HEALTH RELATED QUALITY OF LIFE AND TREATMENT REGIMENS IN PATIENTS WITH MUSCULOSKELETAL DISORDERS AT KENYATTA NATIONAL HOSPITAL

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A RESEARCH DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF PHARMACY IN CLINICAL PHARMACY IN THE SCHOOL OF PHARMACY OF THE UNIVERSITY OF NAIROBI.

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DEDICATION STATEMENT

It is with great honor that I dedicate this work to my late grandmother Esther Njeri Kimani, for inspiring the research topic. Through the men and women you brought up with integrity, it is because of them that I am. May your kindness and love live on.

To my mum Eunice, my dad Stephen, my siblings Esther, Naomi and Abby. Thank you for all your words of encouragement, unwavering support and push for tenacity that kept me going. I am overly privileged to have you as my family members.

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ABBREVIATIONS AND ACRONYMS

COVID-19 Corona Virus Disease of 2019

DMARDs Disease modifying anti-rheumatic agents

EQ-5D Euroqol 5 Dimension

GBD Global Burden of Diseases

HRQOL Health related quality of life

K.N.H Kenyatta National Hospital

LBP Lower back pain

MSDs Musculoskeletal disorders

NSAIDs Non-steroidal anti-inflammatory drugs

QOL Quality of life

SF-36 Short form 36

TNFIs Tumor necrosis factor inhibitors

W.H.O World Health Organization

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ABSTRACT

Background: Globally, musculoskeletal disorders are one of the most neglected diseases despite showing a prevalence that is on the rise and a leading cause of disability. Various regimens have been identified and are used in the management of these conditions. The impact of its treatment from the patient's perspective should be a very important indicator of the desired outcome other than relying on clinical judgment alone from the healthcare provider's perspective. Such an impact is measured by determining the health related quality of life (HRQoL) which can also be used to pick out other issues in the course of treatment.

Objective: To determine the most common musculoskeletal disorder, evaluate the health related quality of life and impact of various treatment regimens in patients who attend the rheumatology clinic at Kenyatta National Hospital for their routine management.

Methodology: A cross - sectional descriptive study was conducted at Kenyatta National Hospital, Rheumatology clinic, targeting adult patients with a diagnosis of a musculoskeletal disorder and on treatment at the facility. Simple random sampling was used to obtain a representative sample of 71 consented participants. Data on HRQoL was collected through a self-administered questionnaire using the EQ-5D-5L questionnaire. This tool has been validated and is used worldwide for assessing HRQoL. Data analysis was carried out using STATA version 13.0 software, with level of significance set at P value < 0.05. Categorical variables such as pattern of HRQoL and treatment regimens were summarized as frequencies and percentages while

continuous variables such as age were represented as mean (\pm standard deviation). Bivariate analysis was carried out using the chi squared test (X^2) to determine any statistically significant association between treatment regimens and HRQoL.

Results

The most common musculoskeletal disorder in this population was rheumatoid arthritis that accounted for 59.1% of all the cases, followed closely by systemic lupus erythematosus which accounted for 23.9% of the cases and osteoarthritis that was reported in 5.6% of the participants. The mean health related quality of life was 10 (3.64) with the physical and mental domain being the one participants complained of the most. Most of the participants (80.1%) in this study were prescribed non-biologic Disease Modifying Anti-Rheumatic Drug (DMARDs) therapy as either monotherapy (35.2%), dual therapy (38%) or triple therapy (7%). The remaining fourteen (19.7%) participants were on analgesics from the Non-steroidal anti-inflammatory (NSAID) group.

Conclusion

Analysis of the data obtained showed that rheumatoid arthritis was the most common musculoskeletal disorder. Majority of the patients had a health related quality of life score that was below the mean. The physical domain which was described in terms of pain and difficulty in walking was the most affected followed by the mental domain that was described in terms of number of patients that reported depression. Increasing the number of drugs in management of MSDs doesn't necessarily improve patients'

quality of life. The different treatment regimens did not seem to improve the patients' quality of life.

Recommendations

- Mandatory assimilation of HRQoL measure as an important tool in determining therapeutic outcomes should be encouraged. This will improve the holistic and multidimensional management of patients with musculoskeletal disorders.
- 2. Embracement of community based hospital support groups that will offer counselling and psychological care to assist patients cope with their new diagnosis and share their experiences.
- 3. Insurance cover policies that will cater for the different treatment modalities that is both pharmacological management such as biologic DMARDs, non-biologic DMARDs and non-pharmacological management such as aculaser and physiotherapy. The insurance policy should cater for all populations irrespective of employment status.

CHAPTER ONE: INTRODUCTION

1.1 Background to the study

Health is a state of complete physical, mental, spiritual and social wellbeing and not merely the absence of disease as was thought of in earlier years (1). Quality of life (QOL) is a broad term used to define all aspects of a patient's life and general wellbeing in terms of healthcare, employment, social, political, environmental, physical and psychological aspects of their life (2). Health related quality of life (HRQoL), related to QOL, is the functional impact of a disease and its management on the patients' quality of life as perceived and experienced by the patient. Health Related Quality of Life (HRQoL) focuses on the effect of the illness and treatment will have on patients' physical, social, economic and psychological wellbeing (3). It also distinguishes aspects of life that are related specifically to health, detect undiagnosed diseases for example; mental health issues and determines burden of injuries and disabilities.

The musculoskeletal system consists of bone, also known as the skeleton, muscles, joints, tendons, ligaments, cartilage and bursae of the body (4). Conditions of the musculoskeletal system are classified depending on the part of the system that is affected. Diseases affecting bone include osteoporosis, osteopenia, myelomas, fragility and traumatic fractures; those affecting muscles include sarcopenia; those affecting joints are osteoarthritis, rheumatoid arthritis, psoriatic arthritis, gout and ankylosing spondylitis and that affecting multiple body systems is systemic lupus erythematosus (5). They can also be classified as acute diseases like in fractures and sprains and as chronic diseases associated with ongoing debilitating pain and disability. Musculoskeletal disorders (MSDs) are a growing health problem and prevalent across

all ages but commonly affect the adolescence to older populations but impact of disease rises as people age. In the U.S.A, in people aged 18 and above MSDs affect more than one out of every two persons while in people aged 65 and above, it affects every three out of four (6).

Pain and restricted mobility are the most common contributors of the HRQoL. Persistency of pain, chronicity of disease, impaired mobility, high cost of drugs, decreased psychological and social wellbeing are some of the most common experiences associated with musculoskeletal diseases and they all have an impact on the quality of life. Diseases of the musculoskeletal system rarely cause death but have been found to be the leading cause of disability in the world, mainly affecting the physical domain of HRQoL more than the social and mental function (7).

In 2017, global burden of disease ranked musculoskeletal conditions as the highest contributor to global disability (8). A systematic analysis of the WHO diseases burden database has shown musculoskeletal disorders to be on the rise and the second leading cause of disability (9). Few epidemiological studies have focused on MSDs with less than 0.54% representation of the abstracts assessed in 2016 (10).

In the U.S.A the most common MSDs have been reported to be trauma, arthritis and back pain with the rate and cost of treatment greater than that of respiratory and circulatory conditions which are most of the times manageable and are not associated with the debilitating pain and disability. Sadly, time and money for research to create new treatment modalities has prioritized other disease conditions other than MSDs (6). A study carried out in Dutch found that participants with multiple MSDs had poorer health related quality of life with a reduction in physical function (11).

In Africa, most of the focus has been put on infectious diseases and debilitating diseases such as musculoskeletal disorders that may have a greater impact both economically and socially neglected (12). Here, MSDs have been neglected as they are associated with a lower mortality rate although its impact is more in terms of morbidity, cost and reduced quality of life (13).

The studies described above have tried to elaborate the effect MSDs may have on the patients' HRQOL and its impact on the disease burden and especially the economy in terms of lost productivity time and expenditure of drugs. Most important is its effect on the disability life years and quality of life years which determine the QOL (13), (14).

In Kenya, there have been limited studies that tried to put an emphasis on health related quality of life in patients with musculoskeletal disorders thus there is scanty data to have adoption and inclusion of HRQOL as a routine monitoring tool to measure patients' general health and treatment efficacy. This study aims to assess HRQOL and impact of the various drug regimens in patients with MSDs among patients at Kenyatta National Hospital.

1.2 Problem statement

One in three people worldwide live with a painful MSD, a prevalence that is comparable to a combination of chronic respiratory and cardiovascular diseases (15). In Sub-Saharan Africa and other developing countries the impact has been on the rise due to a rise in number of, ageing population and obesity (16). Fatal traumatic injuries due to road traffic accidents are a major cause of loss in disability adjusted life years while non-fatal injuries are associated with a burden of MSDs whose prevalence is

unknown (17). Musculoskeletal diseases have been associated with high incidence of physical deformities and pain which have had a negative impact on the patient's productivity and quality of life on a physical, emotional social economical and psychological level (18).

All the domains in HRQoL are interrelated. Persistent pain limits the patients' mobility and can also cause mental symptoms such as depression and anxiety which are over looked or undiagnosed. Mental symptoms and limited mobility causes social withdrawal. The patient due to all the inter-relating factors and economic constraint is not able to seek further treatment and the healthcare worker may underestimate the deteriorating physical symptoms of the disease.

In the course of treatment or as direct impact of the disease, the patient may develop other physical or psychological problems that lead to major injury, loss of function and economic loss which ultimately increases the disease burden worldwide. Most of these upcoming problems are rarely diagnosed during course of treatment and are only evident when irreparable damage has occurred. Improvement in quality of life should be the main aim of any intervention initiated to treat MSDs (19).

A cohort study carried out in 2017 found that MSDs have a more hazardous effect on the physical domain of QOL than the mental and social domains (7). A study assessing impact of lower back pain, a symptom of musculoskeletal disorder, on QOL stated that Lower Back Pain (LBP) is a major problem globally and affects all domains of QOL but most studies assess QOL and not overall impact of HRQOL (20).

Despite the availability of HRQoL assessment tools in our healthcare set up, very little attention is paid to aspects of HRQoL. The health care system in Kenya is yet to

incorporate mandatory assessment of HRQoL in patients with MSDs to evaluate QOL which is a vital predictor of treatment outcomes and patients overall health.

By conducting this study, we seek to identify the most common health related quality of life issue experienced by patients and to find out what treatment regimen best improves the HRQoL. Focusing on HRQoL as an outcome will help bridge between social, mental and in improvement of medication service delivery through monitoring of drug regimen that may be ineffective or a dose that is too low thus impacting the HRQoL negatively.

Findings of this study will contribute to better monitoring of patients with MSDs by having HRQoL as a mandatory aspect of care. Identification of the most common type of health related quality of life issue experienced by the patient will help inform the healthcare workers on the best patient centered approach for managing the patient holistically and also how to mitigate some of these unforeseeable issues. All this will be in an effort to improve the patients overall quality of life.

1.3 Study justification

In recent times, the number of patients suffering from the various musculoskeletal disorders has been on the rise. The prevalence and incidence in Africa and Kenya is unknown but estimated to be at 1% using data collected from American countries.

Effect of this diseases on the patients' health related quality of life has not been fully established in Kenya.

Assessment of HRQoL in patients with MSDs will provide a reliable way for healthcare providers to better understand the effect of MSDs on overall functioning and well-being

of the patient. This study will influence improvement of quality of care provided to patients with MSDs.

This study also aims to identify and establish the most common health related quality of life issues experienced by these patients, to establish clinical evidence on the effect of the disease and treatment and aid in choosing the best drug class for the various musculoskeletal disorders based on overall effect and improvement of patients HRQoL which might be dependent on the regimen.

If the effect of the various MSD regimens on HRQoL is found to be significantly different, guideline review will be done to have the most effective drug regimen as the first line and also incorporate aspects of HRQoL into routine care of patients with MSDs. This will lead to a more patient centered and holistic approach in management of the patients' well-being and health and the healthcare worker will be guided on the best approach to use when monitoring treatment outcomes.

The study will also influence several facets of the patients' life. Depending on the outcome of the study, patients will be encouraged to be more proactive in the course of disease treatment and monitoring patient outcomes by mandatory creation of patient action plans based on some of the domain in HRQoL.

1.4 Research questions

- 1. What are the most common musculoskeletal disorders at Kenyatta National Hospital?
- 2. What is the health related quality of life among patients with musculoskeletal disorders?

3. What is the difference in health related quality of life among patients with different drug regimens for musculoskeletal disorders?

1.5 Objectives

1.5.1 Main objective

To determine the most common musculoskeletal disorder, evaluate the Health related quality of life and impact of treatment regimens in adult patients with musculoskeletal disorders at Kenyatta National Hospital.

1.5.2 Specific objectives

- To determine the most common musculoskeletal disorder in adult patients at Kenyatta National Hospital.
- 2. To describe patterns of health related quality of life issues in patients with musculoskeletal disorders at Kenyatta National Hospital.
- 3. To compare the health related quality of life in patients on the different regimens for musculoskeletal disorders.

1.6 Significance of the study

This study will aim to conceptualize the impact of MSDs on HRQoL. The findings will have a huge impact on the patients living with MSDs in that it will have HRQoL monitoring as a routine mandatory indicator of treatment outcome and thus consequent improvement in the number of quality of life years and a reduction in the disability associated life years. Health care workers will also have a chance to understand the correlation between disease and HRQoL and aim to have a more patient centered

approach in management of the patient, minimizing the number of poor treatment outcomes that lead to morbidity and mortality. Policy makers will also have a chance to be best informed when compiling treatment guidelines for MSDs based on the treatment regimen that produces the most improvement in HRQoL.

Assessment of HRQoL in relation to musculoskeletal disorders will help the healthcare providers to understand and appreciate the impact of bone and joint disease from the patient's own perspective. This will then guide in making the healthcare services more patient oriented with inclusion and adoption of a more holistic approach in management of the patient as a whole being and not just the symptomatic management of the patients presentation. It will also aid in emphasis of monitoring and documentation of patients progress in the course of treatment and not just initiation of therapy.

1.7 Limitations

Attaining the calculated sample size may be a challenge due to the limited number of patients with musculoskeletal disorders and a decrease in the number of patients visiting on clinic days due to the COVID-19 pandemic.

The study will be conducted using questionnaires thus prone to information bias from the patients in terms of reporting and recalling certain aspects of HRQoL. This will be minimized by use of a good and standardized questionnaire tool that is valid, reliable and easy to use.

The study being based only in Kenyatta National Hospital, any obtained results might not be reflective of the larger community or situation in other rural counties. Simple random sampling will be used so as to make it easy to infer the results to the larger population.

1.8 Delimitations

This study will not include patients who are below 18 years or those with other conditions other than musculoskeletal disorders. The burden of MSDs emanates from its association with high morbidity rate due to the pain and disability. The study objectives and questions will be limited to health related quality of life in patients with musculoskeletal disorders at Kenyatta National Hospital which is the facility that gets referrals for most MSDs thus a large representative sample of MSDs in the country.

