almost 15% of the participants in the survey were either illiterate or could only read in their home language, while all the participants in the randomised, control trial group could read and write as this was an inclusion criterion for participation in the randomised, control trial. (Table 2 Education level and employment status of the participants in the survey and the randomised, control trial group) In the survey group 90% of the participants had some level of education, which included primary, secondary or tertiary education while 62% of the participants in the randomised, control trial had secondary education. Only 14% of the participants in the survey had full time employment and 18% of the participants in the survey were pensioners. In contrast most of the participants in the randomised, control trial group (79%) were unemployed and were pensioners. Sixty three percent of the participants in the survey indicated the reason for unemployment as not being able to find a job, followed by health problems 31%. In the randomised, control trial group 52% of the participants indicated that not being able to find a job was the reason for their unemployment while 42% indicated that their health problems prevented them from being employed. Twenty five percent of the participants in the survey group received a grant while 33% in the randomised, control trial group received a grant. The results indicate that 58% of the survey group's participants and 64% of the randomised, control trial group's participants received pension.

Table 2 Education level and employment status of the participants in the survey and the randomised, control trial group

Variable	Categories	Survey (n = 1376)	Survey percentage	RCT (n = 42)	RCT percentage	Between Group (Chi-Square test)
Literacy	None	164	11.92%	0	0%	-
	Read only	38	2.76%	0	0%	
	Read/write	1171	85.10%	42	100%	
	Missing	3	0.22%	0	0%	
Education	None/Primary	634	46.08%	16	0%	Chi-square=0.76* p = 0.383
	Secondary/Tertiary	741	53.85%	26	62%	
	Missing	1	0.07%	0	0%	
Current employment status	Unemployed/Housewife/Pensioner	1070	77.77%	39	79%	Chi-square =4.31* p = 0.060
	Worker - Full time	296	21.51%	3	0%	
	Missing	10	0.72%	0	0%	
Reason for unemployment (n = 675 and n =33)	Cannot find work	425	62.96%	17	52%	-
	Health problems	209	30.96%	14	42%	
	Family care	22	3.26%	2	6%	
	Disabled	6	0.89%	0	0%	
	Husband prevents	4	0.59%	0	0%	
	Missing	9	1.34%	0	0%	
Receive grant benefits	No	1025	74.49%	28	67%	Chi-square=0.96* p = 0.327
	Yes	349	25.36%	14	33%	
	Missing	2	0.15%	0	0%	
*Type of grant benefits (n = 349 and n =14)	Disability	123	35.24%	5	35%	-
	Pension	202	57.88%	9	64%	
	Disability and pension	17	4.87%	0	0%	
	Not known	7	2.01%	0	0%	

*Note that the type of grant is for those individuals who indicated that they do receive grant benefits

Note that frequency of missing data was not included in Chi-Square analysis.

*Calculation only included cells greater than 5.

In summary, the randomised, control trial group were older, fewer participants were employed and they lived in households with a greater number of inhabitants.

1.2 Comparison of health related information of the survey group and the randomised, control trial group

The median weight, height, BMI and haemoglucose level of the participants in the survey group were significantly different ($p < 0.05$) than from the median values of the participants in the randomised, control trial group (Table 3 Health variables of the participants in the survey and the randomised, control trial group). The median height of the participants in the survey group was two cm taller than the survey participants. The median BMI value of the participants from both the survey and randomised, control trial groups fell within the classification of being obese.

Table 3 Health variables of the participants in the survey and the randomised, control trial group

Variable	Survey			RCT			Between Groups (Wilcoxon Two-Sample test) (Z score)
	n	Median	IQR	n	Median	IQR	
Weight (kg)	1372	80.0	65.0 – 92.7	41	93.8	76.3-100.8	p =0.007 (2.72)
Height (cm)	1370	158	154 – 163	41	156	153.0-159.0	p = 0.037 (-2.091)
BMI (kg/m^2)	1370	31.6	26.8 – 37.0	41	37.2	31.8-41.9	p = 0.0001 (3.449)
Haemoglucose (mmol/l)	1366	5.5	4.6 – 7.2	41	5.8	5.4-9.1	p = 0.006 (2.735)
Systolic BP (mmHg)	1369	147	132 – 159	41	143	133.0-155.0	p = 0.427 (-0.794)
Diastolic BP (mmHg)	1369	91	84 - 99	41	92	84.0-99.0	p = 0.66 (-0.429)

(n=41)

In the survey (20%) of the participants had diabetes mellitus type II compared to 27% in the randomised, control trial group. Most of the participants in the survey (33%) and in the randomised, control trial (37%) had stage I hypertension. Sixty percent of the participants in the survey and 83% in the

randomised, control trial were obese (Table 4 Health variables of the participants in the survey and the randomised, control trial group).

