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QUALITY OF LIFE IN PATIENTS WITH CHRONIC LOW BACK PAIN AS SEEN AT KENYATTA NATIONAL HOSPITAL

BY

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A dissertation submitted for examination in partial fulfilment of the requirements for the award of the degree of Master of Medicine in Orthopaedic Surgery of the

University of Nairobi

2017

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I declare that this dissertation/thesis is my original work and has not been submitted elsewhere for examination, award of a degree or publication. Where other people's work or my own work has been used, this has properly been acknowledged and referenced in accordance with the University of Nairobi's requirements.

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<u>DEDICATION</u>

I dedicate this book to my Heavenly Father, the God of whom all honor, wisdom, blessing, and glory belong. And to my wonderful and special ministers, Apostle Janejoy and Prophet Grace, you are honored and greatly appreciated. I dedicate this book to my dearest daughter, Jean Riri, a true gift from God.

ACKNOWLEDGEMENT

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DEFINITIONS

I.   **Low back pain** is defined as pain in the midline located between the lower costal margins above and the inferior gluteal folds below.

II.   **Quality of Life** is multidimensional encompassing 5 areas including physical wellbeing, material wellbeing, social wellbeing, emotional wellbeing and development and activity.

III.   **Health related quality of life (HRQOL)** measurements are instruments developed to assess self-perceived health status and its components e.g. physical functioning, psychological functioning, perception of one's health status, and pain

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LIST OF ABBREVIATIONS

CLBP-   Chronic low back pain

DALYs-   Disability- adjusted life years

EQ5D-   EuroQol five dimensions questionnaire

FBSS-   Failed back surgery syndrome

GBD-   Global Burden of Disease

HRQOL-   Health related quality of life

KNH-   Kenyatta National Hospital

LBP-   Low back pain

MRI-   Magnetic Resonance Imaging

NPRS-   Numeric Pain Rating Scale

SF-12 -   Short form -12 questionnaire

SF-36-   Short form 36 questionnaire

SPSS-   Statistical Package for the Social Scientists

VAS-   Visual analogue scale

VDS-   Verbal descriptor scale

WHO-   World Health Organization

 YLL-   Years of life lost

SSP-   Serious spine pathology

NRP-   Nerve root pain

NSLBP-   Nonspecific low back pain

PCS-   Physical component summary

MCS-   Mental component summary

SD-   Standard deviation

UON-ERC-   University of Nairobi, Ethics and Research Committee

ANOVA-   Analysis of Variance

QOL-   Quality of Life

ODI-   Oswestry Disability Index

<u>ABSTRACT</u>

1.1 Background:

Chronic low back pain (CLBP) is a very prevalent illness in both developing and developed nations. It is a difficult problem to manage, associated with psychological components, dissatisfaction with work, boredom and generous compensation systems contributing to its existence. Previous studies on CLBP have paid more attention on the psychological components associated with it, associated impact with work and rehabilitation initiatives. No study has been conducted in KNH or locally that seeks to look at the effect that CLBP has on the patient's quality of life. The main objective of this study was to describe the pain intensity and identify the health-related quality of life (QOL) of patients with chronic low back pain (CLBP) in KNH.

1.2 *Objective:*

To determine the Health related quality of life and the pain perceived in patients with chronic low back pain as seen in KNH

1.3 Study design:

Cross-sectional study

1.4 *Study setting:*

Physiotherapy department and orthopedic clinic in Kenyatta National Hospital

1.5 Methodology:

140 eligible participants, over 18 years of age, meeting the inclusion criteria were consecutively sampled from the physiotherapy department and orthopedic clinic in KNH. Each participant was requested to fill the data collection sheet. Data concerning the socio-demographic aspects, pain perception, parameters of health status and pain severity were recorded in the questionnaire. The SF-12 questionnaire measured the patient's perceived quality of life through measuring the physical, mental and social wellbeing of the patient. The differences in the Short form-12 means were compared between the different age groups and genders and CLBP clinical diagnostic types.

Data from the Data Collection Sheet was then stored in tables and spread sheets of Microsoft Excel. This questionnaire data was entered in SPSS v20 to generate descriptive statistical data, to create presentations in graphic form for reporting, finding relationships between different question responses, and collating open question responses.

1.6 Results:

CLBP was mainly found to affect middle aged patients with a mean age of 46 years. The male to female ratio was 2:3, with an age range of 18 to 82 years. CLBP seemed to affect people in the formal sector (34%) much more than other occupations that patients presented with. Serious specific pathology accounted for 64% of the MRI diagnoses of patients with CLBP in the study followed by Nerve root pathology (25%) and non-specific LBP (11%). The intensity of pain of low back pain was recorded as severe (7 out of 10) in 26.4% of participants, about a quarter of the participants. More than half of the participants rated their general health condition as fair general health condition on the SF-12 item. 5.7% rated their general health condition as poor while 2.1% rated their condition as excellent.

CHAPTER ONE: INTRODUCTION

1.0 Background

Chronic low back pain (CLBP) is one of the most common health problems that affects all nations, cultures, both genders, a wide and increasing age-range, and all races. It affects approximately 632 million people worldwide with a resultant effect of more years lived with disability than any other medical condition. Chronic low back pain is an important public health concern because of its contribution to absenteeism from work, high cost of health care, and work related disability(1–3)

LBP is the commonest musculoskeletal disorder known so because of its high prevalent nature and the resultant disability with which patients do live with for the longest duration of time. It affects the general population and reaches a peak between 30-50 years, a population at their peak time of development of their career(4,5).

Acute low back pain (ALBP) is the presence of pain and discomfort in the midline between the inferior costal border above and the inferior aspect gluteal folds below lasting for a duration less than 6 weeks while chronic LBP is one lasting greater than 12 weeks. Patients with LBP appreciate pain, altered function, anxiety, depression, and reduced quality of life because of the distress of illness caused, failed management, social seclusion, challenges at work and reliance on medications. In Kenya, most studies concerning low back pain have dwelt on its prevalence, its relation with different occupations, and radiological studies (X-ray, Ct Scans and MRI) on Low back pain(6–10).

Quality of life (QOL) in patients suffering from LBP is important in understanding the natural history that may assist in the treatment of patients by extending the assessment process beyond clinical and functional variables as it has been done traditionally. The QOL measures in chronic LBP have the function to aid ascertain the impact of health care when there is no known cure for most causes(11).

The main aim of this study is to describe pain perceived and the quality of life that patients suffering from chronic low back pain attending Kenyatta National Hospital (KNH) have. No such study has looked into how chronic LBP affects the quality of life of this population of patients.

CHAPTER TWO: LITERATURE REVIEW

2.0 Global Burden of Low back pain

World Health Organization (WHO) defines health not as an entire lack of disease state, but as complete physical, mental, and social wellbeing. From a 2010 study on the global burden of disease, the worldwide burden of orthopedic illnesses was approximated and expressed in disability- adjusted life years (DALYs), a standard metric that is utilized to measure the burden of disease. DALYs is calculated by adding the number of years of life lost (YLL) due to premature mortality and those years lived with disability (YLD). Since nonspecific chronic LBP is not associated with mortality, YLDs and DALYs are approximated to be equal. DALYs increased by 43% between 1990 and 2010(58.2 million to 83.0 million respectively), being higher in men compared with women and highest between 35 and 50 years(12–14).

Low back pain (LBP) is known to be one of the most prevalent and expensive orthopedic illness with reports that more than 25% of adults in North America do suffer from LBP with an economic burden that includes both direct and indirect costs ranging from about $80 billion to $600 billion. Absenteeism and productivity from absenteeism contribute most significantly to this burden. Indirect costs range between $7 billion to about $30 billion. Direct medical costs are raised from use of resources in health care, such as visits by the clinician, pharmacologic and non-pharmacologic and invasive management strategies. LBP is found to be equally distributed among males and females with a great impact on functioning(3,13–17).

In 2010, the worldwide age-standardized point- prevalence of LBP was seen to be 9.4%, which was higher in men (mean of 10.1%) than women (mean of 8.7%). Age and gender distribution among the 85 countries was similar. Prevalence was found to peak at about 80 years of age(12).

Low back pain (LBP) has been studied much among the medical personnel in African countries. In Nigeria, the 12-month prevalence was 73.53% with the female population having the higher prevalence of 68% as compared to 32% in males. The increase in incidence among participants is attributed to poor ergonomics of poor back care and associated occupational hazards. In another cross-sectional study done in Ethiopia and Nigeria among nurses, very little was the difference in 12-month prevalence, 70.87%, as well as a higher female prevalence of 67.5% and 32.5% among male participants. In this study, nurses were found to have lost 202 working days in 12 months,

about 0.14%, with significant gender association with days off duty. More females reported LBP and thus took more days off duty(18,19).

In Mulago hospital in Uganda, Galukande et al. performed two studies looking at the etiology of LBP and disability associated with low back pain in Uganda and found a 20% point prevalence with a mean age of 47years. About 60%, had mechanical LBP and constituted patients in the productive middle years of their lives. 87% of participants in the disability study were found to have had a mean of 14-days off duty due to LBP. Mean duration of the current episodes was found to be 5 months and that the pain interfered with all activities including walking, running, sitting, social life, sex life, grooming, sleeping, bending and travelling measured by the modified Oswestry Disability Index(20,21).

In Kenya, most studies have looked into occupational association with LBP and prevalence. In a 1990 study by Mulimba et al, LBP showed a prevalence of 10% in Nairobi private clinics, with more females affected (male to female ratio of 1:1.7). Majority of those affected constituted professionals such as secretaries, farmers, teachers, and nurses. In another study by Mutiso et al, looking at the prevalence of LBP among workers in a Nairobi pediatric hospital found that as well as occupational stressors did contribute to causing as well as exacerbating LBP. Ole moko in his 2014 dissertation, looked at utility of plain radiographs in LBP of non-traumatic origin in KNH and found that the average age at presentation was 50.9 years, of whom 70.6 constituted females and 29.4% males, a male to female ratio of 1:2.4. He also concluded that farmers and manual workers constituted majority of occupations affected, 21.6% and 20.6% respectively(8,22,23).