1.9 Conceptual framework

Health Related Quality of Life domains in patients with musculoskeletal diseases can be under the influence of both the predictor and intervening variables that have an impact on HRQoL either positively or negatively.

Treatment regimens used for MSDs should ideally lead to improvement in the patients' physical, social, mental, functional and spiritual wellbeing leading to overall improvement in the overall health related quality of life. Sometimes due to cost of medication, adherence issues, side effects, the regimen fails to bring about the desired outcome.

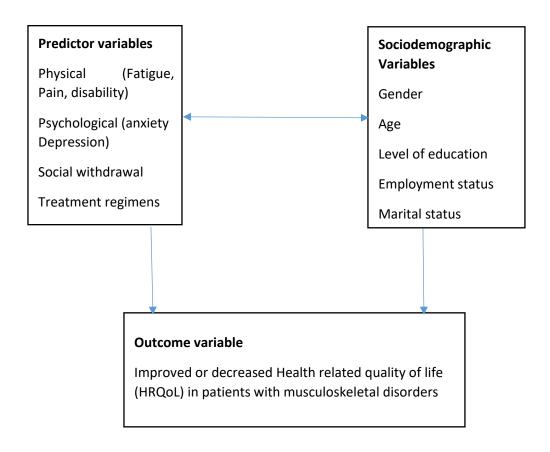


Figure 1: Conceptual framework representing factors influencing health related quality of life in patients with musculoskeletal disorders.

CHAPTER 2: LITERATURE REVIEW

2.1 Burden of musculoskeletal disorders

Musculoskeletal Disorders are defined as diseases and injuries affecting bone, muscle and associated tissues causing pain, deformity, restricted mobility, muscle atrophy and weakness which leads to disability and work loss (21). Some of the risk factors that contribute to development of MSDs include age, family history, occupation and activity that promotes wear and tear (22). MSDS are also classified under the long-term non-communicable diseases that have been shown to increase the global disability- adjusted life years by 61.4% in 2016 mostly common in low income settings.

In a 2010 Global Burden of Disease study (GBD), MSDs were ranked as the highest cause of chronic ill health, disability and consultation with health care workers. A systematic analysis for the GBD study in 2016, found that MSDs came in second after mental health disorders as a common contributor to global disability. In 2017, according to the global burden of diseases initiative, MSDs were ranked as the fourth leading cause of years lived with disability while lower back pain came in as the first (21). Globally in the same year, there were 1.3 billion cases of MSDs, 121300 deaths and 138.7 million adjusted life years (23).

In Africa, prevalence of MSDs is not well known but is associated with the highest disability compared to first world countries (24) with a negative impact on the social, economic and overall health of the population (25). In Kenya most studies have majorly dwelt on prevalence of occupational related musculoskeletal disorders.

2.1.1 Musculoskeletal disorders

The nature of MSDs can either be chronic or acute, with some of the most common and disabling including osteoarthritis, back and neck pain, fractures with bone fragility and rheumatoid arthritis (26). The greatest contribution to disability is osteoarthritis, rheumatoid arthritis, osteoporosis and lower back pain (27), with lower back pain being the most common in developing countries.

In the year 2000, a systematic review carried out by Walker revealed that out of the 56 studies reviewed, only 8% were carried out in developing countries (28). In Kenya, a study looking at musculoskeletal health conditions in slum dwellers found the prevalence of arthritis to be 42.6%, past back pain to be at 44% and those that reported a musculoskeletal condition to be the most severe health condition was 42.6% (29).

2.2 Domains of Health related quality of life

Health related quality of life is an individual's perceived mental and physical health over time. On an individual level, it is a concept that has domains related to physical, functional, emotional, mental and social functioning of a patient which assist in its description and assessment. The domains majorly help focus on impact of health status and outcome on quality of life. In a community level, it is related to resources available at a community level, conditions, policies and practices that influence a population's mental health perception and functional status.

The physical domain encompasses the observed or perceived bodily function or dysfunction that can result from treatment or disease and one has to distinguish the two contributors so as to avoid misinterpretation of symptoms as side effects. Common symptoms associated with the physical domain include: pain, fatigue, immobility (30). Functional well-being involves the ability to carry out the day to day activities as commanded by our need for survival that is to satisfy ones basic needs, societal expectations and self-actualization in terms of ones goals and purpose in life.

Signs of functional distress include inability to bath, feed or dress oneself.

Emotional well-being involves ability to manage and express emotions for example anger, frustration and sadness in contrast mental health can be defined as how the mind processes and understands information and experiences. An inability to express our emotions can lead to deterioration in mental health for example suppressed sadness and melancholy often leads to depression which is a mental health condition.

Social wellness entails community participation for example the kind of social support the patient gets from family and the community at large- social support groups, gratifying relationships with friends and family, intimacy and sexuality which is also dependent on emotional well-being (31).

2.2.1 Effect of MSDs on domains of HRQoL

Musculoskeletal disorders have an effect on HRQoL through the common symptomatology of pain and fatigue that are the largest contributors to a decrease in the quality of life. Pain will affect both the physical and emotional aspects depending on its severity, duration and intensity (32). Healthcare providers are majorly concerned

with having the clinical goals met while sometimes neglecting the patient perception of their treatment and day to day life.

A study looking at the impact of MSDs in Parkinson's disease reported that MSDs affect the HRQoL significantly, with the physical domain being the most affected and affecting more women than men (33). Another study that assessed HRQoL in eight domains found that all the domains were negatively affected by presence of MSDs, with the physical and mental scores being the lowest thus most affected (34). A study carried out in the Dutch population looking at multiple MSDs found the physical domain to be most influential on the patients' health related quality of life (11).

2.2.2 HRQoL measurement instruments

Health related quality of life (HRQoL) cannot be observed directly thus instruments have been developed and validated to measure the broad perceptions of health (patient reported outcomes) well categorized into the physical, mental, social and mental well-being domains. The tools help to explain the extent of difficulty to which activities are carried out and how the perceived difficulty may affect relationships with family, friends and social groups and the patients' well-being holistically. Selected tools should measure the health dimension that is most relevant to a particular group of patients. Health Related Quality of Life instruments are in the form of questionnaires that are available as generic and disease specific (35).

Generic instruments for example the short form 36 questionnaire (SF-36), Euroqol-five item questionnaire (EQ-5D) and World Health Organization quality of life (WHOQoL-

100), are used to capture information from both ill and healthy individuals in differing populations, conditions and set ups, and the results are then compared across groups.

Other generic tools available include the Nottingham health profile, and short form - 6D (36).

The disease specific ones, are used in the particular diseases they are named after, for example, Questionnaire QOL in osteoporosis (QUALIOST) (37), Rheumatoid arthritis quality of life (RAQoL) in rheumatoid arthritis (38), Sarcopenia and quality of life questionnaire (SarQoL) (39), used in sarcopenia, Fibromyalgia impact questionnaire (FiQ) (40) used in fibromyalgia and asthma quality of life questionnaire (AQLQ) used in asthma. These tools are only used to collect data on specific health problems and symptoms pertaining to a particular MSD but cannot be used to compare HRQoL in other types of populations or diseases (35).

In evaluating health related quality of life in MSDs the short form 36 (SF-36) and Euroqol 5 item questionnaire are the most commonly used generic tools (19). The short form SF-36 consists of items assessing eight domains (physical, social, and role limitation due to physical function, role limitation due to emotional function, bodily pain, general health, vitality and mental health) and two summary scores.

The EQ5D looks at 5 domains in terms of mobility, pain, self-care, usual activity and anxiety/depression and a second section with a visual analogue scale where patients rate their general health state on a scale of zero to one hundred (11). The five domains

may have 3 or 5 levels depending on the type of EQ-5D used. EQ-5D-3L has 3 levels: no, some and extreme problems and a score of 1, 2 and 3 respectively (41) while the EQ-5D-5L has 5 levels: no, slight, moderate, severe and extreme problems (42).

In MSD HRQoL studies, either tool can be used, a study using the two instruments found the results to be similar for both the SF-36 and EQ-5D (11). The EQ-5D is a concise, brief and simple to use tool which makes it easy for the participants to fill in while the SF-36 covers a broader range of domains only useful to particular research questions but the social domain has been found to have a lower internal consistency (11) (43). A systematic review of 24 studies comparing EQ-5D-3L to EQ-5D-5L found the EQ5D-5L to have a better measurement property and more informative than EQ-5D-3L (44). A study that used both the EQ-5D and SF-36 in multiple MSDs, found that the two had similar results in terms of assessing the domains of HRQoL (11).

In this study we will be looking at a broad range of MSDs thus a generic tool will be most suitable. The EQ-5D-5L will be employed to quantify and describe the patterns of health related quality of life in patients with musculoskeletal disorders. It is a concise, brief and simple to use tool, this three features make this tool user friendly and allows for a rapid assessment of the patients HRQoL (45). Analysis of the HRQoL data will then be used to assess the gained or perceived benefits of treatment by the patient.

2.3 Drug Regimens used in MSDs

There are numerous drug regimens used for managing MSDs and it's majorly dependent on the type of MSD. Pain being the major symptom that cuts across most MSDs, analgesics and anti-inflammatory agents become a vital part in the management

of pain and inflammation. The analgesics include paracetamol, Nonsteroidal anti-inflammatory Drugs (NSAIDS), opioids and adjunct agents such as gabapentin and amitriptyline. Anti-inflammatories used are majorly corticosteroids. Muscle relaxants such as cyclobenzaprine and methocarbamol are used for muscle stiffness. Both tumor necrosis factors inhibitors (TNFiS) such as infliximab and conventional synthetic Disease modifying anti- rheumatic drugs (DMARDs) for example methotrexate and Janus kinase inhibitors such as barcitinib are used in management of rheumatoid arthritis. In clinical practice, the biologic DMARDs are only prescribed after treatment failure with the conventional synthetic DMARDs (46).

Non-pharmacological treatment such as physiotherapy, acupuncture, massage, surgery can be used in cases of severe disease (47).

2.3.1 Impact of the drug regimens on HRQoL

A study reviewing pharmacologic treatment of MSDs specifically looking at the pain management found the effectiveness of available drugs to be disappointing (48). Another study assessing opioid versus non-opioid therapy found that most patients were on a combination of analgesics to achieve adequate pain relief (49). Corticosteroids improved physical but not mental domain (50).

A systematic overview of pain management in MSDs revealed that the analysis and corticosteroids only provide short term improvement of symptoms (51) and no advantage in the long term. In the case of disease modifying anti-rheumatic agents, an analysis of two randomized control trials, revealed that cDMARDs and TNFiS improved HRQoL in a similar manner (50).

Kenyan study reviewing HRQoL in patients on DMARD therapy found that the DMARDs and glucocorticoids were associated with an improvement in the HRQoL compared to use of NSAIDs alone and the physical domain was more affected than the mental domain (52).

2.4 Literature overview and knowledge gaps

From the above literature, the HRQoL of MSD patients at KNH clinic is unknown. No documented studies have been carried out to assess this phenomena. This study seeks to fill this gap and to find ways to improve on the management of patients with MSDs and have favorable outcomes and not just prolonged life that is of low quality.

CHAPTER 3: METHODOLOGY

3.1 Introduction (Perspective of research methodology)

This chapter outlines the research methods that were followed in order to achieve the stated objectives and address the research questions. The researcher describes the research design that was chosen for purpose of the study and reason for this choice. It will also describe aspects of the study location, study population, sampling technique, research instruments, pretesting, quality assurance, data collection tools, data management. Lastly, the logical and ethical considerations that were followed will be discussed.

3.2 Study design

The research employed a cross-sectional study design to look at adult patients with a clinical diagnosis of a musculoskeletal disorder attending the Rheumatology clinic at Kenyatta National Hospital. It was the most appropriate study design as it is cost effective, minimizes loss to follow up, allowed for determination of prevalence or proportions and it is time efficient also provides enough descriptive data that will be summarized analytically in a snapshot (53). The research paradigm was a mixed method study whereby qualitative data was collected using a predesigned questionnaire and then analyzed quantitatively. Qualitative data in research is based on the fact that firsthand experience provides the most meaningful data in terms of quality and also

aims to understand the participants' world from their perception (54). The researcher was also in a position to interact with the participants continuously.

The dependent variable was health related quality of life while the independent variables were pain, disability and treatment regimens associated with musculoskeletal disorders.

3.3 Study area and site

The study was carried out at Kenyatta National Hospital. It the largest National Referral Hospital in Kenya, located in Nairobi County, to the West of Upper hill area and is approximately 3.5 Kilometers from the Central Business District. It is one of the largest referral hospitals in East and Central Africa. Also serves as a teaching hospital for the University of Nairobi and Kenya Medical Training College students. It has a total bed capacity of 1800, divided into 50 wards and 22 outpatient specialized clinics. The hospital has employed over 6000 staff. This study was carried out at the rheumatology clinic that falls under the medical outpatient clinic, clinic 17. Patients visited the clinic every Thursday afternoon with an average of 22 patients suffering from a musculoskeletal disorder every week. This site was the most appropriate as most patients with MSDs from other catchment areas are referred or tend to seek services from here.

3.4 Study population

The study targeted patients in Kenya suffering from musculoskeletal disorders whose exact number and prevalence is unknown. The population comprised of adult patients who were eighteen years and above with a clinical diagnosis of a musculoskeletal disorder, on treatment and attending clinic at Kenyatta National Hospital during the study period. The participants were sourced from the rheumatology clinic. The sample size included a reasonable number that was not too large or too small, a number that was easy to work with considering the cost implication and time limit assigned. Choosing an appropriate number ensured that the study population was well represented and study had enough statistical power (55).

3.5 Case definition

A patient with a musculoskeletal disorder was defined as one who at diagnosis had presented with symptoms of pain, fatigue or injury that affects any one of the tissues in the skeletal system that is bone, muscle, tendon, joints, and cartilage. As defined by clinical and laboratory characteristics found in the International classification of disease by WHO, 10th revision M00- M99 (56) (57).

3.6 Eligibility criteria

This described a number of requirements that needed to be met for a participant to be included in the study.

3.6.1 Inclusion criteria

Participants were recruited in the study if they:

- Were adult patients who were eighteen years and above.
- Had a clinical diagnosis of a musculoskeletal disorder.
- Were on treatment for a musculoskeletal disorder and attended clinic at KNH.
- Had a voluntary informed consent.

3.6.2 Exclusion criteria

The study excluded the following participants:

- Patients who had a congenital musculoskeletal disorder.
- Patients who had a clinical diagnosis of a MSD but not on treatment.

3.7 Sampling

3.7.1 Sampling technique

A sampling frame was created then simple random sampling used. Creation of the sampling frame was done by use of a register containing list of names of all patients who attend the rheumatology clinic at KNH, the names were then assigned computer generated numbers until each name was randomly assigned a number. Sampling interval was calculated by dividing the population with the sample size and then using this interval to carry out the simple random sampling. This was a simple method, least affected by bias and best for inferential statistics during analysis.

