UNIVERSITY OF NAIROBI

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS

THE BURDEN OF DEPRESSION AMONG AMBULATORY KNEE AND HIP OSTEOARTHRITIS PATIENTS AT THE KENYATTA NATIONAL HOSPITAL

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DECLARATION

I hereby certify that this is my original work. All resources and materials used or quoted have been indicated and acknowledged by means of reference. This work has not been presented for the award of a degree in any other Institution.

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DEDICATION

This work is dedicated to my loving parents Mr. and Mrs. Obiero Bosire.

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I would like to thank my supervisors who have been very supportive and offered me guidance throughout the entire process of this study.

Many thanks to my parents for their encouragement, prayers, always believing in me, and pushing me to do the very best in whatever I do. You have been a strong pillar in my life and excellent role models. I couldn't ask for more.

To my siblings and close friends may God bless you abundantly for all the moral support you have accorded me throughout this process.

To my classmates and other faculty, thank you for your support.

To my niece Patience, thank you for the English to Swahili translation. You have been very selfless and you sacrificed your time and energy in great measure. No words can explain my gratitude. Be blessed abundantly.

Last but not least I would like to thank the Almighty for seeing me through this. May His name be glorified.

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LIST OF ABBREVIATIONS

ACR: American College of Rheumatology

ACTH: Adrenocorticotropic hormone

BMI: Body Mass Index

CBT: Cognitive Behavior Therapy

CRH: Corticotrophin Release Hormone

DSM-IV: Diagnostic and Statistical Manual IV

HPA: Hypothalamic Pituitary Adrenal Axis

IL: Interleukin

KNH: Kenyatta National Hospital

KHOA: Knee and Hip Osteoarthritis

LAI: Lequesne Algofunctional Index

MAO: Monoamine Oxidase Inhibitors

OA: Osteoarthritis

PHQ9: Patient Health Questionnaire 9

PI: Principal investigator

PRIME-MD: Prime Care Evaluation of Mental Disorders

SPSS: Statistical Package for the Social Science

SSRI: Selective Serotonin Reuptake Inhibitors

SNRI: Serotonin and nor epinephrine Reuptake Inhibitors

TCA: Tricyclic Antidepressants

WHO: World Health Organization

WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

DEFINITION OF KEY TERMS

Osteoarthritis: A degenerative joint disorder arising from biochemical breakdown of articular cartilage and surrounding joint structures

Depression: A mood disorder characterized by loss of interest in pleasurable activities and persistent low mood causing significant impairment of daily life

Obesity: Excessive accumulation of body fat

Body mass index: Measurement of a person's weight with respect to their height

Pathophysiology: Disordered mechanical, physical and biochemical changes associated with a disease process

Prevalence: Proportion of a given population with a particular condition at a specific point in time

ABSTRACT

Background: Osteoarthritis (OA) is a degenerative joint disorder arising from biochemical breakdown of articular cartilage and surrounding joint structures. It is the most prevalent type of arthritis and a leading cause of disability world over (1, 2). Prevalence of depression among patients with osteoarthritis has been shown to be higher compared to those without OA(3). Depression is associated with increased pain perception and reduced physical activity leading to increased risk of obesity which further worsens the OA. Prompt diagnosis and treatment of depression among this population improves disease outcomes(4). This has however not been documented in Kenya. The aim of this study was to establish the prevalence of depression among knee and hip osteoarthritis patients and its association with disease severity.

Objectives: The main objective of this study was to determine the burden of depression among patients with knee and hip osteoarthritis (KHOA) at the KNH orthopedic and rheumatology clinic. The secondary objective was to determine factors associated with depression in patients with KHOA and the relationship between depression and severity of OA.

Methodology: This was a cross sectional descriptive study carried out at the rheumatology and orthopedic clinic in KNH over a period of 1.5 months. The study population was adults aged 18 years and above on follow up for knee or hip osteoarthritis (KHOA).Patients that met the inclusion criteria and gave a written informed consent were enrolled into the study. A study proforma was used to obtain socio-demographic and clinical data. Clinical assessment of the patients BMI was done using a calibrated weighing scale and stadiometer. The patient health questionnaire 9 (PHQ-9) was used to establish presence and degree of depression among participants. The Lequesne algofunctional index was used to determine OA disease severity. Data obtained was entered and analyzed using SPSS version 21.0, Chicago- Illinois.

The prevalence of depression was calculated as a proportion of patients with any degree of depression and presented as a percentage. Chi-square test was used to determine the association between presence of depression, and socio-demographic and clinical characteristics.

Results: This study involved 164 KHOA patients with a mean age of 59.4±11.1 years and a sex ratio (M:F) of 1:1.7. The prevalence of depression was 17.1% of which 12.8% had mild depression, 3.1% moderate and 1.2% severe. Obesity (p=0.021) and employment status (p=0.023) had a significant association with depression. There was a strong correlation between KHOA disease severity and depression (r 0.779, p=<0.0001).