2.1 Etiology of low back pain

LBP can have several causes including biomechanical nociception in origin. Majority of the causes of LBP are non-specific hence the reference mechanical LBP, and this accounts for more than 90% of the causes of LBP. Various anatomical structures of the spine are implicated to cause low back pain and include musculature along the vertebrae, annulus fibrosus, ligaments, nerve roots and facet joints. Other conditions known to cause LBP include spinal stenosis, osteoarthritis, spondylolisthesis, infections, ankylosing spondylitis, malignancies, as well as intervertebral disc herniation(24).

In chronic LBP, the older 40-50 year old people are commonly affected. There is usually a long history of involvement in occupations that associated with bending, lifting, standing, sitting, exposure to repetitive vibrations. Trauma contributes to the known causes of LBP from road crashes, falls from heights in the young people and that from trivial falls in the older age group. (22,25).

In about 10 to 39% of patients who have had surgery for low back pain, the pain may persist or may even get worse, a phenomenon known as Failed back surgery syndrome(FBSS). In the United Stated of America, its estimated that annual accumulation of new cases of failed back surgery syndrome amount to 80,000 cases. Hanley et al found that 14% of all the herniated discs operated on for low back pain, 14% of these will have poor operative treatment outcomes. Factors that do contribute to the failure of surgery include recurrent disc herniation, arachnoiditis, formation of scar tissue, poor indication of surgery, misdiagnosis, and failure of technique of surgery. Many patients who develop this condition are known to have a poor morbid lifetime thereafter with persistent pain and disability for the rest of their lifetime. They have poor HRQOL scores as were seen in the PROCESS study where EQ5D and SF-36   FBSS is a syndrome characterized by poorly controlled back, leg pain with additional functional disability(26–32)

2.2 Health-related Quality of Life in chronic low back pain

QOL is multidimensional and puts into account all areas of an individual's existence. It viewed as conceptualizing a person's perception of physical, psychological wellbeing or functioning as well as environmental and social aspects. Health-related Quality of life (HRQOL), hence, refers to dimensions in life that may be influenced by disease or its management(33,34).

HRQOL is important in understanding the development and progression of a condition, helps in improving management of patients, assess the prognosis of disease processes and outline the time course of the impact of a disease process. It does define management strategies as well as factors predicting a higher impact of disease process. Patient oriented outcomes such as morbidity, mortality, and HRQOL are important in rehabilitation and research in health services(35,36).

HRQOL measurement instruments are developed to evaluate self-perceived status of health and its constituents, such as:

i. Pain

ii. social functioning (participation in social activities and relationships with others),

iii. physical functioning (the ability to carry out activities of daily living[ADL])

iv. perception of health status

v. psychological functioning (mental and emotional well-being)

LBP has been associated with a low quality of life (QOL) ascribed to suffering endured, dependence on drugs, failed treatments, emotional distress, difficulties experienced at work, and social isolation experienced. LBP has also been shown to reduce the functionality of patients, limit a patient's leisure and professional activities, cause sleep disorders and contribute to social, psychological and physical derangements(37,38).

In a Netherland study looked at QOL in 132 patients with CLBP with associated leg pain, using VAS pain intensity rating and Oswestry Disability index (ODI), and SF-12 for QOL assessment, statistical differences were found between low (1-2) and high(>3) lower extremity rating (LER) scores in VAS, ODI and SF-12 concluding that LER scores couldn't predict high individual patient's QOL scores. In another study looking at how CLBP influences QOL in Koreans, Korean ODI and SF-12v2 was used in 3121 patients. About 70% had moderate to severe pain,43% had prolonged pain of more than 2 years and about 30% had sleep disturbances as a result of these pain. Mean K-ODI score was 38%, correlating positively with mean pain intensity. SF-12v2 negatively correlated with mean CLBP intensity and with K-ODI score. CLBP was found to thus influence QOL negatively. 23% of these patients were dissatisfied with their current pain management(39,40).

In Brazil, Adriana et al prospectively analysed 35 patients conveniently sampled into 2 arms of 15 participants with CLBP with surgical indication (test group), and 25 patients with CLBP and no surgical indication (control group). VAS, Roland-Morris questionnaire, SF-12 QOL were used. Mental as well as physical sf-12 components recorded lower QOL scores in the test as well as more severe pain, disability and kinesiophobia. In a cross-sectional study done in France

involving 288 patients (199 Axial Spondyloarthritic (AxSpA) and 99 CLBP) were analysed using SF-12 questionnaire and the Life Orientation Test-revised for optimism analysis. 48.6% were males. AxSpA had 4.5 ± 2.4 and CLBP scored 4.3 ± 2.4 while both had poor HRQOL (mean PCS: 43.7 ± 8.2 vs. 41.9 ± 7.1; mean MCS: 45.9 ± 7.8 vs. 46.7 ± 8.1). Optimism was moderate in both(41,42).

A North Carolina cross-sectional study involved 588 participants and looked at their HRQOL in relation to the kind of physical therapy they received. About 30% had 15 visits throughout that year. Higher physical component scores of the SF-12 were positively associated with use of physical therapy(43).

No clear cause-and-effect relationship exists between LBP and comorbidities but certain conditions such as anxiety, depression, and sleep disturbances have high prevalence rates among such patients. LBP is considered a public health problem with contributions both to the social, economic and clinical aspects of any population and thus its management encompasses multiple health aspects in order to be effective.(7,44).

Intensity of pain and health-related quality of life of patients with CLBP will increases the knowledge known about LBP, patients' perception of the condition with different modes of management of the same, and thus help contribute to better treatment methods that are specific, acceptable, and objective towards total patient health care.

2.3 Classification of low back pain

    A. Low back pain (LBP) can be classified based on the clinical course or duration of the illness in to 3 categories:

        1. Acute: LBP lasting up to 3 weeks

        2. Subacute: between 3 and 12 weeks

        3. Chronic: more than 12 weeks(45,46)

Low back pain has an entity where symptoms are intermittent and recurrent, with symptom free periods. This definition overlaps with that of chronic LBP(47).

    B. Low back pain can also be classified into clinical diagnosis:

1. Serious spinal pathology(SSP)
2. Nerve root pain (NRP)
3. Simple or nonspecific LBP(NSLBP)(45,46,48–50)

MRI is a vital study able to characterize specific presentations and facilitate early detection of the various causes of LBP. As MRI study is able to visualize soft tissues especially, as well as bony structures, due to the increase in LBP prevalence should necessitate specific characterizations of LBP patterns(9).

2.4 Bio-psychosocial model of low back pain

The cause of low back pain is multifactorial. Most cases, the cause is mechanical thus called nonspecific or non-pathologic LBP. In addition to pain and impairment of function, patients with CLBP also experience depression, anxiety, effects on social, recreation, leisure, and on occupation. The realization of these widespread effect on the patient's life then led to the bio-psychosocial model of LBP as well as strategies to bring about wholesome management of all aspects of the disorder. These include biological, psychological, environmental, socio-economic and cultural factors. This model reflects on the role that non-physical factors influence and add to causation of LBP(45,51).
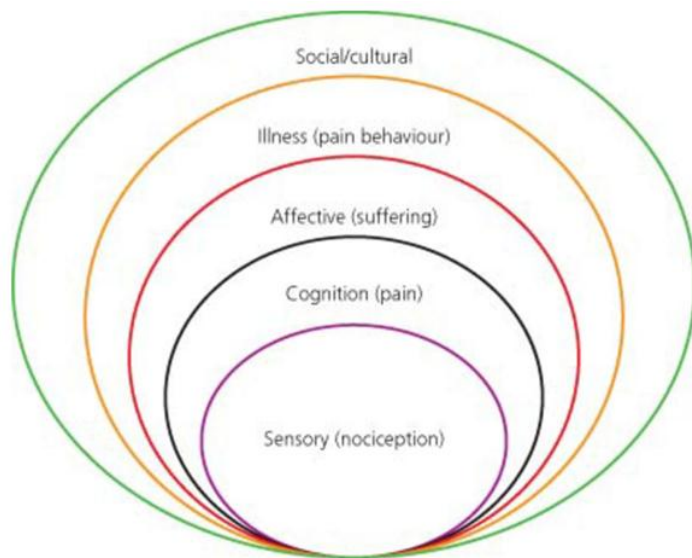
Figure 1: Bio- psychosocial model of low back pain and disability(52)

This model has brought about research efforts on effective multidisciplinary management programs that result in better and acceptable results taking account of the patient's intensity of pain and amount of disability and increasing patients back to work for longer periods as compared to those receiving physical treatments(53).

2.5 Red flags and Chronic Low back pain

Red flags are clinical findings founded on a patient's subjective as well as objective assessment that raises the suspicion level of there being an even more serious pathology than the common benign musculoskeletal condition presenting. They are physical risk factors known to suggest presence of a more serious underlying pathological cause of low back pain. They necessitate further investigations based on the suspected spinal pathology to rule out serious spinal conditions (46,54).