3.7.2 Sample size determination

The Cochran formula was used as this was a descriptive study with categorical variables. As the prevalence of musculoskeletal disorders in Kenya is not known, it was assumed to be at 50%.

$$n = \underline{Z^2 p (1-p)}$$

 $e^{\mathbf{2}}$

n = Sample size

Z =the statistic for 95% level of confidence, value = 1.96

P = Estimated proportion or prevalence of MSDs in Kenyan population, which was unknown, assumed to be 50%

e = Level of precision, was set at 5%

$$n = 1.96^2 * 0.5 (1-0.5)$$

 0.05^{2}

n = 384 participants

The calculated minimum sample size should be 384 participants. Based on the clinical attendance records from the department of musculoskeletal disorders at clinic 17, for the month of January and February 2021, an average of 80 MSD patients attended the rheumatology clinic, which was 17 to 20 patients every week. Data from the Health records information center at KNH indicated the number of new MSD cases recorded

in 2017 was 76 cases, 38 cases in 2018, 76 cases in 2019, 0 cases in 2020 and 38 cases from January 2021 to May 2021.

The decline in the number of new cases in 2020 was attributed to fear of patients contracting the COVID 19 virus and strict measures in hospitals where-by they restricted unnecessary visits and tough economic times (58). A representative sample was drawn from this population. Since the target population was small sample size will be adjusted using the Cochran correction formula.

 $n=\underline{n_0*N}$

 $n_0 + N$

 $\mathbf{n} = \text{Adjusted sample size}$

 n_0 = Calculated sample size (384 participants)

N = Approximate number of patients on management for Musculoskeletal disorders at KNH. Data collected from the Health records department at KNH indicated that a total of 76 patients with MSDs were seen from January to December 2019.

Therefore:

<u>384 * 76</u>

384 + 76

= 63.4 participants

Adjusted for 15 % non- response bias

63.4 * 1.15 = 72.9 participants (73 participants)

Minimum sample size was 73 participants.

3.7.3 Participant recruitment and consenting process

The participants were recruited by the principal investigator with the help of the research assistants every Thursday which was the clinic day at the rheumatology clinic. As the participants awaited attendance by the physician, they were briefly informed about the study. This was done during triaging after their vitals were taken and recorded. They were assessed for eligibility using the eligibility screening criteria and those found eligible and willing to take part in the study were introduced to the consenting process by the principal investigator and all their queries and concerns addressed. After understanding the consenting process, they were offered consent forms to sign. Thereafter, the EQ-5D-5L questionnaire (Appendix 3B) and social demographics questionnaire (Appendix 3A) were issued and ample time allocated to fill in the required information.

3.8 Data collection

3.8.1 Research instruments

After pretesting for validity and reliability the EQ5D-5L, generic standardized tool found in appendix 3B were used to collect data on domains of HRQoL. A guided questionnaire interview was used to counter language barrier and illiteracy levels. A separate questionnaire found on appendix 3A, was used to capture drug regimens, type of MSD and information on patient social demographics.

3.8.3 Data collection technique

After recruitment, questionnaires with close ended questions were administered to the participants by the principal investigator. A data collection sheet was used to capture patients' characteristics, disease characteristics and treatment regimen. Structured interviews were conducted on patients. The principal investigator administered the EQ-5D-5L questionnaire to assess HRQoL domains and also checked the patients' files to counter check information given on drugs, laboratory and diagnosis information.

Infection prevention measures such as keeping the one meter distance, wearing face mask and use of hand sanitizers were followed to the letter.

3.8.3 Study variables

The main study outcome variable was health related quality of life and was also the dependent variable. The predictor variables were sociodemographic factors that is age, gender, level of education, marital status, income level and occupation.

3.9 Quality assurance of data

3.9.1 Validity and Reliability of collected data

The data collection tools, EQ-5D-5L were pre-tested on the first ten participants for validity. Reliability was tested by ensuring reproducibility of data in the first ten participants. EQ-5D-5L tool was used for data collection after validity, reliability and ease of use were ascertained.

3.9.2 Internal and external validity

External validity was ensured by use of adequate sample size while internal validity was guaranteed by clear definition of variables. The EQ-5D-5L tool is a valid, reliable, easy to use and has a Cronbach alpha coefficient of 0.83 (59).

3.9.3 Pilot study/ Pre-testing

Copies of the questionnaire were administered to 5 members of the target population.

Based on the results that were obtained, no modifications were done on any of the questionnaire.

3.9.4 Training of research assistants

The principal investigator identified a research assistant, a nurse working at the rheumatology clinic and possessing a Kenya Enrolled Community Nurse certificate. The research assistant was taken through a detailed explanation of what the study entailed, the objectives and importance of the study. A practical session on how to use the Euroqol- 5D-5L and the social demographics questionnaire which was our data collection tool was done. Ethical considerations to be adhered to were explained. The competence of the research assistant was assessed during piloting by evaluation of their accuracy in how they extracted data and filled the questionnaires. No further training was required.

3.10 Ethical consideration

3.10.1 Study approval

Ethical approval was sought from the KNH/UON Research and Ethics Review

Committee and permission to carry out the study was sought from Kenyatta National

Hospital. Administrative approval was sought from the head of department at the rheumatology clinic.

3.10.2 Informed consent

Voluntary consent was sought from the study participants and only those who consented voluntarily were recruited to the study. Details of the study were explained to the participants and their concerns addressed.

3.10.3 Confidentiality and voluntarism

Confidentiality of the participants was upheld by ensuring password encryption of the data collected and use of codes instead of patient name. The participants were at liberty to leave the study at any time without being victimized or coerced.

3.10.4 Benefits from the study

The study helped provide new insights into health related quality of life as an output of treatment outcomes. The patients with a poor HRQoL as a result of the inappropriate

treatment regimen or inadequate drug dosing, the healthcare provider will be notified for addressing the patients' concerns.

3.10.5 Risks from the study

The study was non-invasive in nature thus minimal or no risk was anticipated in study.

3.11 Data management

Data was collected from the participants and their files using the standardized and structured questionnaires. Information on the questionnaire was entered into a database template that resembled the questionnaire using Microsoft word that was password protected. Confidentiality ensured by use of unique patient identifiers. All documents that linked the collected data to the patients' file were stored under lock and key and only accessible to principal investigator, supervisor and regulatory team. All data collected was coded, cleaned, processed, recorded and stored in a way that allowed accurate reporting, interpretation and verification. Data in the database was cleaned and exported to the STATA version 13 for analysis. Data entry was backed up and after completion of study all data disposed.

3.12 Data analysis

A software, STATA version 13.0 was used to carry out data analysis. Data was entered into the software on a daily basis during data collection. The most common MSD was determined and summarized by use of percentages, pattern of HRQoL described and

the relationship between HRQoL and treatment regimens for MSDs established. These was done by summary statistics for the descriptive data and categorical variables which was represented as frequencies and percentages then presented in form of tables, charts and graphs. Bivariate analysis was carried out to establish presence or absence of association between variables and p value set at 0.05. If an association between any of the variables is established, logistic regression will be carried out and the odds ratio or prevalence ratio determined and interpreted.

CHAPTER 4 RESULTS

4.1 Introduction

This chapter describes the results obtained from the data collected and analyzed from a sample of 71 participants with a musculoskeletal disorder at the KNH rheumatology clinic. To summarize the data, descriptive statistics have been used to describe pattern of health related quality of life in patients with musculoskeletal disorders, determine the most common MSD and compare health related quality of life in MSD patients on different regimens while inferential analysis was carried out using the Chi squared test (X²) to determine association between socio-demographic characteristics and health related quality of life and different treatment regimens.

4.2 Sociodemographic characteristics of the participants.

Table 4.1 summarizes the socio-demographic characteristics of the respondents in the study. The population under study was largely made up of the female gender (n = 62, 87.3%). Age was the only normally distributed continuous variable with a mean of 47.8 (± 16.06) as illustrated in figure 1 below. The median age of the participants was 46 years with a range of 18 to 83 years. More than a quarter of the population consisted of participants in the middle-aged bracket (41 - 60, 40.8%). Adolescents (0-20 years) and the young adults (21 - 40 years) made up 1.4% and 24% of the population respectively whereas

the elderly (> 60 years) made up 23.9% of the population. Majority of the participants were married (n = 47, 66.2%) and were mostly Christians (n = 69, 97.2%). Participants that were employed highly constituted this population (n = 54, 76.1%) but most of them were uncomfortable disclosing the amount of income earned per month (n = 56, 78.9%). 42.3% had a high level of education (tertiary level.)

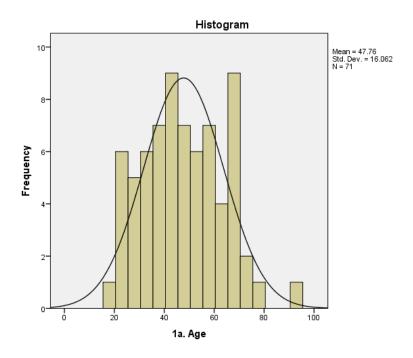


Figure 2: Age distribution of study participants

Table 4. 1: Socio-demographic characteristics of Musculoskeletal disorder patients at KNH rheumatology clinic

Variable	Category	Participants (N = 71)	Percentage (%)
Age	0-20	1	1.4

	21 – 40	24	33.8
	$\begin{vmatrix} 21 - 40 \\ 41 - 60 \end{vmatrix}$	29	40.8
	61 - 80	16	22.5
	81 - 100	1	1.4
Gender	Male	9	12.7
	Female	62	87.3
Marital status	Single	16	22.5
	Married	47	66.2
	Separated	5	7.0
	Widowed	3	4.3
Occupation	Unemployed	17	23.9
	Employed	22	31.0
	Self-employed	32	45.1
Income per month	0-30,000 Ksh	10	14.1
	31,000 – 60,000	4	5.6
	61,000 – 90,000	1	1.4
	Didn't disclose	56	78.9
Level of education	None	2	2.8
	Primary	10	14.1
	Secondary	29	40.8
	Tertiary	30	42.3
Religion	Christian	69	97.2
	Muslim	2	2.8

4.3 Patient social and clinical characteristics

Table 4.2 summarizes the patient specific characteristics of the respondents in the study. Majority of the population did not smoke cigarettes (n = 69, 97.2%) nor did they use alcohol (n = 68, 95.8%). Slightly above a third of the population engaged in regular aerobic or daily walking exercise (n = 26, 36.6%). All the participants knew the name of their condition and the medication they had been prescribed. More than a quarter of the

population had co-morbidities (n = 28, 39.4%) with hypertension being the most common comorbidity (n=19, 67.9.0%) followed by Diabetes mellitus (n=5, 17.9%) then Retro virus disease (n=2, 7.1%) and the least common were hypothyroidism and bipolar disorder each accounting for 3.5%.

Table 4. 2: Patient social and clinical characteristics

Variable	Category	Participants (N = 71)	Percentage (%)
Alcohol	Alcohol user	3	4.2
	No Alcohol use	68	95.8
Smoking	Smoker	2	2.8
	Non – Smoker	69	97.2
Regular exercise	Yes	26	36.6
	No	45	63.4
Know diagnosis	Yes	71	100
	No	0	0
Know medication	Yes	71	100
	No	0	0
Comorbidities	Yes	28	39.4
	Hypertension	19	67.9
	Hypertension only	11	39.3
	• Hypertension + DM	3	10.7
	• Hypertension + asthma	1	3.6
	• Hypertension + HHD	2	7.1
	• Hypertension + HHD +BPH	1	3.6
	• Hypertension + depression	1	3.6
	Total		67.9

Diabetes mellitus	5	17.9	
RVD	2	7.1	
Hypothyroidism	1	3.5	
Bi-polar disorder	1	3.5	
No comorbidity	43	60.1	

Key:

DM : Diabetes mellitus

HHD : Hypertensive heart disease

BPH : Benign prostate hyperplasia

RVD : Retro virus disease

4.4 Musculoskeletal disorders in patients at KNH rheumatology clinic

As shown in Figure 3, the most common musculoskeletal disorder was rheumatoid arthritis (n=42, 59.1%) affecting the female population more than the males, followed by systemic lupus erythematosus (n= 17, 23.9%) then osteoarthritis (n = 4, 5.6%). Inflammatory polyarthritis and polymyositis affected 2.8% of the participants each while gout, scleroderma, low back pain and mixed connective tissue disease which presents as an overlap of lupus, scleroderma and polymyositis, were found to be the least most common musculoskeletal disorders in this population (n=1, 1.4%).

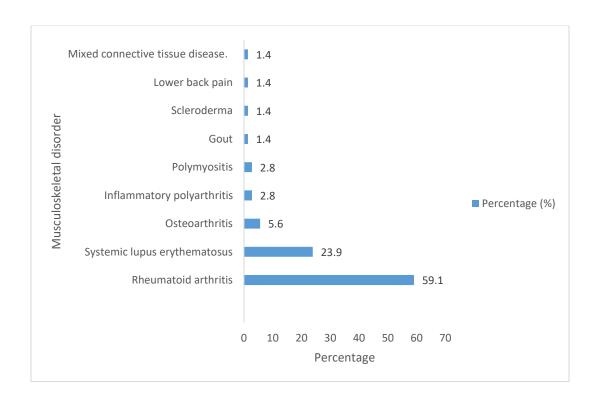


Figure 3: Musculoskeletal disorders in patients at KNH rheumatology clinic

4.5 Health Related Quality of Life in patients with musculoskeletal disorders

4.5.1 Mobility domain

Majority of the patients complained of having problems with mobility, that is they had problems with walking (n=48, 67.7%) while only twenty three (32.4%) of the participants complained of having no problems with their mobility (Table 4.3.).

4.5.2 Self-care domain

In terms of self-care that is in reference to being able to wash and dress oneself, fourty one participants (57.7%) reported having no problem while the other thirty (42.3%) had issues with self-care (Table 4.3.).

4.5.3 Usual activities

More than half of the participants experienced no problem in carrying out their day to day activities such as going to work (n = 38, 53.5%) while thirty two of them (45.1%) reported slight to severe inability in terms of performing their usual activities and one participant (1.4%) reported total incapacitation (Table 4.3.).

4.5.4 Pain or discomfort

Majority of the patients complained of experiencing pain ranging from slight to extreme (n=62, 87.3%) while only nine participants (12.7%) reported no pain (Table 4.3.).

4.5.5 Anxiety/depression

More than half of the participants reported feeling depressed or anxious (n= 46, 64.8%) while only twenty five (35.2%) did not experience any anxiety or depression (Table 4.3.).

4.5.6 Summary of health related quality of life in patients with musculoskeletal disorders

As illustrated in table 4.3, the physical domain is the most affected as indicated by the number of patients that complained of experiencing pain (n=62, 87.3%) and mobility

(n=48, 67.7%). The mental domain is second most affected as represented by the number of patients that complained of being anxious or depressed (n=46, 64.8%). Lastly usual activities and self-care were least affected.