Table 4 Health variables of the participants in the survey and the randomised, control trial group

	Survey (n=1366)	Survey Percentage	RCT (n=41)	RCT Percentage	Between Groups (Chi-Square test)
Diabetes mellitus type II*	275	20%	11	27%	p = 0.294 (Chi-square=1.1025)
Hypertension**	(n=1369)		(n=41)		p = 0.726 (Chi-square=1.313)
Normal	458	34%	15	37%	
Stage I	499	37%	15	37%	
Stage II	232	17%	8	20%	
Stage III	180	13%	3	7%	
Obesity***	(n=1370)		(n=41)		p < 0.001 (Chi-square=43.372)
Underweight	23	2%	0	0%	
Normal	228	17%	3	7%	
Overweight	294	22%	3	7%	
Obese	825	60%	34	83%	

*Diabetes mellitus type II (non-fasting blood glucose >7.8mmol/L)
**Normal: Systolic blood pressure<120-139 Diastolic blood pressure < 80-90
Stage I hypertension: Systolic blood pressure 140-159 Diastolic blood pressure 90-99
Stage 2 hypertension: Systolic blood pressure ≥160-179 Diastolic blood pressure ≥ 100-109
Stage 3 hypertension: Systolic blood pressure ≥ 180 Diastolic blood pressure ≥110
***Underweight: BMI < 18.5; Normal weight: BMI 18.5-24.9; Overweight: BMI 25-30; Obese: BMI > 30 = 4 (n=41)

APPENDIX 36

Intervention study

Comparison of health related quality of life experienced between and within control and intervention group

Dimensions for the quality of life experienced by participants in the control and intervention group

EQ-5D Item	Group	Time	No problems	Some problems	Unable	p-value (within-groups) (Sign test)	p-value (between groups) (Wilxocon Two-Sample test)
Mobility	Control (n=15)	Baseline	8	7	0	p = 0.134 z = 1.500	Baseline: p = 0.178 Z = 1.346 After 6 weeks: **p = 0.034** z = 2.126
		After 6 weeks	12	3	0		
	Intervention (n=22)	Baseline	17	4	1	p = 0.074 z = 1.789	
		After 6 weeks	22	0	0		
Self-care	Control	Baseline	14	1	0	p = 0.480 z = -0.707	Baseline: p = 0.844 z = 0.197 After 6 weeks: p = 0.248 z = 1.156
		After 6 weeks	14	1	0		
	Intervention	Baseline	21	0	1	-	
		After 6 weeks	22	0	0		
Usual Activities*	Control	Baseline	10	5	0	p = 0.248 z = 1.155	Baseline: p = 0.362 Z = 0.912 After 6 weeks p = 0.248 z= 1.156
		After 6 weeks	14	1	0		
	Intervention	Baseline	18	3	1	p = 0.134 z = 1.500	
		After 6 weeks	22	0	0		
Pain/Discomfort	Control	Baseline	3	6	6	p = 0.149 z = 1.443	Baseline: p = 0.123 z= 1.156 After 6 weeks: **p = 0.077** **z = 1.768**
		After 6 weeks	5	10	0		
	Intervention	Baseline	7	12	3	**p = 0.043** z = 2.021	
		After 6 weeks	14	8	0		

EQ-5D Item	Group	Time	No problems	Some problems	Unable	p-value (within-groups) (Sign test)	p-value (between groups) (Wilxocon Two-Sample test)
Anxiety/Depression	Control	Baseline	7	4	4	p = 0.505 z = 0.667	Baseline: p = 0.700 z = -0.385 After 6 weeks: p = 0.171 z = 1.369
		After 6 weeks	9	3	3		
	Intervention	Baseline	6	13	3	**p = 0.010** z = 2.582	
		After 6 weeks	17	5	0		

APPENDIX 37

Intervention study

STROBE checklist

STROBE guidelines for randomised controlled trials and indication of section where items were addressed

Section/Topic	Item No	Checklist item	Reported in
Title and abstract	1b	Identification as a randomised trial in the title Structured summary of trial design, methods, results, and conclusions	Abstract Will be specified for publication
Introduction Background/objective	2a 2b	Scientific background and explanation of rationale Specific objectives or hypotheses	Section 1.3 and 8.1 Section 1.2 and 8.1.1
Trial design	3a 3b	Description of trial design (such as parallel, factorial) including allocation ratio Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Section 8.2.1 N/A
Participants	4a 4b	Eligibility criteria for participants Settings and locations where the data were collected	Section 8.2.2.1 Section 8.2.4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Section 7.2 Appendix 27 and 28
Outcomes	6a 6b	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed Any changes to trial outcomes after the trial commenced, with reasons	Section 5.2 and 8.2.3 Section 8.2.3 and 8.4.3

Section/Topic	Item No	Checklist item	Reported in
Sample size	7a 7b	How sample size was determined When applicable, explanation of any interim analyses and stopping guidelines	Section 8.2.2.3 N/A
Randomisation: Sequence generation	8a 8b	Method used to generate the random allocation sequence Type of randomisation; details of any restriction (such as blocking and block size)	Section 8.2.2.2 Section 8.2.2.2
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Section 8.2.2.2
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Section 8.2.2.2
Blinding	11a 11b	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how If relevant, description of the similarity of interventions	Section 8.2.7 N/A
Statistical methods	12a 12b	Statistical methods used to compare groups for primary and secondary outcomes Methods for additional analyses, such as subgroup analyses and adjusted analyses	Section 8.2.8
Results			
Participant flow (a diagram is strongly recommended)	13a 13b	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome For each group, losses and exclusions after randomisation, together with reasons	Figure 17 and 8.3.1 Section 8.3.1 and 8.3.2