Finding	Diagnosis of concern				Evaluation strategy		
	Cauda eqina syndrome	fracture	cancer	infection	CBC/ESR /CRP level	Plain radiography	MRI
Age >50yrs		X	X		1*	1	2
Fever; chills; recent urinary tract or skin infection; penetrating wound near spine				X	1	1	1
Significant trauma		X				1	2
Unrelenting night pain; pain at rest			X	X	1*	1	2
Progressive motor or sensory deficit	X		X				1E
Saddle anesthesia; bilateral sciatica or leg weakness; difficulty urinating; fecal	X						1E

incontinence							
Unexplained weight loss			X		1*	1	2
History of cancer or strong suspicion of current cancer			X		1*	1	2
History of osteoporosis		X				1	2
immunosuppression				X	1	1	2
Chronic oral steroid use		X		X	1	1	2
Intravenous drug use		X		X	1	1	2
Substance abuse		X		X	1	1	2
Failure to improve after six weeks of conservative therapy			X	X	1*	1	2 (or unnec-essary)

Figure 2: Red Flags Indicating Serious Causes of Chronic Low Back Pain (55)

2.6 Pain intensity

Assessing the severity and quality of pain experienced by patients can be very subjective and therefore several assessment tools are used and include:

1. Wong- Baker FACES Pain Rating Scale
2. 0-10 Numeric Pain Rating Scale (NPRS)
3. Visual Analog Scale
4. Verbal Pain Intensity Scale

In this study, the 0-10 Numeric Pain Rating Scale (NPRS) will be used.
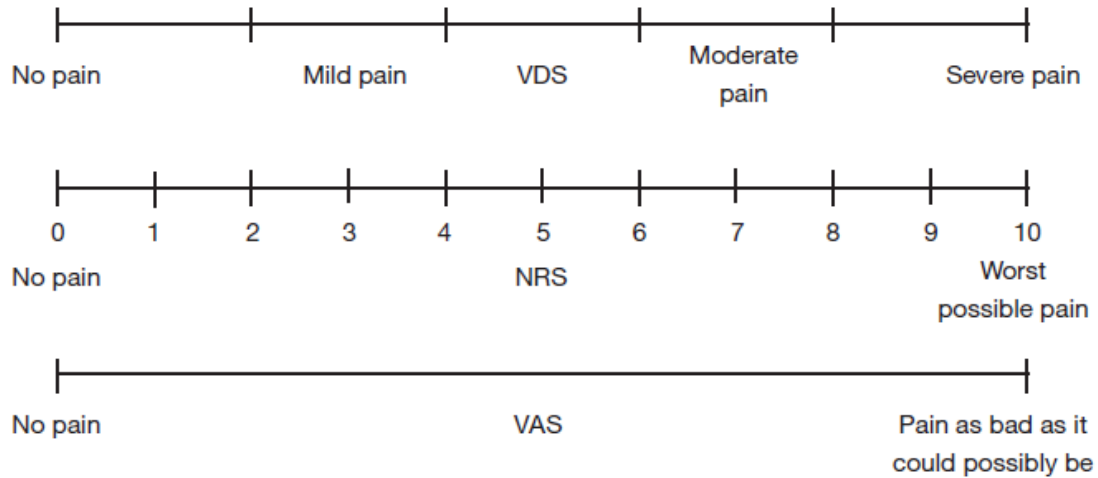
Figure 3: Different Pain intensity scales(56)

The 0-10 Numeric Pain Rating Scale (NPRS) consists of an eleven (11) point scale, commonly employed in clinical trials and clinical setup for patient assessment of the rate of their pain intensity from end points of absent pain (scored 0) to the worst imaginable intensity of pain (scored 10). It represents a longitudinal numeric division of another pain intensity scale, the visual analog scale (VAS). It contains a horizontal line with segments that describe different graduated measures of pain severity. Interestingly, it can be delivered verbally and graphically and because the scale is interval levelled, it can be used in research to provide parametric data on pain intensity. No published data is available to demonstrate error of the data got or distribution when using NRS. It takes less than a minute to complete and like the VAS, the NPRS has minimal difficulties in language translation in different cultures. In a study looking at patients with Rheumatoid arthritis, NPRS had higher reliability in both literate and illiterate populations when compared with VAS and Verbal Descriptor Scale (VDS). In yet another study assessing the responsiveness of NPRS among LBP patients found that a 2 point change had a important difference clinically, duuring the follow up period of the study, making the tool adequately responsive in the clinical and research fields detecting a change in the pain scale the patient experiences. Jensen et al looked at chronic pain intensity measures of different measuring tools and found NPRS as well as the VAS and VDS had good reliability and validity in the 2 months of treatment duration of study(57–60)

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2.7 The Short Form 12 (SF-12) Health Survey

Policy makers as well as clinicians have continued to appreciate the importance of measuring HRQOL to impart knowledge on management of patients and policy decisions.

The major goals of treatment of patients with back pain is improving their HRQOL(61). Ware, in an effort to reduce the participant's burden in filling the SF-36, constructed a subset containing 12 items measuring. This tool measured their functional health and wellbeing from the patient's point of view. The SF-12, like the SF-36, has 2 main components: physical component summary (PCS-12) as well as the mental component summary (MCS-12). The reliability and validity of the SF-12 health survey has been well documented(62)
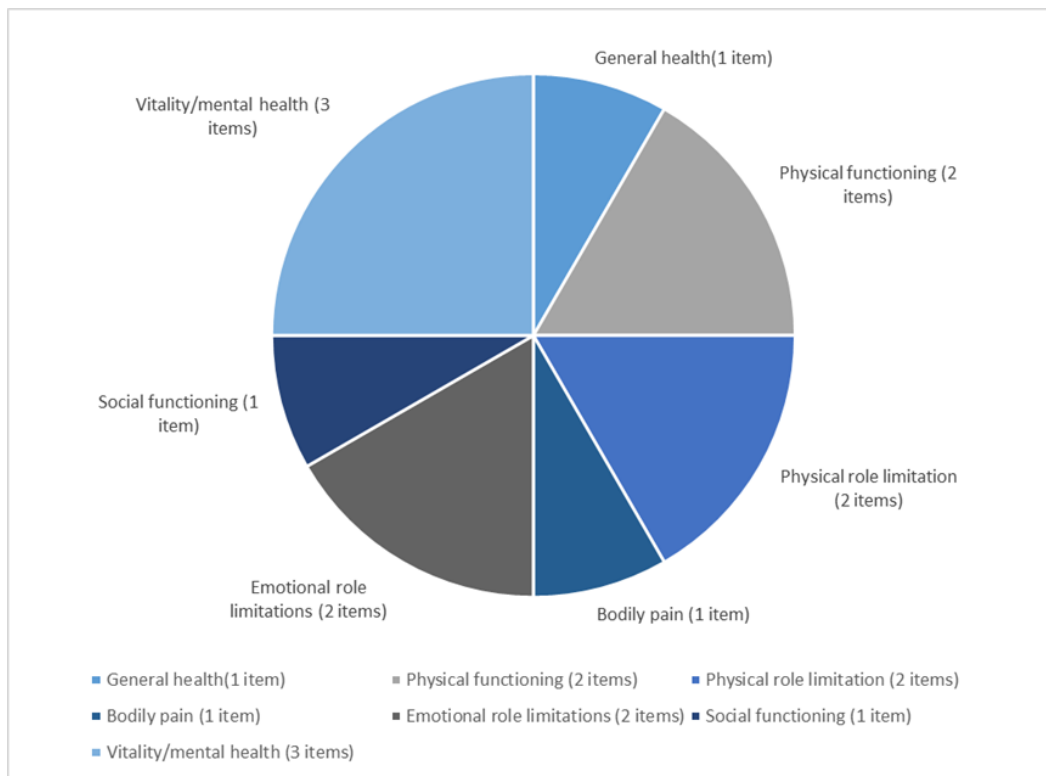
Figure 4:The 2 Subscales of the SF-12 model(63)

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It is reliable, responsive as well as valid in patients with back pain. It is a valuable tool in health research involving large populations for applications that bring together generic and disease-specific health survey. It takes about 2 to 3 minutes to complete(64).

It has been found to be vital in monitoring health of populations and comparing and analyzing burden of disease and predicting medical expenses. SF-12 questionnaire can be used to measure differences in QOL at a point in time in patient cohorts or as an evaluative instrument that measures HRQOL changes occurring over time in patients(62).

CHAPTER 3: STUDY RATIONALE

3.0 Study Justification

LBP has a lifetime prevalence of 74-85% and almost 20% of a population suffers from disabling or severe back pain. CLBP is a very prevalent public health condition in most first-world and third-world nations and altogether too costly economically, as it's both a costly burden on health-care budgets, as well as to the patient. In addition, disability, poor performance at work as well as absenteeism, psychological and social effects plague most patients suffering from CLBP. The objective of most management modalities of CLBP is to improve their QOL through effective treatments that can only result from adequately managing pain. Other factors that directly contribute to LBP need to have a thorough assessment as well as be measured to result in objective as well as subjective goals that benefits the patient.

Quality of life defines all aspects about an individual's existence, while HRQOL defines a part of that individual's existence. Treatment methods are geared best at being patient-oriented and thus factors influencing HRQOL are vital to be understood. MRI scans of the back are necessary in chronic LBP as they provide very vital information that affects treatment. They are devoid of ionizing radiation especially to the gonads, as opposed to radiography. MRI of the lower back not only characterizes the pattern of low back pain but it distinguishes LBP into patterns that facilitate specific management(9).

Despite this relevance statistic on LBP, health service research is seldom done to analyze the HRQOL of such patients. No local studies have looked into patient – oriented outcomes, which are important in rehabilitation and research of CLBP.

3.1 Study objectives

3.1.1 Broad Objective

To determine the Health related quality of life and the pain perceived in patients with chronic low back pain as seen in KNH

3.1.2 Specific Objective

1. To establish the health-related quality of life of patients with chronic low back pain using SF-12.
2. To assess the intensity of pain in patients with different clinical diagnoses of chronic LBP and the effect on their quality of life.

CHAPTER FOUR: METHODOLOGY

4.0 Materials and methods

4.0.1: Study design

Cross sectional study design with convenient sampling of consecutive participants

4.0.2: Role of the Researcher

The primary researcher or investigator was an orthopedic resident, who, together with the research assistant, an orthopedic technician, described the procedure to the participants and collected data after obtaining consent from the participants.

4.0.3: Study setting

The study was conducted at the orthopedic clinic and physiotherapy departments at Kenyatta National Hospital. The orthopedic clinic is run 4 days a week and receives about 40 to 55 patients per day with both acute and chronic LBP. The patients are seen in their respective orthopedic and fracture clinics depending on their ailments. The clinics are run by orthopedic registrars, general surgery registrars rotating in the orthopedic clinics and orthopedic consultants.