Table 4.3 Health Related Quality of Life scores in participants with musculoskeletal disorders as assessed by EROQOL-5D-5L

Table 4.3 below summarizes the characteristics of the Health Related Quality of Life in patients with musculoskeletal disorders. The HRQoL domains represent the five aspects of quality of life that were assessed using the EROQOL-5D-5L questionnaire, that is mobility, self-care, usual activity, pain/discomfort and anxiety/depression. The domains were assessed as categories listed from level one to five. Level 1 indicated no problem, level 2 mild presentation, level 3 indicated moderate severity, level 4 indicated severe while level 5 indicated extreme severity.

HRQOL DOMAIN	CATEGORY	Participants	Percentage (%)
		(n=71)	
Mobility	Level 1 (No problem)	23	32.4
	Level 2 (Mild)	23	32.4
	Level 3 (Moderate)	15	21.1
	Level 4 (Severe)	10	14.1
	Level 5 (Extreme)	0	0
Self-care	Level 1 (No problem)	41	57.7

	Level 2 (Mild)	13	18.3
	Level 3 (Moderate)	13	18.3
	Level 4 (Severe)	4	5.6
	Level 5 (Extreme)	0	0
Usual activities	Level 1 (No problem)	38	53.5
	Level 2 (Mild)	21	29.6
	Level 3 (Moderate)	8	11.3
	Level 4 (Severe)	3	4.2
	Level 5 (Extreme)	1	1.4
Pain/discomfort	Level 1 (No problem)	9	12.7
	Level 2 (Mild)	21	29.6
	Level 3 (Moderate)	20	28.2
	Level 4 (Severe)	19	26.8
	Level 5 (Extreme)	2	2.8
Anxiety/Depression	Level 1 (No problem)	25	35.2
	Level 2 (Mild)	28	39.4
	Level 3 (Moderate)	15	21.1
	Level 4 (Severe)	2	2.8
	Level 5 (Extreme)	1	1.4

4.6 Health related quality of life summary score based on EROQOL-5D-5L

Table 4.4 illustrates the health related quality of life summary score as assessed by the EROQOL – 5D-5L questionnaire. The mean total health related quality of life score in patients with musculoskeletal disorders was 10 (3.64) and was computed by adding up participant scores from categories found in each of the five domains for all participant and then the sum of the scores was divided by the total number of participants (n=71). Fourty two of the participants (59.2%) had a mean score of less than ten while twenty nine (40.8%) of them were above the mean. The summary mean score for each domain was computed by adding up participant scores from one domain and then dividing the sum total gotten in the particular domain with the total number of participants (n=71), this was done for all the five domains. The highest mean score was obtained in pain/discomfort domain 2.77 (1.07) followed by mobility with a score of 2.17 (1.04) and anxiety with a score of 1.96 (0.90). Self-care and usual activities had the least score of 1.72 (0.96) and 1.70 (0.93) respectively. This means that in patients with musculoskeletal disorders, the pain domain is the most affected followed by mobility and anxiety. Self-care and usual activity are the least affected.

Table 4. 4 Health Related quality of life summary score among study participants

Scale	Mean Score (SD)
Mobility	2.17 (1.04)

Self-care	1.72 (0.96)
Usual activities	1.70 (0.93)
Pain or discomfort	2.77 (1.07)
Anxiety or depression	1.96 (0.90)
EROQOL 5D-5L total	10 (3.64)

4.7 Pattern of health related quality of life in patients with the different musculoskeletal disorders.

Table 4.5 gives a summary of the pattern of health related quality of life in patients with the different types of musculoskeletal disorders.

4.7.1 Rheumatoid arthritis

Only ten (23.8%) of the participant with rheumatoid arthritis reported having no problem with mobility while thirty two (76.2%) of them reported having problems with walking. Majority of them reported slight problems with walking (n=15, 35.7%) and the least reported severe difficulty (n=6, 14.3%).

In terms of self-care, twenty two (52.4%) of the participants had no problem with washing or dressing themselves while twenty (47.6%) of the participants had problems in the self-care domain.

Half of the patients reported having no problem in carrying out their usual day to day activities such as going to work (n=21, 50%), quarter of the participants had slight difficulty (n=12, 28.6%) they'd be absent from work for one working day in a week, seven of them had moderate level of difficulty that is they would miss work for two days in a week (n=7, 16.7%). Participants whose condition was severe, that is those that missed work for more than three days in a week and those unable to go to work on any of the working days accounted for one (2.4%) participant each.

Pain was the most common symptom experienced by patients with rheumatoid arthritis. Only three (71.4%) participants reported no pain. Majority of the participants experienced slight pain (n=14, 33.3%) or moderate pain (n=15, 35.7%). Only one (2.4%) participant reported extreme disabling pain.

More than half of the participants (n= 25, 59.5%) reported feeling depressed with the majority being slightly depressed (n=15, 35.7%).

4.7.2 Systemic lupus erythematosus

Only eight (47.1%) of the participants with SLE reported having no problem with walking represented as the mobility domain while nine (52.9%) of them reported difficulty in walking. Majority reported slight difficulty with mobility (n=5, 29.4%). Participant with moderate or severe difficulty in walking accounted for 11.8% of the participants each.

Eleven (64.7%) of the participants had no problem with self-care while six (35.3%) of the participants had problems with washing and dressing themselves.

Majority of the participants with SLE had no problem with performing their day to day activities such as going to work, school or reading (n=11, 64.7%). Most of those that complained of a problem in their usual day to day activities had slight limitation (n=4, 23.5%) and a minority with severe limitation (n=2, 11.8%).

Only six (35.3%) of the participants reported having no pain. Majority of the participants experienced slight pain (n=4, 23.5%) or moderate pain (n=4, 23.5%).

More than half of the participants (n= 10, 58.8%) reported feeling depressed with the majority being slightly depressed (n=6, 35.3%). Only seven (41.2%) participants reported experiencing no depression.

4.7.3 Osteoarthritis

A quarter of the participants with osteoarthritis reported having no problem with mobility (n=1, 25%) while three quarter reported problems with mobility. Majority of them reported slight problem when walking (n=2, 50%).

All the participants reported having no problem with self-care that is washing or dressing themselves (n=4, 100%).

Half of the participants reported having no problem with carrying out their usual day to day activities such as going to work or school (n=2, 50%) while the other half reported slight limitation (n=2, 50%).

All the participants with osteoarthritis reported having experienced pain (n=4, 100%) with majority of them with severe pain (n=3, 75%) and one (25%) with slight pain.

All the participants with osteoarthritis reported having experienced depression or anxiety (n=4, 100%) with majority of them with slight anxiety/depression (n=3, 75%) and one (25%) with severe anxiety.

4.7.4 Inflammatory polyarthritis

One (50%) participant had no problem with walking while the other had severe problem (n=1, 50%).

None of the participants reported any problem in self-care domain that is washing and dressing themselves and usual activity domain. One (50%) of them reported slight problem while washing or dressing themselves and going to work or school and the other reported severe problems (n=1, 50%).

Both participant reported experiencing severe pain and being moderately depressed (n=2, 100%).

4.7.5 Polymyositis

One (50%) participant had no problem with walking while the other had moderate problem (n=1, 50%).

One (50%) of them reported moderate problem while washing or dressing themselves and the other reported no problem with self-care (n=1, 50%).

One (50%) of the participants reported slight problem while the other reported no problem (n=1, 50%).

Both participant reported experiencing pain (n=2, 100%) with one experiencing severe pain while the other slight pain.

Both participants reported being slightly depressed (n=2, 100%).

4.7.6 Gout

One (100%) participant had no problem with walking, washing or dressing and usual activities. Participant only complained of experiencing severe pain.

4.7.7 Scleroderma

One (100%) participant had no problem with walking, washing or dressing and usual activities.

Only reported experiencing slight pain and being moderately anxious or depressed.

4.7.8 Low back pain

One (100%) participant had slight problem with walking, experienced slight pain and was slightly anxious or depressed.

Participant had no problem with washing or dressing and usual activities.

4.7.9 Mixed connective tissue disease

One (100%) participant reported having a problem in all the five domains that is they reported severe problem in walking, slight problem with washing or dressing, usual activities and anxiety/depression. Lastly, they experienced extreme pain.

Table 4. 5: Health related quality of life in the different musculoskeletal disorders

		MSD									
HRQOL	CATE-	R.A	SLE	OA	IPA	P.M	GT	SD	LBP	MCTD	Total
DOMAIN	GORY	n=42	n=17	n=4	n=2	n=2	n=1	n=1	n=1	n=1	n=71
Mobility											
	Level 1	10	8	1	1	1	1	1	0	0	23
	(no	23.8%	47.1%	25%	50%	50%	100%	100%	0%	0%	32.4%
	problem)										
	Level 2	15	5	2	0	0	0	0	1	0	23
	(mild)	35.7%	29.4%	50%	0%	0%	0%	0%	100%	0%	32.4%
	Level 3	11	2	1	0	1	0	0	0	0	15
	(moderate)	26.2%	11.8%	25%	0%	50%	0%	0%	0%	0%	21.1%
	Level 4	6	2	0	1	0	0	0	0	1	10
	(severe)	14.3%	11.8%	0%	50%	0%	0%	0%	0%	100%	14.1%
	Level 5	0	0	0	0	0	0	0	0	0	0
	(extreme)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0.0%
Self-care		•		•				•	•	•	
	Level 1	22	11	4	0	1	1	1	1	0	41
		52.4%	64.7%	100%	0%	50%	100%	100%	100%	0%	57.7%

	(no										
	(no problem)										
	Level 2	9	2	0	1	0	0	0	0	1	13
	(mild)	21.4%	11.8%	0%	50%	0%	0%	0%	0%	100%	18.3%
	Level 3	9	3	0	0	1	0	0	0	0	13.370
	(moderate)	21.4%	17.6%	0%	0%	50%	0%	0%	0%	0%	18.3%
	Level 4	21.470	1	0	1	0	0	0	0	0	4
	(severe)	4.8%	5.9%	0%	50%	0%	0%	0%	0%	0%	5.6%
	Level 5	0	0	0	0	0	0	0	0	0	0
	(extreme)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0.0%
Usual	(CAUCIIIC)	070	0 /0	0 /0	0 /0	0 /0	0 70	0 70	0 /0	070	0.070
activity											
	Level 1	21	11	2	0	1	1	1	1	0	38
	(no	50.0%	64.7%	50%	0%	50%	100%	100%	100%	0%	53.5%
	problem)										
	Level 2	12	4	2	1	1	0	0	0	1	21
	(mild)	28.6%	23.5%	50%	50%	50%	0%	0%	0%	100%	29.6%
	Level 3	7	0	0	1	0	0	0	0	0	8
	(moderate)	16.7%	0%	0%	50%	0%	0%	0%	0%	0%	11.3%
	Level 4	1	2	0	0	0	0	0	0	0	3
	(severe)	2.4%	11.8%	0%	0%	0%	0%	0%	0%	0%	4.2%
	Level 5	1	0	0	0	0	0	0	0	0	1
	(extreme)	2.4%	0%	0%	0%	0%	0%	0%	0%	0%	1.4%
Pain or											
discomfort	T										_
	Level 1	3	6	0	0	0	0	0	0	0	9
	(no	71.4%	35.3%	0%	0%	0%	0%	0%	0%	0%	12.7%
	problem)										
	Level 2	14	3	1	0	1	0	1	1	0	21
	(mild)	33.3%	17.6%	25%	0%	50%	0%	100%	100%	0%	29.6%
	Level 3	15	4	0	0	0	1	0	0	0	20
	(moderate)	35.7%	23.5%	0%	0%	0%	100%	0%	0%	0%	28.1%
	Level 4	9	4	3	2	1	0	0	0	0	19
	(severe)	21.4%	23.5%	75%	100%	50%	0%	0%	0%	0%	26.8%
	Level 5	1	0	0	0	0	0	0	0	1	2
	(extreme)	2.4%	0%	0%	0%	0%	0%	0%	0%	100%	2.8%
Anxiety/ Depression											
	Level 1	17	7	0	0	0	1	0	0	0	25
		40.5%	41.2%	0%	0%	0%	100%	0%	0%	0%	35.2%
<u> </u>	1		1	1		1		1	1	ı	,

`	no roblem)										
Le	evel 2	15	6	3	0	2	0	0	1	1	28
(n	nild)	35.7%	35.3%	75%	0%	100%	0%	0%	100%	100%	39.4%
Le	evel 3	9	4	0	2	0	0	1	0	0	16
(n	noderate)	21.4%	23.5%	0%	100%	0%	0%	100%	0%	0%	22.5%
Le	evel 4	0	0	1	0	0	0	0	0	0	1
(s	evere)	0%	0%	25%	0%	0%	0%	0%	0%	0%	1.4%
Le	evel 5	1	0	0	0	0	0	0	0	0	1
(e	extreme)	2.4%	0%	0%	0%	0%	0%	0%	0%	0%	1.4%

4.8 Comparison of health related quality of life in patients with musculoskeletal disorders

4.8.1 Mobility

Patients with lower back pain (100%) and mixed connective tissue disease (100%) followed by those with rheumatoid arthritis (76.2 %) were most affected in terms of mobility. Least affected were those with gout and scleroderma at 0%.

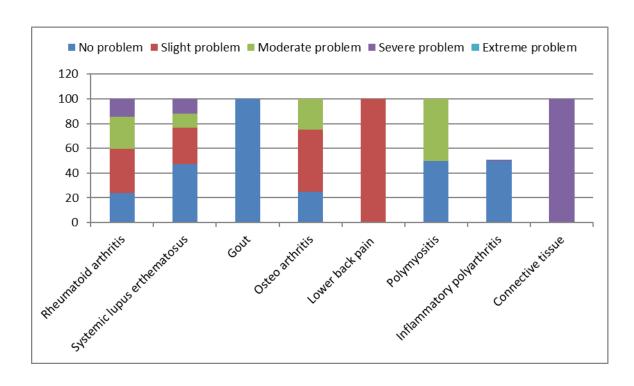


Figure 4: Comparison of mobility domain among study participants

4.8.2 Self-care

In the self-care domain, participants with connective tissue disease, inflammatory polyarthritis followed by polymyositis and rheumatoid arthritis were the most affected that is majority of the patients in this group reported having problems with dressing and washing themselves while the patients with lower back pain, osteoarthritis, scleroderma and gout reported having no problems with self-care.