Section/Topic	Item No	Checklist item	Reported in
Recruitment	14a 14b	Dates defining the periods of recruitment and follow-up Why the trial ended or was stopped	Section 8.2.2.2 and 8.2.4 and 8.2.7 and Figure 17
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Section 8.3
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Section 8.3
Outcomes and estimation	17a 17b	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Section 8.3 N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Section 8.3
Harms	19	All important harms or unintended effects in each group	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Section 8.6 and 8.7
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Section 8.6
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Section 8.4 – 8.7
Other information			
Registration	23	Registration number and name of trial registry	Section 8.2.7

Section/Topic	Item No	Checklist item	Reported in
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Acknowledge

APPENDIX 38 (a)

Good Clinical Practice certificate 2013

This is to certify that

Roline Barnes

HPCSA Practitioner's number: PT 0040363

Has successfully completed the following course

GCP for the Experienced Researcher

PRESENTED BY: Denise Richardt

SACRA registration No: SACRA/GCP/82/2013

Held at. Department of Physiotherapy, University of Free State, Bloemfontein

Session #	Topic	Date
	Pre-Test	2 October 2013
	Declaration of Helsinki, the South African Perspective and proposed update 2013	2 October 2013
3	Use of Placebo in Clinical Trials	2 October 2013
4	Adaptive clinical trial design – what's the fuss about?	2 October 2013
5	Ethics in Research – Sensitive Populations	2 October 2013
6	Fraud in Clinical Research	2 October 2013
	Recap – SAE/SUSAR reporting – the process	2 October 2013
8	Recap on problem areas identified in Pre-test	2 October 2013

University of Free State CPD Accreditation / Activity Nos:

MDB004/009/05/2013 = 3 general CPD points: Level 1

MDB004/010/05/2013 = 9 ethics CPD points in Level 2

[redacted]

Signature:

Name: Denise Richardt

Designation: Trainer

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APPENDIX 38 (b)

Good Clinical Practice certificate 2015

This is to certify that

Roline Barnes

HPCSA Practioners number: ***PT 0040363***

Has successfully completed the following course

GCP for the Experienced Researcher

PRESENTED BY: **Denise Richardt**

SACRA registration No: **SACRA/GCP /82/2013**

Held at: Department of Physiotherapy, University of Free State, Bloemfontein

Session #	Topic	Date
1	Pre-Test	18 November 2015
2	Declaration of Helsinki 2013 – update from 2008 version	18 November 2015
3	Ethics in Health Research: Principles, Structures and Processes DOH version 2014 vs 2004	18 November 2015
4	Workshop – eConsent for Clinical Trials – ethical/regulatory dilemma or not?	18 November 2015
5	Adaptive clinical trial design – what's the fuss about?	18 November 2015
6	Ethics in Research – Sensitive and Vulnerable Populations	18 November 2015
7	Fraud in Clinical Research	18 November 2015
8	Recap – SAE/SUSAR reporting – the process	18 November 2015
9	Recap on problem areas identified in Pre-test	18 November 2015

HPCSA (University of Free State) CPD Accreditation Activity Nos:

MD8004/006/08/2015 for 2 general ceu's in Level 1.

MD8004/007/08/2015 for 8 ethical ceu's in Level 1.

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Designation: Trainer

Date: 24 November 2015

This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma, Inc. as necessary to enable mutual recognition of GCP training among trial sponsors

APPENDIX 39

Health Professional Council of South Africa registration certificate 2016

HPCSA

Health Professions Council of South Africa

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NAME
Ms. ROLINE YVETTE VAN DEN BERG
REGISTRATION NUMBER
PT 0040363
VALID FOR
01 Apr 2016 - 31 Mar 2017
REMARKS

DATE	DESCRIPTION	AMOUNT
2016/02/08	Invoice: 3178106 Registration Renewal 19676868	
	Physiotherapist Annual Fee 2016	R 1181.00
	VAT (Included above)	R 145.04
2016/02/26	Amount Received	R -1181.00
	Amount outstanding on this invoice	R 0.00

Inhoteth SP 012 327 3239 SAM002/2 05/13 146589

HPCSA
Health Professions Council of South Africa

NAME	Ms. ROLINE YVETTE VAN DEN BERG
ID NUMBER	6602220071085
CARD NUMBER	29825146
REG. NO.	PT 0040363
VALID FOR	01 Apr 2016 - 31 Mar 2017
REGISTER	PHYSIOTHERAPIST
CATEGORY	PHYSIOTHERAPIST (INDEPENDENT PRACTICE)
SPECIALITIES / SUB-SPECIALITIES	

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Step 3: Pop out card and peel silicon sheet off back of card - **Step 4:** Refold carefully making sure the edges line up