The physiotherapy department manages orthopedic patients with different conditions but mostly patients with acute and chronic LBP. Approximately 90 to 110 such patients with LBP are attended to in the physiotherapy departments every week. Orthopedic physiotherapy technicians offer the needed service to these patients.

4.0.4: Inclusion criteria

1. Participants over 18 years
2. Participants who gave consent
3. Participants with chronic low back pain for 6 months or more, with or without a traumatic or infective etiology, with Magnetic resonance imaging (MRI) scans of the lumbosacral spine

4.0.5: Exclusion criteria

1. Participants less than 18 years of age

2. Participants who did not give consent

3. Participants with multiple spine segmental back pain other than LBP

4. Participants with chronic LBP for less than 6 months

5. Participants with chronic LBP and any form of paralysis or weakness

4.0.6: Sample size calculation

The sample size calculation was based on the formula(65):

$$n = \frac{Z^2 \sigma^2}{d^2}$$

Where,

n represents the required sample size

Z represents the value from the table of probabilities of the standard normal distribution for the desired confidence level (e.g., Z = 1.96 for 95% confidence)

σ represents the standard deviation of the outcome (mean SF 12 score). The mean (± SD) SF 12 normative values in general population are mean = 50 (SD = 10). Therefore, an SD of 10 was used in this calculation.

d represents the margin of error around the estimate of mean SF 12 score. To increase precision around the estimate of mean SF 12 (normative value = 50) a margin of error of 1.65 units was used.

$$n = \frac{1.96^2 \times 10^2}{1.65^2}$$

n = 140

4.0.7 Methodology

Eligible participants over 18 years of age, with chronic LBP and having had lumbosacral MRI scans attending physiotherapy services and orthopedic clinics in KNH were recruited into the study based on the inclusion and exclusion criteria.

Orthopedic and General Surgery Senior House Officers attending to patients at the KNH orthopedic clinic, and the research assistant, were educated and made aware about the study and how to use the data collection sheet (Appendix 2). The research assistant was an orthopedic technologist working at the Foot and orthopedic clinics in KNH. He recruited participants at the physiotherapy department. The orthopedic Registrars alerted the primary researcher or the assistant for data collection when a participant meeting the inclusion criteria was found in the clinic.

The principle investigator or the research assistant explained the aim and purpose of the study to these participants. The participants read the consent form and signed on their own accord. All who consented were recruited into the study and registered. The recruitment of participants and filling of data collection forms and SF-12 Questionnaires (Appendix 2) was ongoing until the sample sizes of 140 was met. Those participants who met the inclusion criteria but could not read and write in English and Swahili were excluded.

Instruments used

Participants accounted for their pain intensity appreciated over the past 6 weeks between 0 (no pain) and 10 (worst possible pain) by filling the Numeric Pain Rating Scale (NPRS), and the Short Form-12 Questionnaire.

4.0.8: Data Collection

Participant's data was collected from filled data collection sheets equal in number to the sample size. Participants' names were included, and thereafter assigned study serial numbers to their data collection sheets. Socio-demographic variables included data collected to describe the study sample and were represented on tables. They included sex (male or female), and age. The HRQOL (SF-12) measured the patient's perceived quality of life through measuring the physical, mental and social wellbeing of the patient. It includes 12 stem questions and 8 options and will

be tabulated with mean value and standard deviation. The MRI diagnoses given was classified The differences in the Short form-12 means were compared between the different age-groups, genders, and patient's diagnosis based on their lumbosacral MRI scans.

4.0.9: Data Analysis

Categorical or nominal data as well as continuous data were presented in terms of tables and bar graphs. Evaluation of the relationship between mean pain score and the SF-12 score was done using analysis of variance (ANOVA). Pearson correlation coefficients was used for correlation analysis between mean pain intensity and other variables (SF-12).

Data from the Data Collection Sheet was stored in tables and spread sheets of Microsoft Excel. This questionnaire data was then electronically stored in SPSS v20 to generate descriptive statistical data, to create presentations in graphic form for reporting, finding relationships between different question responses, and collating open question responses.

5.0 Ethical Consideration

Ethical approval to conduct the study was sought from the Department of Orthopedic Surgery, University of Nairobi, KNH administration, and from the Kenyatta National Hospital/University of Nairobi - Ethics & Research Committee (KNH/UoN-ERC).

From the participants or their relatives or next of kin, informed consent was voluntarily sought to allow the principle investigator and his assistant to collect data. Participants were counseled on the objectives of the study and the importance of the findings in adding to the knowledge on low back pain and its management. Withdrawal or refusal to participate would have no effect in the management or treatment that the patient will be entitled to.

6.0 Limitations of the Study
Some limitations to the study included:

1. Some illiterate participants had challenges in giving consent and answering the SF-12 questions
2. Memory bias especially with recall for more than 6 weeks' scope of pain

6.1 Delimitations of the study

Interpreter-or assisted-completion of questionnaire was required for some participants.

CHAPTER 5: RESULTS

Sample characteristics

One hundred and forty adult patients with low back pain were recruited in KNH. The mean age of the patients was 46 years (SD ± 14.4), range 18 to 82 years. Table 1 presents the demographic characteristics of low back pain patients. The modal age group was 40-49 years accounting for 23.6% of patients followed by 50-59 years (22.9%) and 30-39 years (21.4%). There were 54 (38.6%) males giving a male to female ratio of approximately 2:3.

Table 1: Characteristics of patients with low back pain in KNH

Variable		n	%
Age	18-29 years	18	12.9
	30-39 years	30	21.4
	40-49 years	33	23.6
	50-59 years	32	22.9
	60-69 years	16	11.4
	70 years and above	11	7.9
Sex	Male	54	38.6
	Female	86	61.4

All the patients (n = 140) reported that they were actively involved in an occupation (Figure 5).

Figure 5: Occupation of patients with low back pain in KNH
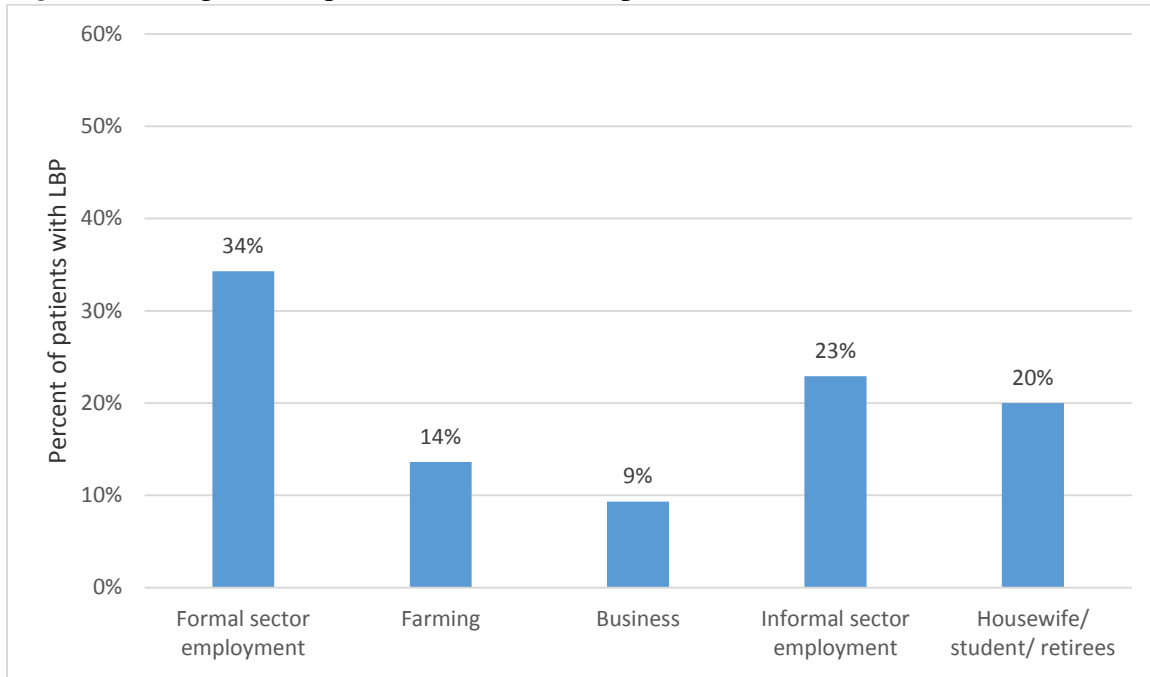
There was one (0.7%) patient who reported smoking and 15 (10.7%) were former drinkers while one (0.7%) was currently drinking alcohol (table 2).

Table 2: Alcohol consumption and smoking habits in patients with low back pain in KNH

Variable		n	%
Smoking	Yes	1	0.7
	No	139	99.3
Alcohol	Never taken alcohol	124	88.6
	Former drinker	15	10.7
	Current drinker	1	0.7

Diagnosis made by MRI

The findings of MRI investigations conducted in low back pain patients are shown in Figure 6. Of the 140 patients there were 89 (64%) patients with SSP while the remaining patients either had NRP (25%) or NSLBP (11%).

The cases that constituted Serious spinal pathology were 89 and are shown in Table 3. There were 35 cases of Nerve root pain that mainly featured disc prolapse or herniation aetiologies, while Nonspecific low back pain constituted 16.