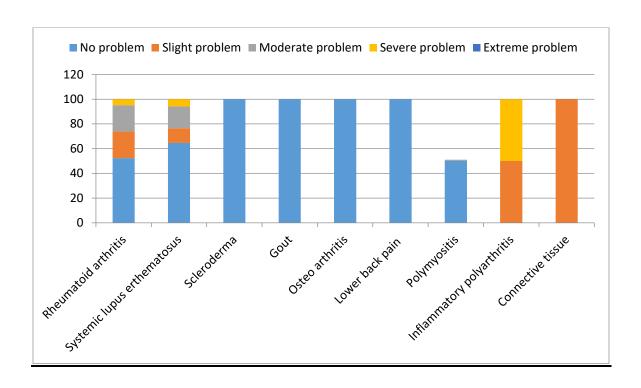


Figure 5: Comparison of self-care domain among study participants

4.8.3 Usual activities

All the participants with connective tissue disorder and inflammatory arthritis complained of having limitation in performing their usual activities thus were the most affected followed by half of the patients with polymyositis, rheumatoid arthritis and osteoarthritis with the least being patients with SLE, gout, scleroderma and low back pain as none of the participants with this conditions complained of having problems with usual activities.

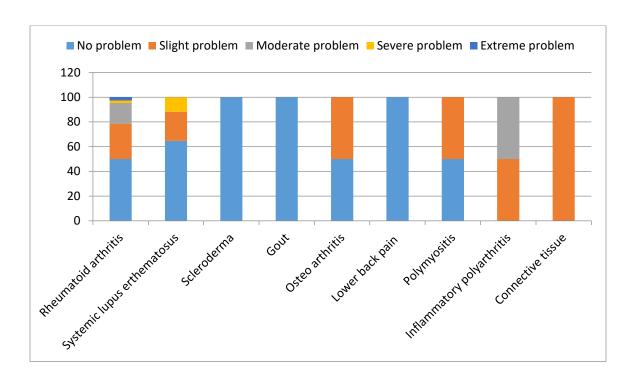


Figure 6: Comparison of usual activity domain among study participants

4.8.4 Pain or discomfort

All the participants with the different musculoskeletal conditions complained of having pain with the least being in patients with systemic lupus erythematosus at 64.7%.

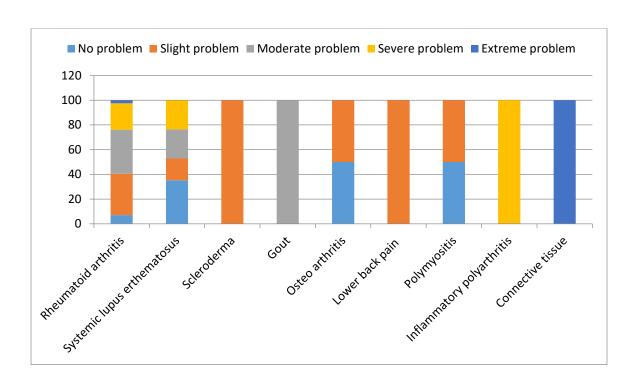


Figure 7: Comparison of pain domain among study participants

4.8.5 Depression or anxiety

Majority of the study participants complained of being anxious with the least being in patients with gout.

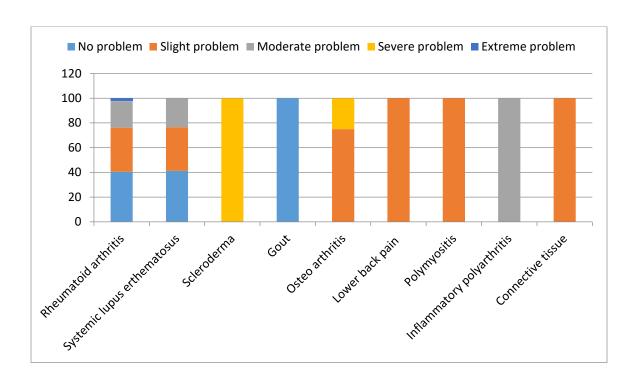


Figure 8: Comparison of Anxiety domain among study participants

4.9 Treatment regimens of patients with musculoskeletal disorders

Table 4.6 describes the treatment regimens of patients with musculoskeletal disorders. Most patients were prescribed Disease Modifying Anti-Rheumatic Drugs (DMARDs) (n=57, 80.1%) either as monotherapy (n=25, 35.2%), dual therapy (n=27, 38%). or triple therapy (n=5, 7%). The remaining fourteen (19.7%) participants were on analgesics from the Non-steroidal anti-inflammatory (NSAID) group, opioid or adjuvant drugs without a drug from the DMARD group. Methotrexate was the most common drug used as monotherapy followed by Hydroxychloroquine (HCQS) with leflunomide and

mycophenolate used in rare instances. In dual and triple therapy combinations, Hydroxychloroquine was found in majority of the combinations.

Table 4. 6: Treatment regimens of patients with musculoskeletal disorders

Treatment		Participant	Percentage
regimen		(n=71)	(%)
DMARD	Methotrexate	15	(n=25, 35.2%)
monotherapy	Hydroxychloroquine	8	
	Leflunomide	1	
	Mycophenolate	1	
DMARD dual	HCQS + salzapyrizine	3	(n=27, 38.0%)
therapy	HCQS + methotrexate	14	
	HCQS + azathioprine	3	
	HCQS + Leflunomide	2	
	HCQS + mycophenolate	3	
	Methotrexate + azathioprine	1	

		Mycophenolate + azathioprine	1	
DMARD	triple	HCQS + methotrexate + azathioprine	1	(n=5, 7.0%)
therapy		HCQS + methotrexate + leflunomide	2	
		HCQS + methotrexate + mycophenolate	1	
		HCQS + leflunomide + mycophenolate	1	

4.10 Health related quality of life in patients on the different DMARD musculoskeletal regimens

Table 4.7 describes the health related quality of life in patients on the different treatment regimens for musculoskeletal disorders. In terms of mobility, none of the participants on DMARD therapy complained of complete inability in walking. A higher number of participants on monotherapy (n=8, 32.0%) and those on dual therapy (n=9, 33.3%) complained of having no problem in mobility that is they were able to move around every day compared to the lower number observed in those on triple therapy (n=1, 20%). Majority of the participants complained of having slight problems in walking despite the type of regimen that is (n=7, 28.0%) for those on monotherapy, (n=9, 33.3%) for those on dual therapy and (n=2, 40%) for those on triple therapy.

In the self-care domain, more than half of the participants had no problem in dressing and washing themselves. Patients on monotherapy and dual therapy had an equal number of

participants that had problems with washing and dressing themselves with those on monotherapy experiencing a higher level of difficulty that is moderate problems (n=8, 32.0%) in that they needed to rest in between the processes involved in washing and dressing. Those on triple therapy had slight difficulty (n=7, 25.9%) that is they are able to wash and dress themselves but the process took longer.

Majority of the participants on triple therapy had no problem with going to work or school (n=4, 80%) while patients on monotherapy had the lowest number of participants with no problems in usual activity domain (n=12, 48.0%). Most of the participants on monotherapy (n=8, 32.0%) and dual therapy (n=9, 33.3%) reported slight problems that is they were in apposition to dress and wash themselves but the process took longer than usual.

Symptom of pain did not seem to improve despite addition of a drug to the monotherapy regimen as all the participants on triple regimen complained of pain (n=5, 100%). We also had patients on monotherapy (n=1, 4.0%) and those on dual therapy (n=1, 3.7%) complaining of extreme incapacitating pain while none of the patients on triple therapy complained of extreme incapacitating pain.

In the anxiety/depression domain, 36.8% of the participants reported having experienced no anxiety. One participant on monotherapy reported extreme anxiety that necessitated treatment.

Table 4. 7: Health related quality of life of patients on the different treatment regimens

		REGIMEN	Ī		
HRQOL DOMAIN	CATEGORY	DMARD Mono- therapy n=25	Dual- therapy n=27	Triple- therapy n=5	Total n=57
		(n, %)	(n, %)	(n, %)	(n, %)
Mobility			1	•	•
•	Level 1 (No problem)	8 32.0	9 33.3	1 20.0	18 31.6
	Level 2 (Mild)	7 28.0	9 33.3	2 40.0	18 31.6
	Level 3 (Moderate)	6 24.0	6 22.2	1 20.0	13 22.8
	Level 4 (Severe)	4 16.0	3 11.1	1 20.0	8 14.0
	Level 5 (Extreme)	0 0.0	0 0.0	0.0	0.0
	Total	25 35.2	27 38.0	5 7.0	57 100.0
Self-care					
	Level 1 (No problem)	13 52.0	15 55.6	3 60.0	31 54.4
	Level 2 (Mild)	3 12.0	7 25.9	1 20.0	11 19.3
	Level 3 (Moderate)	8 32.0	4 14.8	0 0.0	12 21.1
	Level 4 (Severe)	1 4.0	1 3.7	1 20.0	3 5.3
	Level 5 (Extreme)	0 0.0	0 0.0	0 0.0	0 0.0
Usual activity					
	Level 1 (No problem)	12 48.0	15 55.6	4 80.0	31 54.4

	Level 2 (Mild)	8	9	0	17
		32.0	33.3	0.0	29.8
	Level 3 (Moderate)	3	2	0	5
		12.0	7.4	0.0	8.8
	Level 4 (Severe)	1	1	1	3
		4.0	3.7	20.0	5.3
	Level 5 (Extreme)	1	0	0	1
		4.0	0.0	0.0	4.0
Pain or discomfort					
	Level 1 (No problem)	4	4	0	8
		16.0	14.8	0.0	14.0
	Level 2 (Mild)	5	9	4	18
		20.0	33.3	80.0	31.6
	Level 3 (Moderate)	8	9	0	17
		32.0	33.3	0.0	29.8
	Level 4 (Severe)	7	4	1	12
		28.0	14.8	20	21.1
	Level 5 (Extreme)	1	1	0	2
		4.0	3.7	0.0	3.5
Anxiety/ Depression				,	
	Level 1 (No problem)	10	10	1	21
		40.0	37.0	20.0	36.8
	Level 2 (Mild)	8	12	2	22
		32.0	44.4	40.0	38.6
	Level 3 (Moderate)	6	4	2	12
		24.0	14.8	40.0	21.1
	Level 4 (Severe)	0	1	0	1
		0.0	3.7	0.0	1.8
	Level 5 (Extreme)	1	0	0	1
		4.0	0.0	0.0	1.8

4.11 Association between social demographic characteristics and HRQoL mean score

Health related quality of life mean score was compared with sociodemographic traits of the study participants and the results presented in table 4.8. The middle age (n=18, 62.1%) and elderly (n=10, 62.5%) categories had the highest number of participants with a HRQoL that was below the mean and majority of the ones above the mean found in the young adult category (n=11, 45.8%). However, the difference among the age categories was not statistically significant (p=0.634). In terms of gender, both male (n=5, 55.6%) and female (n=37, 59.7%) had a higher number falling below the mean although this similarity was not statistically significant (p=0.814). The other variables such as marital status, occupation and level of education were not significantly associated with health related quality of life as illustrated in the table below.

Table 4. 8: Association between sociodemographic characteristics and health related quality of life mean score

Social demographic Variable	Category	HRQoL Mean <10 n,	HRQoL mean >10 n, %	Total	X² test P-value
Age					
<=20	Adolescent	1	0	1	0.634
		100.0	0.0	100.0	
21-40	Young adult	13	11	24	
		54.2	45.8	100.0	
41-60	Middle age	18	11	29	
	_	62.1	37.9	100.0	
61-80	Elderly	10	6	16	

		62.5	37.5	100.0	
>=81	Elderly	0	1	1	
		0.0	100.0	100.0	
Total		42	29	71	
		59.2	40.8	100.0	
Sex	Male	5	4	9	0.814
		55.6	44.4	100.0	
	Female	37	25	42	
		59.7	40.3	100.0	
	Total	42	29	71	
		59.2	40.8	100.0	
Marital	Single	9	7	16	0.781
status		56.3	43.8	100	
	Married	27	20	47	
		57.4	42.6	100	
	Separated	4	1	5	
		80.0	20.0	100	
	Divorced	2	1	3	
		66.7	33.3	100	
	Total	42	29	71	
		59.2	40.8	100	
Occupation	Unemployed	10	7	17	0.999
		58.8	41.2	100.0	
	Employed	13	9	22	
		59.1	40.9	100.0	
	Self-	19	13	32	
	employed	59.4	40.6	100.0	
	Total	42	29	71	
		100.0	100.0	100.0	
Level of	None	0	2	2	0.214
education		0.0	100.0	100.0	
	Primary	5	5	10	
		50.0	50.0	100.0	
	Secondary	20	9	29	
		69.0	31.0	100.0	
	Tertiary	17	13	30	
		56.7	43.3	100.0	
	Total	42	29	71	
		59.2	40.8	100	

4.12 Association between socio-demographic characteristic and Health related quality of life domains

The socio-demographic traits: gender, level of education, religion, alcohol use were not significantly associated with the HRQoL domains of the study participants as illustrated in table 4.12. Table 4.9 illustrates the significant associations found between sociodemographic characteristics and the health related quality of life domains. There was a statistically significant association (p= 0.003) between comorbidities and self-care. Participants with three comorbidities (n=1, 100%) reported a severe problem in self-care in that they had to support themselves by sitting down while dressing or washing themselves compared to a lesser proportion of participants with one (n=2, 10%) or two comorbidities (n=0,0%). A second statistically significant association (p=0.036) was found between marital status and anxiety with majority of participants that were single (n=7, 43.8%) and those separated (n=3, 60%) reporting having no depression compared to the lower number in the married group (n=15, 31.9%).

Table 4. 9: Association between socio-demographic characteristics and HRQoL domains

Number							
of comorbi							
dities							
HRQoL	Category	0	1	2	3	Total	X ² test
Domain		(n,	(n,	(n,	(n,	(n,	P-value
		%)					
Self-care	Level 1	25	11	5	0	41	0.003

	(No problem)	58.1	55.0	71.4	0	57.7	
	Level 2	7	6	0	0	13	
	(Mild)	16.3	30.0	0.0	0.0	18.3	
	Level 3	10	1	2	0	13	
	(Moderate)	23.3	5.0	28.6	0.0	18.3	
	Level 4	1	2	0	1	4	
	(Severe)	2.3	10.0	0.0	100.0	5.7	
	Level 5	0	0	0	0	0	
	(Extreme)	0.0	0	0.0	0.0	0.0	
	Total	43	20	7	1	71	
		100.0	100.0	100.0	100.0	100.0	
Marital							
status							
HRQoL	Category	Single	Married	Separated	Widowed	Total	0.036
Domain		(n,	(n,	(n,	(n,	(n,	
		%)	%)	%)	%)	%)	
Anxiety/	Level 1	7	15	3	0	25	
Depressi	(No problem)	43.8	31.9	60.0	0.0	35.2	
on							
	Level 2	3	22	1	2	28	
	(Mild)	18.8	46.8	20.0	66.7	39.4	
	Level 3	5	9	0	1	15	
	(Moderate)	31.3	19.1	0.0	33.3	21.1	
	Level 4	1	1	0	0	2	
	(Severe)	6.3	2.1	0.0	0.0	2.8	
	Level 5	0	0	1	0	1	
	(Extreme)	0.0	0.0	20.0	0.0	1.4	
	Total	16	47	5	3	71	
		100.0	100.0	100.0	100.0	100.0	

4.13 Association between health related quality of life and treatment regimens

Table 4.10 illustrates the association between health related quality of life and treatment regimens. Majority of the participants had a mean of less than ten irrespective of the number of DMARDs they were taking, that is monotherapy (n=13, 52%), dual therapy (n=17, 63%) or triple therapy (n=4, 80.0%). Participants that had a score above the mean

were found in the category on monotherapy (n=12, 48%) compared to the fewer participants on triple therapy (n=1, 20%). Despite the difference in treatment regimens there was no statistically significant association between the different treatment regimens and health related quality of life.