Conclusion: The prevalence of depression is relatively high among ambulatory KHOA patients at KNH. Majority of the participants with depression had mild form of the disease. Participants who were unemployed and obese had increased proportion of depression. There was a strong positive correlation between depression and KHOA disease severity.

CHAPTER 0NE

1.0 INTRODUCTION AND PROBLEM STATEMENT

1.1 INTRODUCTION

Osteoarthritis is a progressive degenerative disorder of the joints arising from the biochemical breakdown of articular cartilage and surrounding joint structures. It occurs as a result of an inflammatory process within the joint leading to release of metalloproteinase that cause matrix degradation thus cartilage degeneration. This then leads to exposure of underlying bone which undergoes cystic degeneration. Surrounding neuromuscular apparatus is also involved. These changes occur as a result of an imbalance between repair and breakdown of joint tissue. Primary symptoms include joint pain, stiffness and limitation of movement. It predominantly involves the weight bearing joints e.g. Knee, hip and the spine, the knee being the most common site. OA has been on the rise with the increase in life expectancy and obesity rates world over(5). Worldwide, 10-15% of adults over 60 years have some degree of osteoarthritis (WHO). Prevalence of OA at KNH is around 9.6%(6)

Depression is a mood disorder characterized by loss of interest in pleasurable activities and persistent low mood causing significant impairment of daily life. Other symptoms include feeling of guilt, reduced self -esteem, suicidal tendencies, sleep and psychomotor disturbances. Depression results from a complex interaction of social, biological and psychological factors. It affects more than 350 million people worldwide and is ranked as the fourth leading cause of disability worldwide. It is projected that by 2020 depression will be the second leading cause of disability worldwide (WHO). It is estimated that about 800000 people commit suicide globally on an annual basis(7). The lifetime prevalence of depression is about 20% in the general population worldwide. The M:F ratio is about 1.7:1(8)

Depression arises as a reactive condition in osteoarthritis in response to the disabling physical and social wellbeing from the pain experience in these patients. The rise in pro inflammatory cytokines that occurs in osteoarthritis has also been implicated as a pathological mechanism of depression. Interleukin 1 beta has been shown to decrease neurogenesis with reduced hippocampal cell proliferation leading to anhedonic effects(9). Patients with osteoarthritis have a fourfold increased risk of developing depression.

OA patients who are also depressed tend to be less motivated, have poorer disability scores and are less compliant to their medication. Depression has been shown to be a potential barrier to physical activity in OA patients (10).This is important since physical activity reduces pain, disability and obesity among this population(11). Obesity increases the risk of other lifestyle diseases in these patients e.g. type 2 diabetes mellitus and cardiac disease. The interplay between depression and osteoarthritis ends up becoming a vicious cycle leading to high rates of healthcare utilization with increased costs to both the patient and society at large. Depression still remains largely unrecognized by health care providers in patients with osteoarthritis thus leading to poorer patient outcomes. Prompt diagnosis and treatment of depression will lead to less OA related morbidity and mortality(12).

1.2 PROBLEM STATEMENT

OA is the most common type of arthritis world over. It has been shown to be a leading cause of disability leading to loss of productivity years and an increase in economic burden both at individual and societal level. The prevalence of depression in Kenya has been on the rise. According to a 2017 report by WHO 1.9 million Kenyans were found to be suffering from depression. Kenya was ranked as the sixth most depressed nation in Africa. Individuals with OA have been shown to have increased risk of developing depression. Osteoarthritic patients who are also depressed have been shown to have poorer disease outcomes. Despite depression being a treatable illness whose prompt diagnosis and treatment leads to less OA related morbidity and mortality, it remains largely unrecognized even by healthcare providers.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 BACKGROUND

2.1.1 Pathophysiology of osteoarthritis

OA occurs as a result of interplay between mechanical, biochemical and genetic factors leading to degradation of articular cartilage, remodeling of subcondral bone and inflammation of synovial membrane. These factors initiate an imbalance between matrix synthesis and degradation leading to chondral loss with impaired cartilage self-repair. The activity of degradation enzymes is balanced by that of synthetic enzymes in healthy cartilage and is usually regulated by tissue inhibitors of matrix metalloproteinases. Chronic joint stress leads to tissue injury with an increase in pro inflammatory cytokines e.g. Interleukin (IL) 1, 6, 8, 11, 17 and TNF alpha. These cytokines lead to a cascade whose net effect on chondrocyte metabolism is increased synthesis of aggrecanases, matrix metalloproteinases, and decreased synthesis of matrix metalloproteinases inhibitors. Matrix metalloproteinases cause degradation of collagen and gelatin while aggrecanases cause degradation of aggrecans (collagen specific proteoglycan). This leads to impaired cartilage biomechanical properties i.e. compressibility and elasticity.IL 1 beta and TNF alpha also stimulates nitric oxide release which inhibits collagen and proteoglycan synthesis, increases matrix metalloproteinases activity and induces apoptosis of chondrocytes further accelerating the degradation process since chondrocytes are not regenerated.