Table 3: Cases constituting Serious Spinal pathology

Aetiology of SSP	Frequency
Degenerative causes (spondylosis, spondylolisthesis)	44
Tuberculosis of the spine	8
Fractures of the Lumbar Spine	14
Tumors of the spine	8
Post-surgery	15

Figure 6: Diagnosis made by MRI in patients with low back pain in KNH
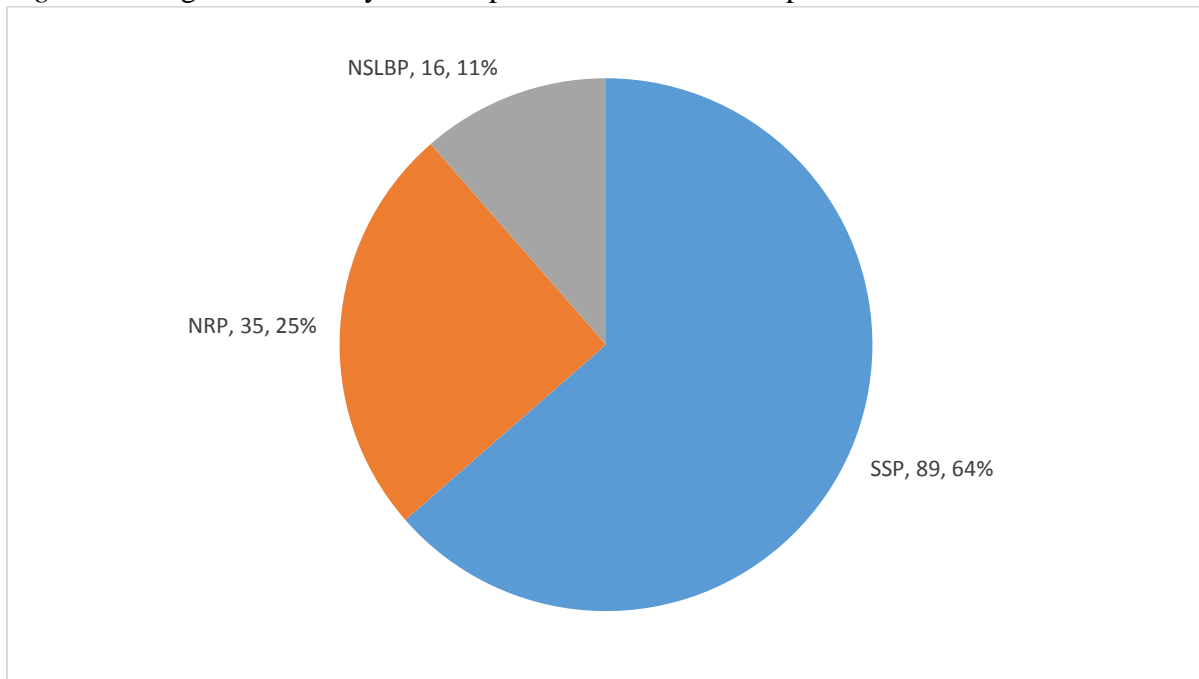
The intensity of low back pain was assessed using the 0-10 Numeric Pain Rating Scale (Figure 7). The pain scores ranged between 3 and 10 with higher scores representing increasing pain severity. The median score was 7 (interquartile range 5 to 8). There were 37 (26.4%) patients with a pain score of 7 out of 10. 27 (19.2%) patients scored 5, 6 or 8 out of 10.

Figure 7: Pain intensity in low back pain assessed using 0-10 Numeric Pain Rating Scale
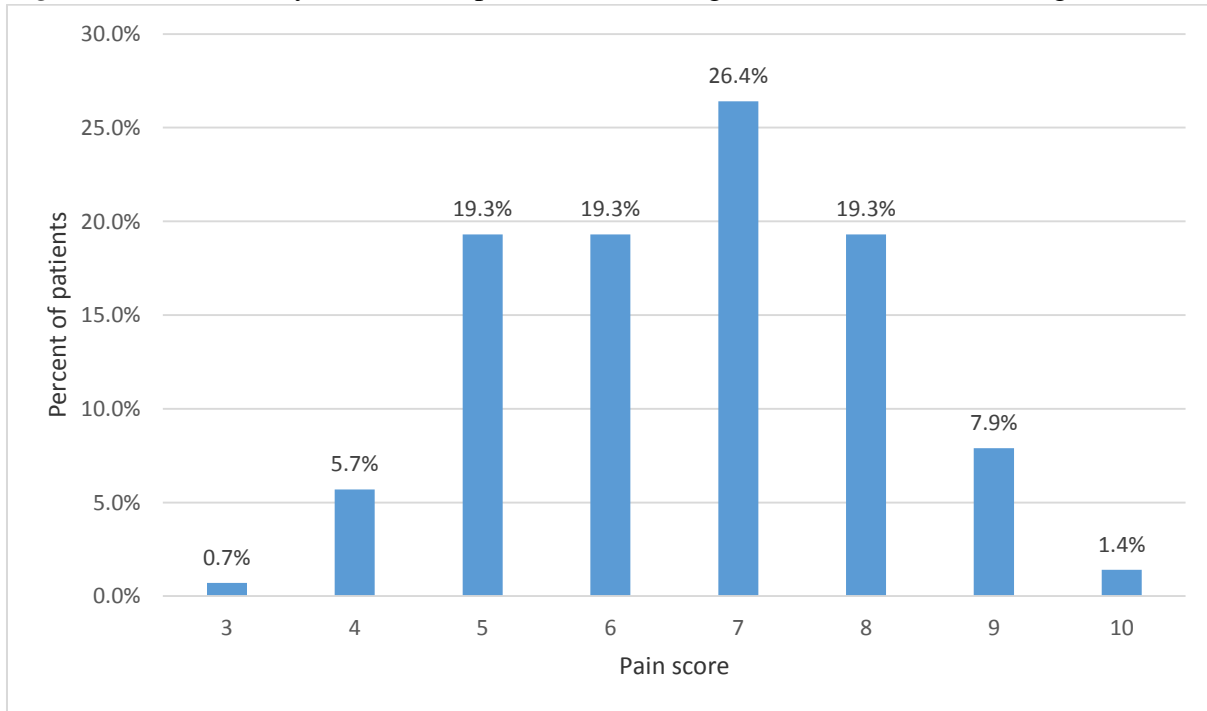
There was a significant association between pain intensity reported by patients with chronic low back pain and the diagnosis made by MRI (p = 0.024), table 4. Patients with NRP had higher scores with 40% scoring 8 out of 10 compared to 12.4% of SSP and 12.5% of NSLBP who also scored 8 out of 10. Conversely, 8.6% of NRP patients score 5 out of 10 while 22.5% of SSP and 25% of NSLBP patients scored 5.

Table 4: Pain intensity in patients with diagnosis of chronic LBP

	Diagnosis made by MRI			
	SSP	**NRP**	**NSLBP**	**P value**
NSPR score				
3	1(1.1)	0(0.0)	0(0.0)	0.024
4	7(7.9)	0(0.0)	1(6.3)	
5	20(22.5)	3(8.6)	4(25.0)	
6	20(22.5)	4(11.4)	3(18.8)	
7	22(24.7)	11(31.4)	4(25.0)	
8	11(12.4)	14(40.0)	2(12.5)	
9	8(9.0)	1(2.9)	2(12.5)	
10	0(0.0)	2(5.7)	0(0.0)	

Health-related quality of life of patients with chronic low back pain

Figure 8 shows that most (50%) of patients with low back pain rated their general health condition as fair on the SF-12 item measuring general health condition. On the extremes of the scale 5.7% and 2.1% of patients rated their condition as poor and excellent, respectively.

Figure 8: General health condition of patients with chronic low back pain
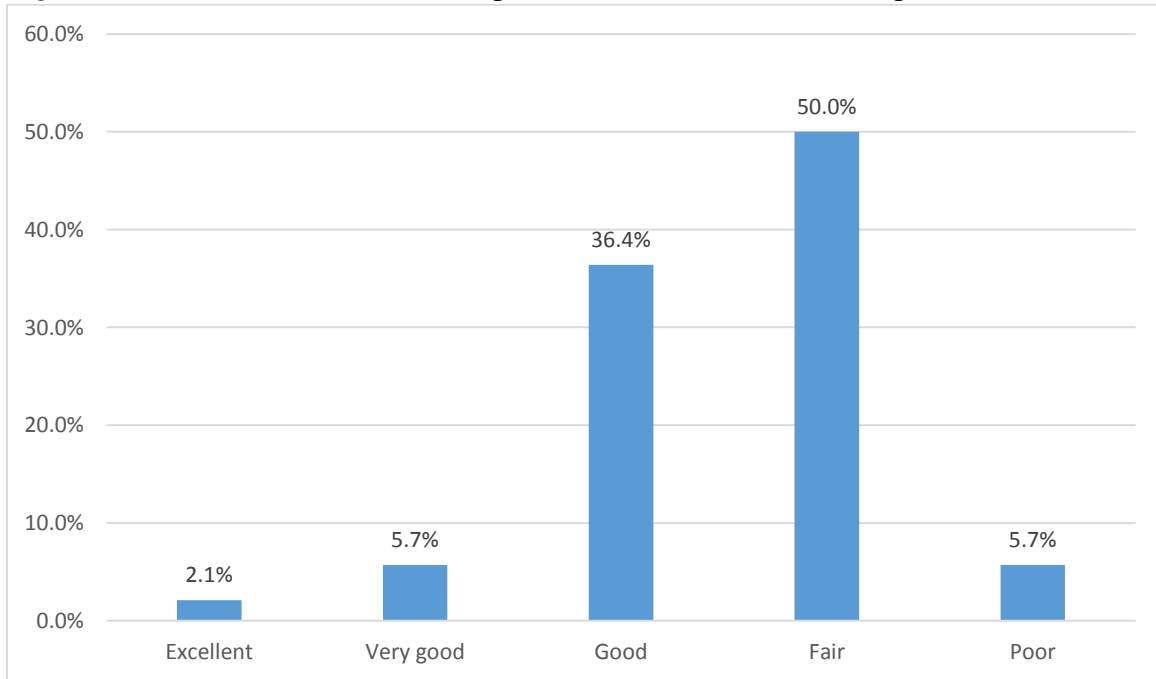
Approximately two-thirds of all patients with low back pain indicated that as a result of the pain their ability to perform moderate activities (65%) or activities requiring exertion (69.3%) like climbing several flights of stairs had been limited a little (Figure 9). Out of the participants approximately one-fifth reported that the pain had impacted on their ability to perform moderate (21.4%) and exerting (18.6%) activities a lot.