Table 4. 10: Association between health related quality of life and treatment regimens

Treatment regimen	Category	HRQoL Mean <10	HRQoL mean >10	Total	X ² test P-value
		(n,	(n,	(n,	
N. DMADD		%)	%)	%)	0.656
No DMARD	0	8	6	14	0.656
		57.1	42.9	100.0	
DMARD	1	13	12	25	
		52.0	48.0	100.0	
	2	17	10	27	
		63.0	37.0	100.0	
	3	4	1	5	
		80.0	20.0	100.0	
	Total	42	29	71	
		59.1	40.9	100.0	

4.14 Association between Health Related Quality of Life domains and treatment regimens

There was no statistically significant association between the treatment regimens and health related quality of life in patients with musculoskeletal disorders as illustrated in table 4.11 below.

Table 4. 11 Association between Health related quality of life domains and treatment regimens

		REGIM				
		EN				
		DMAR				
IIDOOI	CATE-	D Mono-	Dual-	Twints	Total	X ² test
HRQOL DOMAIN	GORY			Triple-	Total	A- test
DOMAIN	GOKI	therapy n=25	therapy n=27	therapy n=5	n=57	
		11=25	11=27	11=5	11-57	P-
		(n,	(n,	(n,	(n,	value
		%)	(h, %)	(h, %)	%)	Value
Mobility		70)	70)	70)	1 ,	
Wiobility	Level 1	8	9	1	18	0.990
	(No problem)	32.0	33.3	20.0	31.6	0.550
	Level 2	7	9	2	18	1
	(Mild)	28.0	33.3	40.0	31.6	
	Level 3	6	6	1	13]
	(Moderate)	24.0	22.2	20.0	22.8	
	Level 4	4	3	1	8	
	(Severe)	16.0	11.1	20.0	14.0	
	Level 5	0	0	0	0	
	(Extreme)	0.0	0.0	0.0	0.0	
	Total	25	27	5	57	
		35.2	38.0	7.0	100.0	
Self-care	1	1				
	Level 1	13	15	3	31	0.359
	(No problem)	52.0	55.6	60	54.4	
	Level 2	3	7	1	11	1
	(Mild)	12.0	25.9	20	19.3	
	Level 3	8	4	0	12	
	(Moderate)	32.0	14.8	0.0	21.1	
	Level 4	1	1	1	3	
	(Severe)	4.0	3.7	20	5.3	
	Level 5	0	0	0	0	
	(Extreme)	0.0	0.0	0.0	0.0	
Usual activity						
	Level 1	12	15	4	31	0.561
	(No problem)	48.0	55.6	80	54.4	
_	Level 2	8	9	0	17	

	(Mild)	32.0	33.3	0.0	29.8	
	Level 3	3	2	0	5	
	(Moderate)	12.0	7.4	0.0	8.8	
	Level 4	1	1	1	3	
	(Severe)	4.0	3.7	20.0	5.3	
	Level 5	1	0	0	1	
	(Extreme)	4.0	0.0	0.0	4.0	
Pain or discomfort						
disconnert	Level 1	4	4	0	8	0.387
	(No problem)	16.0	14.8	0.0	14.0	0.367
	Level 2	5	9	4	18	
	(Mild)	20.0	33.3	80.0	31.6	
	Level 3	8	9	0	17	
	(Moderate)	32.0	33.3	0.0	29.8	
	Level 4	7	4	1	12	
	(Severe)	28.0	14.8	20.0	21.1	
	Level 5	1	1	0	2	
	(Extreme)	4.0	3.7	0.0	3.5	
Anxiety/	,		•	•	•	
Depression						
	Level 1	10	10	1	21	0.776
	(No problem)	40.0	37.0	20.0	36.8	
	Level 2	8	12	2	22	
	(Mild)	32.0	44.4	40.0	38.6	
	Level 3	6	4	2	12	
	(Moderate)	24.0	14.8	40.0	21.1	
	Level 4	0	1	0	1	
	(Severe)	0.0	3.7	0.0	1.8	
	Level 5	1	0	0	1	
	(Extreme)	4.0	0%	0.0	1.8	

Table 4. 12 Association of socio-demographic characteristics and HRQoL domains

a) Mobility

Socio-	HRQo	Mobility			X ² test
demographic	L				р-
					value

Characteristi	Domai						
c	n						
Age	Catego	Level 1	Level 2	Level 3	Level 4	Total	0.780
	ry	(No problem)	(Mild)	(Moderate)	(Severe)		
		(n,	(n,	(n,	(n,	(n,	
		%)	%)	%)	%)	%)	
<=20		1	0	0	0	1	
		100.0	0.0	0.0	0.0	100.0	
21-40		10	3	8	3	24	
		41.7	12.5	33.3	12.5	100.0	
41-60		6	14	6	3	29	
		20.7	48.3	20.7	10.3	100.0	
61-80		6	6	1	3	16]
		37.5	37.5	6.3	18.8	100.0	
>=81		0	0	0	1	1	
		0.0	0.0	0.0	100.0	100.0	
Total		23	23	15	10	71	
		32.4	32.4	21.1	14.1	100.0	
Gender							0.771
Male		2	3	3	1	9	
		22.2	33.3	33.3	11.1	100.0	
Female		21	20	12	9	62	
		33.9	32.3	19.4	14.5	100.0	
Total		23	23	15	10	71	
		32.4	32.4	21.1	14.1	100.0	
Marital							0.621
status							
Single		7	3	3	3	16	
		43.8	18.8	18.8	18.8	100.0	
Married		13	16	12	6	47	
		27.7	34.0	25.5	12.8	100.0	
Separated		2	3	0	0	5	
		40.0	60.0	0.0	0.0	100.0	
Widowed		1	1	0	1	3	
		33.3	33.3	0.0	33.3	100.0	
Total		23	23	15	10	71	
		32.4	32.4	21.1	14.1	100.0	
Occupation				_			0.119

		1	1	1		٦ ١
Unemploy	5	5	4	3	17	
ed/student	29.4	29.4	23.5	17.6	100.0	
/retired						
Civil	4	12	5	1	22	
servant/e	18.2	54.5	22.7	4.5	100.0	
mployed						
Self	14	6	6	6	32	-
employed	43.8	18.8	18.8	18.8	100.0	
Total	23	23	15	10	71	1
	32.4	32.4	21.1	14.1	100.0	
Level of			·			0.102
educatio						
n						
None	0	0	1	1	2	
	0.0	0.0	50.0	50.0	100.0	
Primary	6	2	2	0	10	1
	60.0	20.0	20.0	0.0	100.0	
Secondar	18	5	3	3	29	
y	62.1	17.2	10.3	10.3	100.0	
Tertiary	17	6	7	0	30	
	39.5	20.0	23.3	0.0	100.0	
Total	41	13	13	4	71	
	57.7	18.3	18.3	5.6	100.0	
Comorbi						0.998
dities						
0	17	12	10	4	43	1
	39.5	27.9	23.3	9.3	100.0	
1	5	8	4	3	20	1
	25.0	40.0	20.0	15.0	100.0	
2	1	3	0	3	7	1
	14.3	42.9	0.0	42.9	100.0	
3	0	0	1	0	1	1
	0.0	0.0	100.0	0.0	100.0	
Total	23	23	15	10	71	1
	32.4	32.4	21.1	14.1	100.0	

b) Self-care

Socio-	HRQoL	Self-					X ² test
demographic	domain	care					p-
characteristic							value
Age	Category	Level 1	Level 2	Level 3	Level 4	Total	0.41
		(n,	(n,	(n,	(n,	(n,	
		%)	%)	%)	%)	%)	
<=20		1	0	0	0	1	
		100.0	0.0	0.0	0.0	0.0	
21-40		14	5	5	0	24	
		58.3	20.8	20.8	0.0	100.0	
41-60		16	4	7	2	29	
		55.2	13.8	24.1	6.9	100	
61-80		10	4	1	1	16	
		62.5	25.0	6.3	6.3	100.0	
>=81		0	0	0	1	1	
		0.0	0.0	0.0	100.0	0.0	
Total		41	13	13	4	71	
		57.7	18.3	18.3	5.6	100.0	
Gender							0.328
Male		7	0	1	1	9	
		77.8	0.0	11.1	11.1	100.0	
Female		34	13	12	3	62	
remate		54.8	21.0	19.4	4.8	100.0	
Total		41	13	13	4	71	
Total		57.7	18.3	18.3	5.6	100.0	
Marital status							0.279
Single		8	6	1	1	16	1
		50.0	37.5	6.3	6.3	100.0	
Married		29	4	11	3	47	
		61.7	8.5	23.4	6.4	100.0	
Separated		2	2	1	0	5	
1		40.0	40.0	20.0	0.0	100.0	
Widowed		2	1	0	0	3	
		66.7	33.3	0.0	0.0	100.0	
Total		41	13	13	4	71	
		57.7	18.3	18.3	5.6	100.0	
Occupation							0.505
Unemployed/st		9	4	3	1	17	
udent/retired		52.9	23.5	17.6	5.9	100.0	

Civil	14	2	6	0	22	
servant/employ	63.6	9.1	27.3	0.0	100.0	
ed						
Self employed	18	7	4	3	32	
	56.3	21.9	12.5	9.4	100.0	
Total	41	13	13	4	71	
	57.7	18.3	18.3	5.6	100.0	
Level of education						0.102
None	0	0	1	1	2	
	0.0	0.0	50.0	50.0	100.0	
Primary	6	2	2	0	10	
	60.0	20.0	20.0	0.0	100.0	
Secondary	18	5	3	3	29	
	62.1	17.2	10.3	10.3	100.0	
Tertiary	17	6	1	0	30	
	56.7	20.0	23.3	0.0	100.0	
Total	41	13	13	4	71	
	57.7	18.3	18.3	5.6	100.0	

c) Usual activity

							X ² test
		1	Usual activ	vities			
	Level 1	Level 2	Level 3	Level 4	Level 5		
	(n,	(n,	(n,	(n,	(n,		p-value
Age	%)	%)	%)	%)	%)	Total	
<=20	1	0	0	0	0	1	0.719
	100.0	0.0	0.0	0.0	0.0	100.0	
21-40	13	7	2	2	0	24	
	54.2	29.2	8.3	8.3	0.0	100.0	
41-60	14	11	2	1	1	29	
	48.3	37.9	6.9	3.4	3.4	100.0	
61-80	10	2	4	0	0	16	
	62.5	12.5	25.0	0.0	0.0	100.0	
>=81	0	1	0	0	0	1	
	0.0	100.0	0.0	0.0	0.0	100.0	
Total	38	21	8	3	1	71	

	53.5	29.6	11.3	4.2	1.4	100.0	l
	55.5	<i>2 7</i> ⋅ 0	11.5	1.2	1.1	100.0	

Sex							
		Į	Jsual activ	vities			
	Level 1	Level 2	Level 3	Level 4	Level 5		
	(n,	(n,	(n,	(n,	(n,		
	%)	%)	%)	%)	%)	Total	0.183
Male	5	1	3	0	0	9	
	55.6	11.1	33.3	0.0	0.0	100.0	
Fem	33	20	5	3	1	62	
ale	53.2	32.3	8.1	4.8	1.6	100.0	
Tota	38	21	8	3	1	71	
1	53.5	29.6	11.3	4.2	1.4	100.0	

		1	Usual activ	vities			X ² test p-value
	Level 1	Level 2	Level 3	Level 4	Level 5	Total	
Marital	(n,	(n,	(n,	(n,	(n,		0.637
status	%)	%)	%)	%)	%)		
Single	9	4	1	1	1	16	
	56.3	25.0	6.3	6.3	6.3	100.0	
Married	24	14	7	2	0	47	
	51.1	29.8	14.9	4.3	0.0	100.0	
Separat	2	3	0	0	0	5	
ed	40.0	60.0	0.0	0.0	0.0	100.0	
Widow	3	0	0	0	0	3	
ed	100.0	0.0	0.0	0.0	0.0	100.0	
Total	38	21	8	3	1	71	
	53.5	29.6	11.3	4.2	1.4	100.0	

			Jsual activ	rities		Total	
	Level 1	Level 2	Level 3	Level 4	Level 5		
Occup	(n,	(n	(n,	(n,	(n,		
ation	%)	%)	%)	%)	%)		0.974
Unemp	8	6	2	1	0	17	
loyed	47.1	35.3	11.8	5.9	0.0	100.0	
/student							
/ retired							
Civil-	12	7	2	1	0	22	
servant	54.5	31.8	9.1	4.5	0.0	100.0	
Self-	18	8	4	1	1	32	
employ	56.3	25.0	12.5	3.1	3.1	100.0	
ed							
Total	38	21	8	3	1	71	
	53.5	29.6	11.3	4.2	1.4	100.0	

			Usual act	ivities			
	Level	Level	Level	Level	Level		
Level	1	2	3	4	5	Total	0.380
of	(n,	(n,	(n,	(n,	(n,	(n,	
education	%)	%)	%)	%)	%)	%)	
None	0	2	0	0	0	2	
	0.0	100.0	0.0	0.0	0.0	100.0	
Primary	5	2	1	1	1	10	
	50.0	20.0	10.0	10.0	10.0	100.0	
Secondary	17	7	4	1	0	29	
	58.6	24.1	13.8	3.4	0.0	100.0	
Tertiary	16	10	3	1	0	30	
	53.3	33.3	10.0	3.3	0.0	100.0	
Total	38	21	8	3	1	71	
	53.5	29.6	11.3	4.2	1.4	100.0	

Comor-	Level 1	Level 2	Level 3	Level 4	Level 5		0.171
bidities	(n,	(n,	(n,	(n,	(n,		
	%)	%)	%)	%)	%)	Total	