Figure 9: Impact of chronic low back pain on patient ability to perform moderate and exerting activities
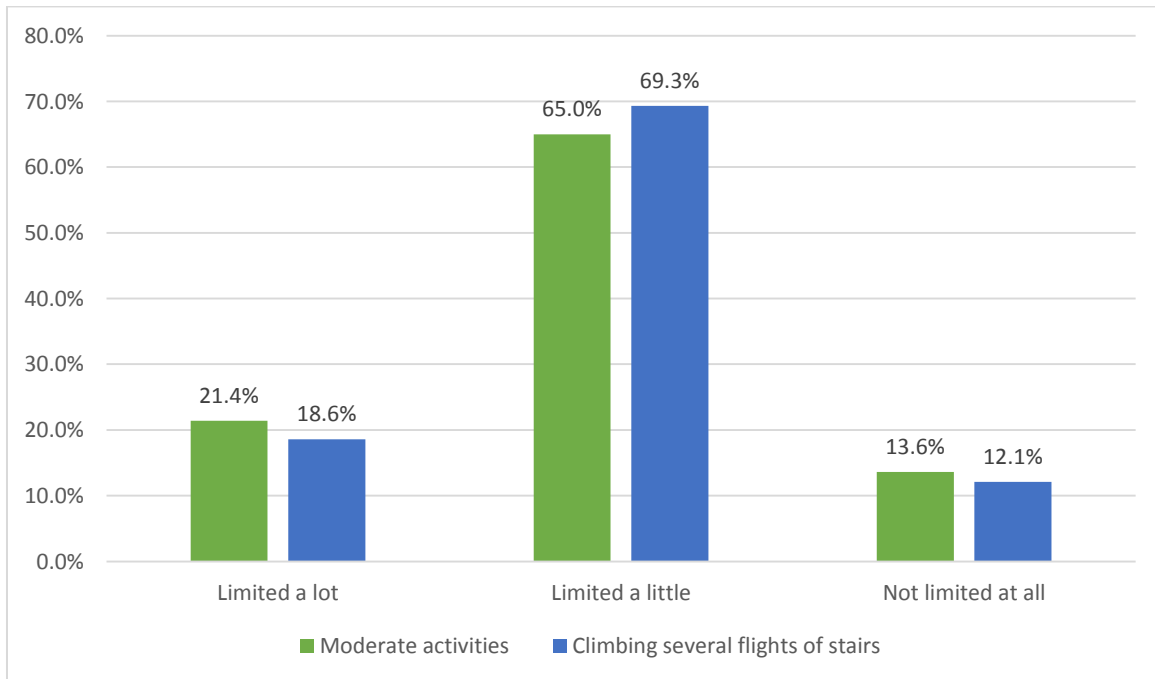
Most patients reported that they had had problems with their work or other regular daily activities during the past 4 weeks with 80% accomplishing less than they would like and 77.9% being limited in the kind of work done or other activities (Table 5). Emotional problems resulted in 72.9% of patients accomplishing less than they would like and 58.6% doing work or activities less carefully than usual (Table 6).

Table 5: Emotional and physical impact of chronic low back pain on regular daily activities

	Yes n (%)	No n (%)
During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>		
Accomplished less than you would like.	112(80.0)	28(20.0)
Were limited in the kind of work or other activities	109(77.9)	31(22.1)
During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?		
Accomplished less than you would like.	102(72.9)	38(27.1)
Did work or activities less carefully than usual.	82(58.6)	58(41.4)

Table 6: Response to SF12 items (item 8-12) in patients with low back pain in KNH

	Not at all	A little bit	Moderately	Quite a bit	Extremely	-
During the past 4 weeks:						
How much did pain interfere with your normal work?	2(1.4)	17(12.1)	63(45.0)	45(32.1)	13(9.3)	-
	All of the time	**Most of the time**	**A good bit of the time**	**Some of the time**	**A little of the time**	**None of the time**
Have you felt calm & peaceful?	5(3.6)	24(17.1)	35(25.0)	57(40.7)	18(12.9)	1(0.7)
Did you have a lot of energy?	6(4.3)	19(13.6)	28(20.0)	50(35.7)	31(22.1)	6(4.3)
Have you felt down-hearted and blue?	2(1.4)	21(15.0)	29(20.7)	56(40.0)	26(18.6)	6(4.3)
How much of the time has physical health or emotional problems interfered with social activities	5(3.6)	32(22.9)	NA	53(37.9)	40(28.6)	10(7.1)

Table 7 shows the mean scores for all patients with low back pain in KNH. The lowest mean scores were in the emotional role limitation 15.2 SD ± 4.2 and physical role limitation 22.3 ± 3.3. The areas in which patients scored highly were vitality 41.7 ± 11.3, physical functioning 38.1 ±

8, social functioning 37.7 ± 9.8 and general health 36.7 ± 10.1. The overall SF-12 scores in physical and mental domains were 34.7 ± 5.1 and 33.5 ± 6.7, respectively.

Table 7: Health-related quality of life of patients with chronic low back pain assessed using SF-12

	Mean	SD	Median	IQR	
Physical functioning (0-100)	38.1	8	39.3	30.7	39.3
Role functioning (0-100)	22.3	3.3	20.3	20.3	24.9
Bodily pain (0-100)	33.4	8.8	37.1	26.9	37.1
General health (0-100)	36.7	10.1	29.6	29.6	44.7
Vitality (0-100)	41.7	11.3	37.7	37.7	47.7
Social functioning (0-100)	37.7	9.8	36.4	26.3	46.5
Role emotional (0-100)	15.2	4.2	16.9	11.3	16.9
Mental health (0-100)	41.3	8.3	40.2	40.2	46.3
Physical aggregate (PCS 0-100)	**34.7**	**5.1**	**35**	**32**	**38.3**
Mental aggregate (MCS 0-100)	**33.5**	**6.7**	**32.7**	**29.3**	**37.3**

Patient demographics and quality of life (SF-12)

Figure 10 shows that patient age was not correlated with aggregate score for physical health (Pearson's coefficient = 0.096, p = 0.28) but age showed a negative significant correlation with mental health score (Pearson's coefficient = -0.237, p = 0.007). On average the SF-12 mental health score declined by 0.11 units for each additional year of life in patients with lower back pain.

Figure 10: Relationship between SF-12 scores and age in patient with low back pain in KNH
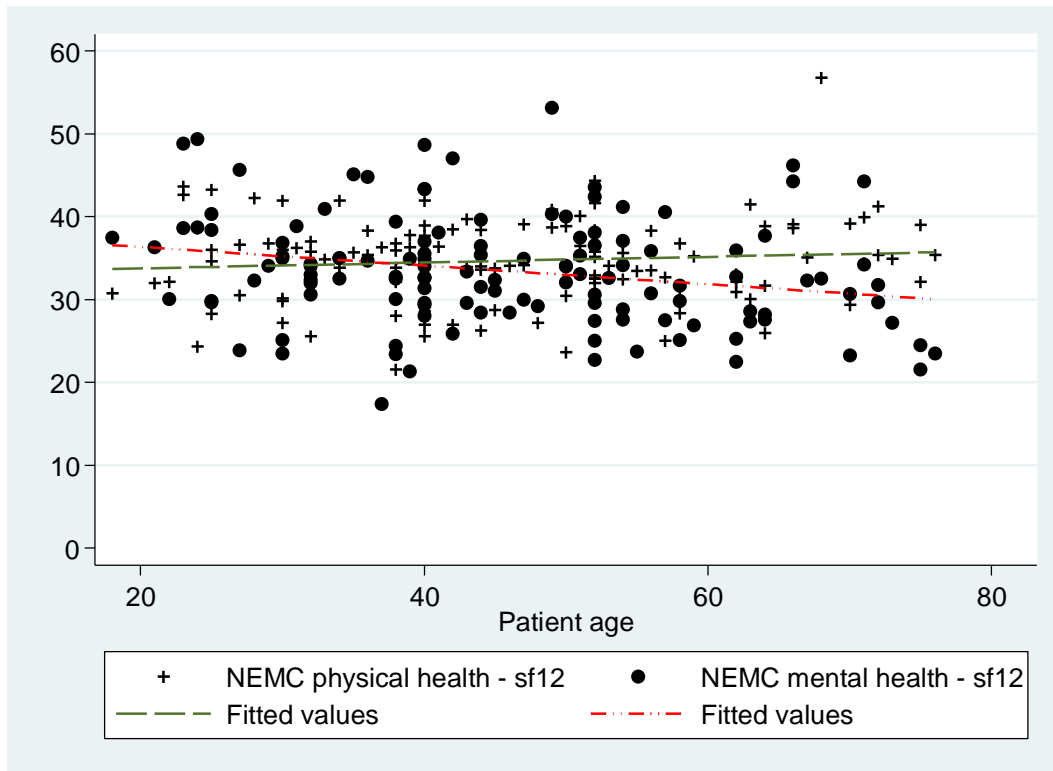
Table 8 shows that the aggregate SF-12 scores were higher in males with low back pain compared to females but patients sex was not significantly associated with either physical (p = 0.23) or mental (p = 0.15) score.

Table 8: Aggregate SF-12 scores according to patient gender

	PCS	P value	MCS	P value
Sex				
Male	35.3±4.9	0.23	34.5±7	0.15
Female	34.3±5.2		32.8±6.5	

Intensity of pain and quality of life (SF-12)

There was a statistically significant association between intensity of pain reported by patients and SF-12 score on both the physical (p < 0.001) and mental (p = 0.02) domains (Table 9).