0	24 55.8	12 27.9	4 9.3	3 7.0	0 0.0	100.0
1	10 50.0	8 40.0	1 5.0	0 0.0	5.0	100.0
2	4 57.1	1 14.3	2 28.6	0.0	0.0	7 100.0
3	0 0.0	0 0.0	1 100.0	0 0.0	0 0.0	1 100.0
Total	38 53.5	21 29.6	8 11.3	3 4.2	1 1.4	71 100.0

d) Pain/discomfort

		I	Pain/discor	nfort			
	Level 1	Level 2	Level 3	Level 4	Level 5		X ² test
	(n,	(n,	(n,	(n,	(n,		p-value
Age	%)	%)	%)	%)	%)	Total	
<=20	1	0	0	0	0	1	0.165
	100.0	0.0	0.0	0.0	0.0	100.0	
21-	6	3	8	6	1	24	
40	25.0	12.5	33.3	25.0	4.2	100.0	
41-	2	12	6	8	1	29	
60	6.9	41.4	20.7	27.6	3.4	100.0	
61-	0	6	6	4	0	16	
80	0.0	37.5	37.5	25.0	0.0	100.0	
>=81	0	0	0	1	0	1	
	0.0	0.0	0.0	100.0	0.0	100.0	
Total	9	21	20	19	2	71	
	12.7	29.6	28.2	26.8	2.8	100.0	

	Level 1	Level 2	Level 3	Level 4	Level 5		
	(n,	(n,	(n,	(n,	(n,		
	%)	%)	%)	%)	%)		0.571
Male	0	2	4	3	0	9	
	0.0	22.2	44.4	33.3	0.0	100.0	
Female	9	19	16	16	2	62	
	14.5	30.6	25.8	25.8	3.2	100.0	
Total	9	21	20	19	2	71	
	12.7	29.6	28.2	26.8	2.8	100.0	

		I	Pain/disco	mfort			
	Level	Level	Level	Level	Level		
	1	2	3	4	5		
Marital	(n,	(n,	(n,	(n,	(n,		
status	%)	%)	%)	%)	%)	Total	
Single	4	3	3	4	2	16	0.287
	25.0	18.8	18.8	25.0	12.5	100.0	
Married	5	14	15	13	0	47	
	10.6	29.8	31.9	27.7	0.0	100.0	
Separated	0	2	1	2	0	5	
	0.0	40.0	20.0	40.0	0.0	100.0	
Widowed	0	2	1	0	0	3	
	0.0	66.7	33.3	0.0	0.0	100.0	
Total	9	21	20	19	2	71	
	12.7	29.6	28.2	26.8	2.8	100.0	

]	Pain/disco	omfort			
	Level	Level	Level	Level	Level		
	1	2	3	4	5		
Occupati	(n,	(n,	(n,	(n,	(n,		
on	%)	%)	%)	%)	%)	Total	
Unemplo	3	4	6	4	0	17	0.172
yed	17.6	23.5	35.3	23.5	0.0	100.0	
/student							
/retired							
Civil	1	10	8	3	0	22	
servant/	4.5	45.5	36.4	13.6	0.0	100.0	

employe d							
Self	5	7	6	12	2	32	
Employe	15.6	21.9	18.8	37.5	6.3	100.0	
d							
Total	9	21	20	19	2	71	
	12.7	29.6	28.2	26.8	2.8	100.0	

		F	Pain/discor	nfort			
Level of	Level 1	Level 2	Level 3	Level 4	Level 5		
educatio	(n,	(n,	(n,	(n,	(n,	Total	
n	%)	%)	%)	%)	%)		
None	0	0	0	2	0	2	0.255
	0.0	0.0	0.0	100.0	0.0	100.0	
Primary	2	1	2	4	1	10	
	20.0	10.0	20.0	40.0	10.0	100.0	
Secondar	4	7	10	8	0	29	
у	13.8	24.1	34.5	27.6	0.0	100.0	
Tertiary	3	13	8	5	1	30	
	10.0	43.3	26.7	16.7	3.3	100.0	
Total	9	21	20	19	2	71	
	12.7	29.6	28.2	26.8	2.8	100.0	

Pain/Discomfort									
Comorbidity	Level 1	Level 2	Level 3	Level 4	Level 5	Total	0.601		
	(n,	(n,	(n,	(n,	(n,	(n,			
	%)	%)	%)	%)	%)	%)			
0	8	12	12	10	1	43			
	18.6	27.9	27.9	23.3	2.3	100.0			
1	1	8	5	5	1	20			
	5.0	40.0	25.0	25.0	5.0	100.0			
2	0	1	2	4	0	7			

	0.0	14.3	28.6	57.1	0.0	100.0
3	0	0	1	0	0	1
	0.0	0.0	100.0	0.0	0.0	100.0

e) Anxiety/ depression

		Anx	iety/Dep	ression			
	Level	Level	Level	Level	Level	Total	X ² test
	1	2	3	4	5	(n,	p-value
	(n,	(n,	(n	(n,	(n,	(II, %)	
Age	%)	%)	%)	%)	%)	70)	
<=20	1	0	0	0	0	1	0.783
	100.0	0.0	0.0	0.0	0.0	100.0	
21-40	10	9	5	0	0	24	
	41.7	37.5	20.8	0.0	0.0	100.0	
41-60	9	13	4	2	1	29	
	31.0	44.8	13.8	6.9	3.4	100.0	
61-80	5	5	6	0	0	16	
	31.3	31.3	37.5	0.0	0.0	100.0	
>=81	0	1	0	0	0	1	
	0.0	100.0	0.0	0.0	0.0	100.0	
Total	25	28	15	2	1	71	
	35.2	39.4	21.1	2.8	1.4	100.0	

		An	xiety/Dep	ression			
	Level	Level					
	1	2	3	4	5	Total	
	(n,	(n,	(n,				
Gender	%)						
Male	2	5	2	0	0	9	0.806
	22.2	55.6	22.2	0.0	0.0	100.0	
Female	23	23	13	2	1	62	
	37.1	37.1	21.0	3.2	1.6	100.0	
Total	25	28	15	2	1	71	

	35.2	39.4	21.1	2.8	1.4	100.0	
	Level	Level	Level	Level	Level	Total	0.036
	1	2	3	4	5		
Marital	(n,	(n,	(n,	(n,	(n,	(n,	
status	%)						
Single	7	3	5	1	0	16	
	43.8	18.8	31.3	6.3	0.0	100.0	
Married	15	22	9	1	0	47	
	31.9	46.8	19.1	2.1	0.0	100.0	
Separated	3	1	0	0	1	5	
	60.0	20.0	0.0	0.0	20.0	100.0	
Widowed	0	2	1	0	0	3	
	0.0	66.7	33.3	0.0	0.0	100.0	
Total	25	28	15	2	1	71	
	35.2	39.4	21.1	2.8	1.4	100.0	

		An	xiety/D	epressio	n		
	Level	Level	Level	Level	Level	Total	
	1	2	3	4	5		
	(n,	(n,	(n,	(n,	(n,	(n, %)	
Occupation	%)	70)	0.242				
Unemployed/	6	9	2	0	0	17	
student/retired	35.3	52.9	11.8	0.0	0.0	100.0	
Civil servant/	5	8	7	2	0	22	
employed	22.7	36.4	31.8	9.1	0.0	100.0	
Self employed	14	11	6	0	1	32	
	43.8	34.4	18.8	0.0	3.1	100.0	
Total	25	28	15	2	1	71	
	35.2	39.4	21.1	2.8	1.4	100.0	

		Anxiety/	Depress				
	Level	Level	Level	Level	Total		
	1	2	3	5	,		
Level	(n,	(n,	(n,	(n,	(n, %)		
of education	%)	%)	%)	%)	%)	70)	0.621

None	1	1	0	0	0	2
	50.0	50.0	0.0	0.0	0.0	100.0
Primary	4	3	2	0	1	10
	40.0	30.0	20.0	0.0	10.0	100.0
Secondary	10	12	7	0	0	29
	34.5	41.4	24.1	0.0	0.0	100.0
Tertiary	10	12	6	2	0	30
	33.3	40.0	20.0	6.7	0.0	100.0
Total	25	28	15	2	1	71
	35.2	39.4	21.1	2.8	1.4	100.0

Comorbidity							
	17	18	8	0	0	43	0.599
0	39.5	41.9	18.6	0.0	0.0	100.0	
	6	7	5	1	1	20	
1	30.0	35.0	25.0	5.0	5.0	100.0	
	2	2	2	1	0	7	
2	28.6	28.6	28.6	14.3	0.0	100.0	
	0	0	1	0	0	1	
3	0.0	0.0	100.0	0.0	0.0	100.0	
	25	28	15	2	1	71	
Total	35.2	39.4	21.1	2.8	1.4	100.0	

CHAPTER 5 DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter discusses the key findings of the research within the context of the laid out objectives. Similarities and differences of the study findings in comparison to other related studies have also been discussed. Conclusion and recommendation for policy making, practice and further research have been highlighted based on the key findings.

5.2 Discussion

Characteristics of the study participants

Study findings revealed that majority of the participants were female at 87.3%. This finding correlates with studies carried out in Thailand and South Africa that showed female predominance in MSDs at 75.7% (60) and 95.3% respectively (61). Another study by European Foundation for the improvement of living and working conditions concluded that women represent 58% of all cases of MSDs that are work-related (62). The high predominance in women may be explained by the fact that women have more type one muscle fibers than men, the need to engage more muscles at full capacity and work more hours (63). This type one muscle fibers require repetitive motion to activate completely thus predispose women to injury from repetitive motion (23). The median age was 46 years with the middle age group that is those between 41 to 60 years being the most affected at 40.8% and the lowest being adolescents that accounted for 1.4%.

This finding is consistent with that of burden of musculoskeletal diseases report in the United States of America that showed prevalence of MSDs to be at 40% and 8.1% in those aged 41 to 60 years and adolescents respectively (64). The high prevalence in the middle aged group might be attributed to the fact that connective tissue loses its elasticity and flexibility as we age (65), decreased bone mass (66) increase in stress levels due to high workload demands (67) (68) and reduced physical activity that promotes musculoskeletal health (69).

Most of the participants were employed 76.1%, this tallies with what was reported by a study in China that reported a high prevalence of MSDs in the working population (70). This would be likely in this population due to poor work posture, monotonous repetitive tasks that may promote connective tissue injury (71). The most common comorbid condition was hypertension that accounted for 67.9% of the cases followed by diabetes mellitus at 17.9% and retrovirus disease 7.1%. This findings are similar to those found in a study conducted in Finland that reported a high prevalence in hypertension (48.7%), followed by hypothyroidism (19.3%), diabetes mellitus (10.7%) and asthma (8.1%). This diseases also caused a faster degradation in physical activity in patients with MSDs (72). Another study conducted at KNH found hypertension to be the most prevalent at 41.3% followed by diabetes mellitus at 5.1% (73).

Most common musculoskeletal disorder

In this population the most common MSD was found to be rheumatoid arthritis affecting 59.1% of the population followed by systemic lupus erythematosus which accounted for 23.9% of the cases and lastly osteoarthritis that was reported in 5.6% of the participants. Contrary to this findings, a study in South Africa found osteoarthritis to be the most common form of arthritis accounting for 55% of the cases while gout accounted for 0.7% (74). Similar to the findings in South Africa, a study conducted in in Zambia found osteoarthritis to be the most common musculoskeletal disorder accounting for 30.4% of the cases, rheumatoid arthritis (24.0%), polymyositis (9.3%), soft tissue lesions (8.6%), spondyloarthropathy (6.7%), SLE (5.3%) and gout (3.6%) (75). The difference in the findings could be attributed to the fact that Kenyatta National hospital is the only hospital that offers affordable rheumatological services compared to most private hospitals that charge exorbitant prices thus most patients can only afford treatment at KNH. Referral rate from other peripheral facilities is also high as patients seek for specialized care. The County government hospitals have limited capacity when it comes to empowering their healthcare workers to be able to identify symptoms of the various MSDs, laboratory parameters needed for diagnosis of MSDs are not available and lastly inadequate manpower in terms of number of rheumatologists per county.

Pattern of health related quality of life

In patients with musculoskeletal disorders, the physical domain was the most affected as indicated by the number of patients that complained of experiencing pain 87.3% and mobility 67.7%. The mental domain is second most affected as represented by the number of patients that complained of being anxious or depressed 64.8%. Lastly usual activities and self-care were least affected. In support of the above findings, a study assessing quality of life in teachers with MSDs found that the physical and mental domain were most affected (76). The huge effect of MSDs on pain and mobility might be attributed its direct effect on the locomotor system that are useful in walking (77).

Treatment regimens and health related quality of life

Most of the participants (80.1%) in this study were prescribed non-biologic Disease Modifying Anti-Rheumatic Drug (DMARDs) therapy as either monotherapy (35.2%), dual therapy (38%) or triple therapy (7%). The remaining fourteen (19.7%) participants were on analgesics from the Non-steroidal anti-inflammatory (NSAID) group, opioid or adjuvant drugs without a drug from the DMARD group. A study assessing pain management in MSDs found that 47% of the participants were on NSAIDs. Methotrexate was the most common drug used as monotherapy followed by Hydroxychloroquine (HCQS). triple therapy combinations, In dual and Hydroxychloroquine was found in majority of the combinations.

Bivariate analysis

The study found a statistical significance between comorbidities and self-care (p= 0.003) with low HRQoL in participants with three comorbidities (100%) that reported a severe problem in self-care in that they had to support themselves by sitting down while dressing or washing themselves compared to a lesser proportion of participants with one (10%) or two comorbidities (0,0%). A second statistically significant association (p=0.036) was found between marital status and anxiety with majority of participants that were single (43.8%) and those separated (60%) reporting having no depression compared to the lower number in the married group (31.9%).

5.3 Study strengths and weaknesses

This is the first study that has assessed HRQoL in patients with musculoskeletal disorders and tried to compare the quality of life amongst patients with MSDs and also the effect of treatment regimens on Health related quality of life.

5.4 Limitations

The COVID-19 pandemic may have influenced the patients' perception of their quality of health in a negative manner and especially financially.

5.5 Conclusion

Musculoskeletal disorders

HRQoL in patients with MSDs was poor with a mean summary score of 10 (3.64). Majority of the participants (59.2%) were below the mean while only 40.8% were above the mean. The domain that had the highest score was pain, followed by mobility, anxiety, self-care and finally usual activities. The domain with the highest score was interpreted as having the lowest HRQoL score. It is the domain that most patients complained of and had difficulty with the most. Additional therapy in patients with musculoskeletal disorders may not necessarily improve their quality of life.

5.6 Recommendations

5.6.1 Recommendations for policy and practice

- Measurement of height and weight with final computation of Body Mass Index
 (BMI) in all patients with musculoskeletal disorders.
- 2. Encourage early referral of patients with MSDs so that specialized care is initiated soon as a diagnosis is made.
- 3. Routine assessment of patient's health related quality of life assessment in those with musculoskeletal disorders and other chronic illnesses. Clinical improvement as assessed by laboratory parameters may not necessarily correlate with patient's perspective on their quality of life.
- 4. Encourage patients to engage in regular exercise that has been shown to improve overall musculoskeletal health.

- Creation of hospital based support groups aimed at offering counselling services to assist patients cope with their new diagnosis.
- 6. Insurance cover policies that will cater for both pharmacological and non-pharmacological modalities of treatment. The insurance policy should cater for all populations irrespective of employment status.