Table 9: Aggregate SF-12 scores according to reported pain intensity

	PCS	P value	MCS	P value
Pain score				
4	33.9+4.1	<0.001	37.5+10.4	0.02
5	37.1+5.7		36.7+6.5	
6	36.4+3.7		32.2+6	
7	35.2+4.9		32.4+6.2	
8	31.5+4.6		33.6+6.4	
9	30.6+2.9		29.6+5.3	

Clinical diagnoses of LBP and quality of life (SF-12)

There was no significant association between diagnosis made by MRI and the SF-12 scores for patients with low back pain in KNH. Table 10 shows that the mean PCS ranged between 33.5 and 35.2 (p = 0.27) while mean MCS ranged between 32.4 and 35.1 (p = 0.46).

Table 10: Aggregate SF-12 scores according to clinical diagnosis

	PCS	P value	MCS	P Value
Diagnosis made by MRI				
Serious spinal pathology (SSP)	35.2±5	0.27	33.6±7	0.46
Nerve root pain (NRP)	33.5±5.3		32.4±6	
Simple or nonspecific LBP (NSLBP)	34.1±5.1		35.1±5.9	

CHAPTER 6: DISCUSSION

Sample characteristics

This study was performed in KNH to find out the pain intensity and the quality of life of patients with chronic low back pain. One hundred and forty adult participants with chronic low back pain were recruited from the physiotherapy and orthopedic clinic. Of these, women were found to be affected with CLBP more than men with a male to female ratio of 2:3 (61.4% female compared to 38.6% male participants enrolled). The more prevalent women affected compares with findings from other studies by Mulimba (1.7:1), Ole-moko (4:1.2), Galukande (2:1). CLBP is found to affect adults all across the age groups, which in this study, was found to be 18-89 years, with a mean of 46 years. However it is much more common in prevalence as the age progresses(8,20,23).

Most of the participants were in some form of occupation. These occupations are associated with standing, sitting, bending for prolonged periods and thus predisposing to LBP, as found in Mulimba et al. study(23).

Men do drink much more than women but there seemed to be no obvious relationship between alcohol intake and cigarette smoking with presence of CLBP. About 10% of participants were former drinkers while 0.7% reported smoking, and similarly currently drinking. Ferreira et al, in a systematic analysis, found that only people with alcohol dependence were associated with LBP that is chronic and complex in nature(67). No alcohol dependence was found in this study though.

Diagnosis made by MRI

MRI has become more affordable and available than before making diagnosis of chronic LBP more specific and definitive. Diagnoses was done based on the classification of 'diagnostic triage' into simple or nonspecific LBP (NSLBP), where no obvious pathology is seen on the MRI films, nerve root pain (NRP) or radicular pain, where nerve roots are compressed by an anatomic structure such as prolapsed disc, or serious spinal pathology (SSP), where specific abnormality in the spine leads to LBP e.g. fractures, or spondylolisthesis(68). From the study, the common pathology seen to be associated with chronic LBP was SSP (64%) compared to NRP (25%) and NSLBP (11%). This compared differently to Galukande et al. study, where he found

close to 20% of patients to have NRP, about 17% having SSP, while only close to 2% had NSLBP. Bardin et al in his study found less than 1% having SSP, about 10% having NRP and NSLBP presented by close to 95%. In these 2 studies, no NSLBP was diagnosed by exclusion of the 1st two. The differences in the prevalence of CLBP may arise from MRI use in determining the specific LBP pathologies that may be difficult to distinguish(9,20,68).

MRI diagnoses was greatly associated with the age with NSLBP being more commonly found in the younger patients, but a lack of association between MRI diagnoses of LBP and sex of the patient, comparing well with a Ugandan study showing no association between age and gender with the different diagnoses(20).

The Numerical Pain Rating Scale (NPRS) was used to subjectively quantify pain intensity. It is entirely based on how the participants describe the pain to be. There was, however no appreciable association between the pain intensity reported by the participants and diagnosis made by MRI though patients with NRP rated their pain higher compared with SSP and NSLBP. This may be attributed to the presentation of radicular pain being associated with numbness and at times weakness. This symptom may possibly cause patients to rate their pain higher.

Health-related quality of life of patients with chronic low back pain

Half of the participants in this study rated their general health condition as fair with a small proportion rating their quality of health as poor (5.7%) and excellent (2.1%). Close to 66% of participants with LBP attributed pain to limiting their ability to perform moderate activities (65%) and limited activities (69.3%) similar to a study by Andrea et al in one of the two models of his study(69).

This translated to a bigger burden of patients with CLBP in their most active period of their profession contributing negatively to the economy, by performing poorly at work, and also socially. These patients spend a good part of their time seeking treatment and care for their pain at the expense of working or contributing negatively to their functions in the society, matching a study be Wolter et al. He found out that patients with CLBP visited up to six physicians because of their pain(70).

Approximately 20% of participants reported that the pain had affected their ability to perform moderate (21.4%) and exerting (18.6%) activities a lot. This shows that at the extreme, low back

pain contributes to some form of disability and poor performance at work and socially. Chronic low back pain affects function of a patient by affecting the performance of activities of daily living and reducing adult activities including formal employment(71).

Most participants (about 80%) reported that they had reduced productivity of their daily regular activities while 77.9% were limited in the kind of work done. These was compounded too by emotional problems which contributed to 72.9% of patients accomplishing less than they would like or less carefully than usual. These findings like others done before do show how CLBP does affect patients' performance as well as productivity at their workplaces. Such individuals fall back in opportunities to improve their capacity or compete with others at work.

Patient demographics and quality of life (SF-12)

Patient's age did not correlate with their physical health score. Age, however, showed a decline in mental health score by 0.11 units for each additional year of life in such patients with CLBP. This showed that age may have a significant influence of self-perceived health status. This may imply similarly from a Tunisian health related survey that CLBP does give patients poor health the older they get(72). From the Utah health status survey, people were found to have lower physical health scale (PCS) but scored high on the mental health scale (MCS). The author went on to conclude that the interpretation of a person's health score was better based on persons of similar age(73).

Male patients with CLBP scored higher aggregate SF-12 compared to females in this study. Similar results were reported from a Tunisian HRQOL with men, young respondents, and those with higher education status scoring better than women, older participants and those with lower education. Moheddine, et al, Ware et al, and Xuemei et al in the same study, also found that respondents with chronic conditions scored poorer on the SF-12 PCS and MCS, than those without chronic illnesses(64,72,74). This ultimately shows that age and female patients with CLBP have associated poorer health scores.

Intensity of pain and quality of life (SF-12)

The intensity of pain experienced by a patient ailing from a particular disease condition has an important bearing on patient care, especially when analysed in the context of quality of life. This further helps to understand and administer specific treatment care by assessing pain control and the treatment outcomes. Assessment and quantification of pain is by all means very challenging as pain is complex, subjective and has multiple domains(7).

Of the 140 participants, there was a statistically significant association between patient reported intensity of pain and SF-12 score (PCS and MCS) in this study, similar to other studies. This shows that pain in both male and female will affect the patient's physical and mental function and therefore care for such patients should both incorporate the physical as well as the mental aspect(64,75,76).

Clinical diagnoses of LBP and quality of life (SF-12)

Summation of QOL produces either a higher score which indicates a higher quality of life while a lower score indicating a lower quality of life. In this study, there was no significant association between diagnosis made by MRI and the SF-12 scores for patients with CLBP in KNH. The different causes of CLBP did not seem to differ in effect to patient's quality of life. This may be due to the appreciation of pain regardless of the cause(11).

Hollingworth et al found that discogenic LBP (NRP) at MRI was not strongly associated with poor QOL. Such patients showed worse pain appreciation and limitation of physical activity, but also did report a better general health(77).

CHAPTER 7: CONCLUSION

In this study, CLBP has been found to affect middle aged patients with a mean age of 46 years, with a range between 18 and 82 years. Females were affected more than males with a female to male ratio of 3:2.

CLBP seemed to affect people in the formal sector (34%) much more than other occupations that patients presented with.

Serious specific pathology accounted for 64% of the MRI diagnoses of patients with CLBP in the study followed by Nerve root pathology (25%) and non-specific LBP (11%).

Age, however had a strong association with diagnosis made by MRI, with NSLBP found to be more common among younger age groups, but no association was found between MRI diagnoses and patient sex.

The intensity of low back pain was recorded as severe (7 out of 10) in 26.4% of participants, about a quarter of the participants. There was also a significant association between the pain intensity and the MRI diagnoses. Patients with NRP had higher scores with 40% scoring 8 out of 10 compared to 12.4% of SSP and 12.5% of NSLBP who also recorded 8 out of 10.

More than half of the participants rated their general health condition as fair general health condition on the SF-12 item. 5.7% rated their general health condition as poor while 2.1% rated their condition as excellent.

Males had higher aggregate SF-12 scores compared to female participants but sex was not significantly associated with either physical or mental scores.

CLBP affected ability to perform moderate activities or activities requiring exertion, with associated emotional problems resulting in more than 70% of patients accomplishing less than they would like.

CHAPTER 8: STUDY LIMITATIONS

1. There were patients who were unable to understand the questionnaire due to language barrier. We had to exclude them due to there being no Swahili version of the SF-12 questionnaire.

2. Some participants did not fill the questionnaire completely and these we had to exclude from the study.

3. Some questions in the questionnaire were difficult for some participants to identify with, or understand. We therefore had to exclude them from the study.

CHAPTER 9: RECOMMENDATION

1. Further studies are needed to establish the quality of life of patients with different diagnoses of CLBP with specific treatment modalities to govern patient specific treatments.

2. Women seem to be affected by CLBP more than men therefore research has to be geared toward addressing the risk factors that predispose them to the pain

3. A Swahili version of the Short form- 12 or 36 is very helpful in capturing the patients who speak Swahili alone. This will help research in different fields of medicine looking into qualities of life in different diseases.