5.6.2 Recommendations for further research

- 1. A study comparing whether improvement in clinical lab parameters correlates with health related quality of life in patients with musculoskeletal disorders.
- 2. Prevalence and types of articular disorders in patients with RVD at KNH
- 3. Factors influencing health related quality of life in patients with musculoskeletal disorders.
- 4. Factors affecting MSD patient follow up and its effect on quality of life.

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7.0 APPENDICES

APPENDIX 1: ANTIPLAGIRISM REPORT

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ORIGINA	LITY REPORT			
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APPENDIX 2: ETHICAL APPROVAL



UNIVERSITY OF NAIROBI COLLEGE OF HEALTH SCIENCES P O BOX 19676 Code 00202 Telegrams; varsity Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC

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Website: http://www.erc.uonbl.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter:@UONKNH_ERC https://wiiter.com/UONKNH_ERC

Ref: KNH-ERC/A/219

Dr. Sally Wangari Irungu
Reg. No. U56/34603/2019
Dept. of Pharmaceutics and Pharmacy Practice
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Dr. Irungu,

RESEARCH PROPOSAL:

THE MOST COMMON MUSCULOSKELETAL DISORDER, HEALTH RELATED QUALITY OF LIFE AND TREATMENT REGIMENS IN PATIENTS AT KENYATTA NATIONAL HOSPITAL (P113/02/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 22rd June 2021 - 21st June, 2022.

This approval is subject to compliance with the following requirements:

- i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of patification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (<u>Attach a comprehensive progress report to support the renewal</u>).
- vii. Submission of an executive summary report within 90 days upon completion of the study.

Protect to discover



KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202

Tel: 726300-9 Fax: 725272

Telegrams: MEDSUP, Nairobi

22nd June, 2021



APPENDIX 3: INSTITUTIONAL APPROVAL



Tel.: 2726300/2726450/2726550 Fax: 2725272 Email: <u>knhadmin@knh.or.ke</u>

Ref: KNH/HOD-MED/37/VOL.II

Date: 2nd July, 2021

Dr. Sally Wangari Irungu Department of Pharmaceutics & Pharmacy Practice School of Pharmacy College of Health Sciences University of Nairobi

RE: APPROVAL TO CONDUCT A STUDY AT THE KNH MEDICINE DEPARTMENT

Following approval by the KNH/UON-Ethics & Research Committee for your research proposal and subsequent filing of the study registration certificate, this is to inform you that authority has been granted to collect data in Medicine Department, Rheumatology Clinic on your study titled "The most common musculoskeletal disorder, health related quality of life and treatment regimens in patients" at Kenyatta National Hospital.

Kindly liaise with the Assistant Chief Nurse Incharge, Medical Outpatient Clinic (MOPC) for facilitation. By a copy of this letter, the Assistant Chief Nurse Incharge is informed and requested to facilitate.

You will also be required to submit a report of your study findings to the office of the undersigned after completion of your study.

0. K. MECCE

Dr. Kinoti Ndege HOD, MEDICINE

Cc. A.C.N. Incharge, MOPC

APPENDIX 4: ELIGIBILITY SCREENING CRITERIA FORM

All study subjects that will be enrolled must meet the eligibility criteria based on the inclusion and exclusion criteria detailed and approved by the KNH/UoN Research and Ethics Committee.

RHEUMATOLOGY CLINIC		
PATIENT CODE		
SEX: MALE FEMALE		
Criteria	Remark	
	YES	NO
Aged 18 and above		
Clinical diagnosis of a musculoskeletal disorder		
On treatment for a musculoskeletal disorder and		
On follow up at KNH		
Has a voluntary consent form		
No cognitive impairment		
No congenital musculoskeletal disorder		
If all responses are YES , participant will fill questionnaire after consent process	1	

APPENDIX 4 A: CONSENT FORM

Patient	
Caregiver Relationship to patient	
Study title : Health related quality of life in patients with musculoskeletal Kenyatta National Hospital.	disorders at
Institution : Department of Pharmaceutics and Pharmacy practice, School of Pharmacy, University of Nairobi, P.O Box 30197- 00200, Nairobi	of
Principal investigator	
Dr. Sally Wangari Irungu, Post graduate student (Clinical Pharmacy) P.O I 10200, Murang'a	Зох 955-
Supervisors/ Co-investigator and institutional affiliation	

Supervisors/ Co-investigator and institutional affiliation

Dr. Sylvia Atisa Opanga, PhD,

Senior Lecturer, Department of Pharmaceutics and Pharmacy practice, University of Nairobi.

Dr. Beatrice Amugune, PhD, Senior Lecturer, Department of pharmaceutical chemistry, University of Nairobi.

Ethics approval

Kenyatta National hospital/university of Nairobi ethical and research committee What

is the purpose of the study?

The study you are being requested to participate in aims at evaluating the pattern of health related quality of life, effect of various musculoskeletal regimens on the health related quality of life and proportion of patients with musculoskeletal disorders at Kenyatta national hospital.

Why have I been invited to participate?

You have been approached as a participant in this study because you are an adult patient aged 18 and above with a musculoskeletal disorder and attending clinic at Kenyatta national hospital.

What is expected of me as a participant?

Should you agree to participate in this study, you will be asked to be interviewed using two structured questionnaires that will collect your sociodemographic data, diagnosis, treatment regimen and perception of health related quality of life. This expected to take thirty minutes of your time.

Who will have access to collected data?

All the data collected from you will be coded, entered and backed up into a computer without access to the public and only the principal investigator and ethics review committee will have access to your personal information in case they need to review collected data. Published work from this study will not bear your name.

Must I participate?

Participation in this study is completely voluntary and no consequences will be harbored upon you if you chose to withdraw from participating and no reason is required for your withdrawal.

Are there benefits of participating?

The findings obtained from this study will be used to improve the management of musculoskeletal disorders with more emphasis put in the patients' health related quality of life as an important measure of treatment outcome. You will not benefit directly from study but the findings will be shared with your regular Doctor for any possible addressing any noted issues.

What are the risks associated with my participation?

No risks or harm is anticipated from this study but you might feel uncomfortable responding to questions in the study tools. All information will be treated as confidential.

What will happen to the study findings?

The study findings will form part completion of the master of pharmacy in clinical pharmacy project dissertation and published in a peer reviewed journal. The findings will also be shared with University of Nairobi College of Health Sciences administration, Kenyatta National Hospital administration and at conferences.

What do I do in case of a problem?

You have the right to raise any concern pertaining to the study and your participation to my university supervisors Dr. Sylvia Atisa at sopanga@uonbi.ac.ke or the

KNHUON ethics and review committee on email: uonknh.ac.ke, committee Secretary: Prof. Mark Chindia Tel: +254207726300 who have approved this study.

If the patient only understands Kiswahili, use the section below.

APPENDIX 4 B: RIDHAA YA KUSHIRIKI KATIKA UTAFITI

	Mgonjwa 🗔
	Mlezi Uhusiano na mgonjwa
	Kuhusu utafiti huu:
	UBORA WENYE UHUSIANO WA KIAFYA KWA WAGONJWA WENYE
	TATIZO LA MIFUPA NA MISULI
	Mtafiti Mkuu
	Dk. Sally Wangari.
	Wasimamizi:
1.	Dk. Opanga, Mhadhiri Mwandamizi, Idara ya Pharmaceutics and Pharmacy Practice,
	Shule ya Famasia, Chuo Kikuu cha Nairobi
2.	Dk. Beatrice Amugune, Mhadhiri mwandamizi idara ya pharmacia na kemia, Shule ya
	Famasia, Chuo kikuu cha Nairobi
	Idhini ya kimaadili
	Kamati ya kimaadili na utafiti ya hospitali kuu ya Kenyatta na chuo kikuu cha Nairobi
	Nini madhumuni ya utafiti?
	Utafiti huu unalenga kuangalia jinsia mbalimbali ambazo hu Mbona
	mimi nimealikwa kushiriki?

Umealikwa kuwa mshiriki kwa sababu wewe ni mtu mzima mwenye umri wa miaka kumi na nane na zaidi, unauguwa ugonjwa wa misuli na mifupa na unapokea matibabu katika hospitali kuu ya Kenyatta.

Nini kinachotarajiwa kwangu kama mshiriki?

Ukikubali kuwa mshiriki, utahojiwa kwa kutumia muundo wa dodoso kukusanya nakala kuhusu dawa unazotumia, na jinsi afya yako imebadilika kulingana na unavyo hisi baada ya matibabu kuanzishwa. Hii shughuli itachukuwa dakika thelathini za muda wako.

Nani watakuwa nafursa ya kutizama nakala zilizokusanywa?

Nakala zote zitahifadhiwa kwa siri na zitatumika tu kwa utafiti huu. Baada ya kumaliza utafiti, hakuna jinsi jina lako litahusishwa na kiungo chochote cha utafiti huu. Kazi itakayo chapishwa kutokana na utafiti huu haitahusisha jina lako kwa njia yoyote.

Ni lazima nishiriki?

Kushiriki katika utafiti huu ni kwa hiari yako, iwapo utakubli kushiriki bado utakuwa huru kuondoka ama kukataa kujibu swali lolote wakati wowote bila kuweka matibabu yako hapa KNH hatarini. Sio lazima upeane sababu ya kuondoka ama kutotaka kushiriki katika utafiti huu.

Kuna faida ya kushiriki?

Matokeo ya utafiti huu yatatumiwa kuboresha jinsi ya kushughulikia wanaougua magonjwa mbalimbali ya mifupa na misuli na pia kuboresha maisha yao. Matokeo haya pia yatatumiwa kuboresha sera zinazotumiwa kutibu wanaougua magonjwa haya.

Nini hatari ya kushiriki?

Hakuna hatari inayotarajiwa kutokana na utafiti huu lakini kuna uwezekano hutafurahia kujibu maswali mengine utakayoulizwa. Taarifa zote zitawekwa siri.

Matokeo ya utafiti yatafanyiwa nini?

Matokeo ya utafiti yatakuwa sehemu moja ya mradi wa shada ya uzamili wa utabibu wa dawa. Pia yatachapishwa katika jarida la mapitio ya rika. Na yatapewa wasimamizi wa hospitali kuu ya Kenyatta, wasimamizi wa chuo kikuu cha Nairobi, Kitengo cha sayansi cha afya na pia kuwasilishwa katika mikutano ya sayansi.

Nitafanya nini ikiwa kutatokea shida?

Utakuwa huru kuangazia tatizo lolote kama mshiriki katika utafitu huu kwangu au kwa kamati ya kimaadili na utaditi ya KNH- UoN

APPENDIX 4A: CONSENT DECLARATION FORM

Informed consent
Patient
Caregiver Relation to the patient
I, the undersigned voluntarily agree to participate in this research study. I have had the
nature of the study explained to me in detail, had the opportunity to ask questions which
were addressed satisfactorily and I understand my responsibilities as a participant. I
also understand that I can withdraw from the study anytime and will not be penalized
or prejudiced in any way. I understand that information gathered will be used for this
study only and confidentiality will be maintained.
I will receive a copy of this consent document to take away and keep.
Respondents name
Signature
Date
Witness (colleague)
Signature Date
Investigator's statement

I, the undersigned, have explained the information in this document pertaining this study to the participant and answered all the questions. I am satisfied that the participant

	understands all aspects of this study as discussed in the consent process document
	above.
	Name and signature of person obtaining consent
	In case of any concerns, you may contact my university supervisors Dr.Sylvia
	Opanga at sopanga@uonbi.ac.ke or Tel: 0721296448 or Dr. Beatrice Amugune on
	Beatrice.amugune@uonbi.ac.ke or Tel: 0722802074 or the KNH-UON ethics and
	review committee on email: uonknh.ac.ke, committee Secretary: Prof. Mark Chindia
	Tel: +254207726300
	If the patient only understands Kiswahili, use the section below.
AI	PPENDIX 4B: RIDHAA YA KUSHIRIKI KATIKA UTAFITI
	Mgonjwa

Mimi mtiaji sahihi kwa hiari yangu nimekubali kushiriki katika utafiti huu. Nimesoma na kuelewa asili ya utafiti,majukumu yangu kama mshiriki. Ninaelewa kwamba ushiriki wangu ni wa hiari na naweza kujitoa katika utafiti wakati wowote bila udhalimu au kupoteza faida yoyote. Ninajua pia kuwa juhudi zote zitafanywa kutunza habari kuhusu kitambulisho changu binafsi kuwa siri.

Uhusiano na mgonjwa.....

Mlezi

Jina la mshiriki
Tarehe
Saini va mshiriki

APPENDIX 5 A: DATA COLLECTION TOOL

	Patient code number	
1. l	Biodata	
a.	Date of birth: Day Month Year Age	
b.	Sex: Male Female	
c.	Weight Height BMI	
d.	Marital status	
;	Single Married Separated Divorced Wid	owed 🔲
2. 5	Social history	
a.	Occupation	
b.	Income per month (Kshs)	
c.	Level of education None Primary Secondary	•
	Religion: Christian Muslim Traditional Alcohol: Yes No	None
f.	Smoking: Yes No	
g.	Regular exercise: Yes No	
3. (Clinical history	
a.	Do you know your diagnosis Yes	No 🔲
	If yes, which are they	
	If no, why	
b.	Do you know the name of your medication? Yes	No 🗔
	If yes, which are they	

If no, why	
c. Any other conditions Yes	No 🔛
If yes, which are they	

d. What musculoskeletal regimen is the patient on?

APPENDIX 5 B: EROQOL FIVE DIMENSION QUESTIONNAIRRE (EQ-5D- 5L)

	Patient code
	By placing a tick in one box in each group below, please indicate which statements best
	describe your own health state today.
1.	Mobility
	I have no problems in walking about
	I have slight problems in walking about
	I have moderate problems in walking about
	I have severe problems in walking about
	I am unable to walk about
2.	Self-care
	I have no problems washing or dressing myself
	I have slight problems washing or dressing myself
	I have moderate problems washing or dressing myself
	I have moderate problems washing or dressing myself I have severe problems washing or dressing myself
3.	I have severe problems washing or dressing myself
3.	I have severe problems washing or dressing myself I am unable to wash or dress myself

	I have moderate problems with performing my usual activities
	I have severe problems with performing my usual activities
	I am unable to perform my usual activities
4.	Pain/discomfort
	I have no pain or discomfort
	I have slight pain or discomfort
	I have moderate pain or discomfort
	I have severe pain or discomfort
	I have extreme pain or discomfort
5.	Anxiety/ Depression
	I am not anxious or depressed
	I am slightly anxious or depressed
	I am moderately anxious or depressed
	I am severely anxious or depressed
	I am extremely anxious or depressed
	VISUAL ANALOGUE SCALE
	Please indicate on the scale how good or bad your health is today.

The best health state you can imagine is marked 100 and the worst health state you can
imagine is 0. Please draw a line from the box to the point on the scale that indicates
how good or bad your health state is today.
Now please write the number you marked on the scale in the box below
YOUR HEALTH TODAY =