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APPENDIX 1: ENGLISH INFORMED CONSENT FORM

Title: QUALITY OF LIFE IN PATIENTS WITH CHRONIC LOW BACK PAIN AS SEEN AT KENYATTA NATIONAL HOSPITAL

Investigator: Dr. P. Gituri Mwawingwa

Supervisors: Dr. V. Mutiso and Dr. T. Mogire

Investigator Note: Thank you for agreeing to read this form. It offers information about this study which will help you decide if you will take part in this study or not. Appropriate translation will be carried out in the language you are most comfortable with.

Introduction: Low back pain is very common. Patients with LBP do experience pain, impaired function, anxiety, depression, and reduced quality of life due to suffering, failed treatments, social isolation, difficulties at work and dependence on medications. The purpose of this research is to determine the pain perceived and the quality of life in patients with chronic low back pain. This will help in policy making and strategies aimed at improving the care of low back pain

Procedure: If you agree to be part of this study, I will ask you personal questions, about your lifestyle and how low back pain has affected your day to day activities and its severity.

Benefits: Findings of this study will be interpreted to you, the University of Nairobi, and Kenyatta National hospital. This will help in policy making and in improving care of patients with chronic low back pain.

Confidentiality: If you agree to be part of this study, the information you give will be held in strict confidence and only used for the purpose of the study

Reassurance: Please note that the information you give will be used by none other than the researcher and or supervisor for material transcribing purposes only. Your participation is voluntary and you may refuse to answer any specific questions you feel uncomfortable..

Ethical consideration: I have been granted approval from the Research and Ethics Committees to conduct this study.

I confirm that I have explained the study to the participant and answered any questions and concerns.

Name of Investigator: _____ Date: _____

Investigator's signature: _____

Inquiries on ethical considerations can be gotten from:

Prof. Chindia,

Secretary, KNH/UON-ERC,

Kenyatta National Hospital,

Hospital Rd, along Ngong Rd,

P.O.Box 20723, Nairobi

Tel: (020) 726300-9

Fax: 725272

To indicate that you understand the conditions of this study and that you consent to participate in it, please sign or put your thumbprint in the space provided below.

I confirm that the study has been fully explained to me and I give full consent to participate in it.

Participant's name: _____

Signature/thumbprint: _____

APPENDIX 2: FOMU YA IDHINI

<u>Kichwa:</u> HALI YA AFYA NA UBORA WA MAISHA KWA WAGONJWA WANAOUGUA ASILI YA MAUMIVU YA MGONGO YA MUDA MREFU

<u>Mpelelezi:</u> Dr P. Gituri Mwaingwa

<u>Wasimamizi:</u> Dr V. Mutiso na Dr. T. Mogire

<u>Maono ya mpelelezi:</u> Mpelelezi angependa kukushukuru kwa wakati wako na kumpa nafasi ya kusoma fomu hii. Fomu hii itakupa maelezo kuhusu utafiti huu ambayo itakusaidia kuamua kama utahusika katika utafiti huu. Usipoelewa lugha hii, utatafsiriwa katika ile lugha ambayo unaelewa.

<u>Utangulizi:</u> Unaulizwa kushiriki katika utafiti huu kuhusu athari za maumivu ya mgongo kwenye vipimo mbalimbali mtu binafsi kama hali ya akili, utendaji kazi, ustawi wa jamii na mtazamo wa kuhisi maumivu. Lengo kuu la utafiti huu ni kutathmini athari hii kwa mgonjwa anayeugua maumivu hii ya mgongo.

<u>Utaratibu:</u> Kama utakubali kuwa sehemu ya utafiti huu, nitakuuliza maswali, mengine yatakuwa nyeti, kuhusu kiwango chako cha elimu na baadhi ya adhari za maumivu ya mgongo kwa afya yako. Maswali haya yatachukua muda ya dakika kumi tu.

<u>Matokeo ya faida:</u> Matokeo ya utafiti huu yatatumika mojawapo katika kuhitimu kwangu katika kitivo cha upasuaji wa mifupa katika chuo Kikuu cha Nairobi, na kuchapishwa kwenye jarida mbalimbali.

<u>Usiri:</u> Kama utakubali kuwa sehemu ya utafiti huu, taarifa ambayo utatoa utatumiwa katika utafiti huu peke yake na wasiohusika kaatika kuchukua taarifa huu hawatapata kujua taarifa unayotupa. Majina yako hayatatumiwa katika fomu ya taarifa, na yataonekana tu katika fomu ya idhini.

Ningependa kuzingatia kuwa matibabu yako au ya mtoto wako hautaathirika kutokana na uamuzi wako wa kukataa au kushiriki katika utafiti huu. Umepewa uhuru na nafasi ya kuacha kuhusika katika utafiti huu bila gharama yoyote wakati wowote utafiti huu unapoendelea.

Mimi mpelelezi wa utafiti huu ninathibitisha kuwa nimemwelezea mhusika wa utafiti huu kwa ukamilifu kuhusu kuhusika kwa utafiti.

Jina la mpelelezi: _____ Tarehe: _____

Sahihi la mpelelezi: _____

Nimepewa kibali kutoka Utafiti na Kamati za Maadili ya Kituo Kikuu cha Nairobi na Hospitali Kuu ya Kenyatta ya kufanya utafiti huu. Maoni juu ya masuala ya kimaadili inaweza kupatikana kutoka:

Prof. Chindia,

Katibu, KNH/UON-ERC,

Hospitali kuu ya Kenyatta,

Hospital Rd, karibu na Ngong Rd,

S.L.P. 20723, Nairobi

Nambari ya simu: (020) 726300-9

Fax: 725272

Kuonyesha ya kwamba umeelewa hali ya utafiti huu na umetupatia ridhaa ya kushiriki katika utafiti huu, tafadhali saini au weka kidole chako katika nafasi iliyotolewa hapo chini:

Mimi ninathibitisha kuwa utafiti huu umeelezwa kwangu mimi vizuri na ninaitikiea na kupeana ridhaa ya kuhusika katika utafiti huu.

Jina la mhusika: _____ Tarehe: _____

Sahihi yangu au kidole cha mhusika: _____

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APPENDIX 3: DATA COLLECTION SHEET

Patient Study Number: _____   Sex: M ☐   F ☐

Age: _____   Hospital Number: _____

Occupation: _____

Work status: Currently working ☐   not currently working ☐

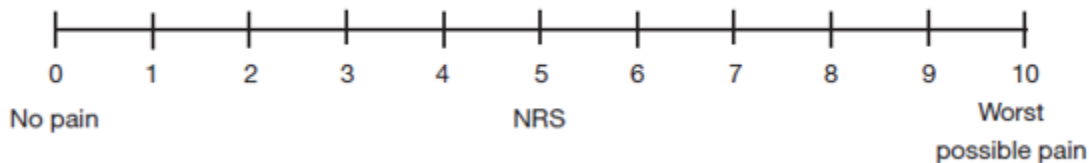Time off work due to disease: _____

Smoking cigarettes: Yes ☐   No ☐

Use of Alcohol: Never drinkers ☐   Former drinkers ☐   Current drinkers ☐

Lumbosacral   diagnosis   made   by MRI: _____

Worst pain score in the last 6 weeks: (1-10) _____

```
  |----+----+----+----+----+----+----+----+----+----|
  0    1    2    3    4    5    6    7    8    9    10
No pain                      NRS                  Worst
                                          possible pain
```

SF-12 Questionnaire

This Questionnaire asks for your views concerning your health. **Answer each question by choosing just one answer**. If you feel unsure about how to answer a question, please give the best answer you can

1. **In general, would you say your health is**:

☐$_1$ Excellent   ☐$_2$ Very good   ☐$_3$ Good   ☐$_4$ Fair   ☐$_5$ Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	YES, limited a lot	YES, limited a little	NO, not limited at all
2. **Moderate activities** such as moving a table, pushing	☐$_1$	☐$_2$	☐$_3$

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a vacuum cleaner, bowling, or playing golf.

3. Climbing **several** flights of stairs. $\square_1$ $\square_2$ $\square_3$

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	YES	**NO**
4. **Accomplished less** than you would like.	$\square_1$	$\square_2$
5. Were limited in the **kind** of work or other activities.	$\square_1$	$\square_2$

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	YES	**NO**
6. **Accomplished less** than you would like.	$\square_1$	$\square_2$
7. Did work or activities **less carefully than usual**.	$\square_1$	$\square_2$

8. **During the <u>past 4 weeks</u>, how much <u>did pain interfere</u> with your normal work (including work outside the home and housework)?**

$\square_1$ Not at all $\square_2$ A little bit $\square_3$ Moderately $\square_4$ Quite a bit $\square_5$ Extremely

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$	$\square_6$
10. Did you have a lot of energy?	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$	$\square_6$
11. Have you felt down-hearted and blue?	$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$	$\square_6$

12. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?**

$\square_1$ All of the time $\square_2$ Most of the time $\square_3$ Some of the time $\square_4$ A little of the time $\square_5$ None of the time

Thank you for completing these questions!

APPENDIX 4: ETHICAL APPROVAL FORM

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

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KENYATTA NATIONAL HOSPITAL
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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/36

3rd February 2017

Dr. Philip Gituri Mwawingwa
Reg. No.H58/69307/2011
Dept.of Orthopaedic
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Gituri

REVISED RESEARCH PROPOSAL: "QUALITY OF LIFE IN PATIENTS WITH CHRONIC LOW BACK PAIN AS
SEEN AT KENYATTA NATIONAL HOSPITAL   (P650/09/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 3rd February 2017 – 2nd February 2018.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN
   ERC before implementation.
c) 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
   notification.
d) 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.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period.
   (_Attach a comprehensive progress report to support the renewal_).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of
   shipment.
g) Submission of an _executive summary_ report within 90 days upon completion of the study.
   This information will form part of the data base that will be consulted in future when processing related
   research studies so as to minimize chances of study duplication and/ or plagiarism.

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For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c.   The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH- UoN ERC
The Dean, School of Medicine, UoN
The Chair, Dept.of Orthopaedics, UoN
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