Chondrocytes respond to the degenerative consequences by releasing anti- inflammatory cytokines IL4, 10 and 13. Overtime, this is overpowered by the degradation effects as chondrocyte apoptosis and malfunction progresses leading to a net destruction of cartilage(13)(14). The inflammatory process also causes synovial membrane destruction and bone remodeling.

The net effect of the above process is progressive cartilage destruction with synovial membrane inflammation and subcondral bone remodeling thus development of osteoarthritis.

2.1.2 Pathophysiology of depression

Depression results from an interplay of environmental and genetic factors. Several theories have been postulated to explain the underlying mechanism in the development of depression. Some of these include the hypothalamic pituitary adrenal axis (HPA) hyperactivity(15), monoamine theory(16), inflammation theory(17). It is postulated that depressed individuals have malfunctioning glucocorticoid receptors thus impaired negative feedback mechanisms. Persistently elevated cortisol levels leads to calcium influx through opening of the voltage gated calcium channels which stimulates enzymatic neural tissue degradation. High cortisol levels also causes a reduction in brain derived neurotropic factor in the hippocampus thus impaired neurogenesis leading to inadequate regulation of HPA by the hippocampus. Corticotrophin releasing hormone (CRH) has also been shown to have direct toxic effects to the hippocampal tissue. Depressed individuals have been shown to have reduced monoamine levels. Dopamine, serotonin and norepinephrine influence brain circuits involved in regulation of mood. Pro inflammatory cytokines have been shown to reduce neurogenesis in the hippocampus and amygdala.

2.1.3 Link between Osteoarthritis and depression

The relation between OA and depression seems to be bidirectional. OA leads to chronic joint inflammation causing pain which is both physically and emotionally stressful. Inflammation causes a painful stimulus within the joint which is detected by nociceptors. These then generate electrical impulses which travel via the peripheral nerves to synapse at the dorsal horn of the spinal cord. From here the impulse travels via the spinothalamic tract to the brain. The neurosecretory cells within the hypothalamus are then stimulated to secrete CRH which in turn stimulates the anterior pituitary gland to produce adrenocorticotropic hormone (ACTH). The ACTH stimulates production of cortisol from the

zona fasiculata of the adrenal gland. Cortisol stimulates tryptophan oxygenase which leads to reduced tryptophan levels. Tryptophan is used in the synthesis of serotonin thus a high cortisol level causes reduced serotonin levels. Reduced serotonin levels leads to sleep disturbances, low self-esteem, low mood, reduced sexual desire and poor memory hence development of depression. High cortisol level has also been associated with a reduction of dopamine levels in the brain which also leads to development of depression. High cortisol level is associated with insulin resistance, visceral obesity, hypertension and dyslipidemia hence an increased risk of lifestyle diseases in osteoarthritic patients.

Depression has been shown to be a barrier to physical activity (10). This together with poor feeding habits further worsens the obesity. Increased joint stress from the excess weight causes further progression of osteoarthritis. This then ends up being a vicious cycle with progression of osteoarthritis, depression and obesity.

2.2 PREVALENCE OF DEPRESSION IN OSTEOARTHRITIS

A cross -sectional study done in Germany among 1021 individuals with osteoarthritis showed high BMI, perceived pain and physical limitation were predictors of depression in osteoarthritis(18). In 2016, Mehdi et al conducted a study on predictors of comorbid depression in Iran. They found there is a fourfold increased risk of depression in patients with osteoarthritis compared to healthy individuals. Reported prevalence of depression in OA varies from 4.1% to 61.3%(19).The prevalence rate depends on the study setting, design and tools used. Low socioeconomic status, low education level, substance use and female gender are associated with an increased likelihood of depression. A meta- analysis done using 49 studies, representing 15, 855 patients with 59% women, from several databases in January 2015 showed a pooled prevalence of depression of 19.9%(3). The mean age for the study subjects was 65.2 years.

An observational multicenter study done in Spain in 2016 showed a depression prevalence of 17.4% in individuals with osteoarthritis against 5% in healthy controls matched for sex and age. Study population consisted of 576 healthy controls and 576 with osteoarthritis. The mean age was 67.9 years in the OA group, 67.8 in the controls and 70.3% were women in both groups(20). A cross-sectional descriptive study conducted in 2015 at the Toronto western teaching hospital on 475 patients with end stage knee or hip osteoarthritis showed a 12.2% prevalence of depression. This was done using the hospital anxiety depression scale. The mean age of the study participants was 64.7 years with 57% being female. Having a high BMI, being female and having other comorbidities increased the risk of developing depression(21).

In 2007, T. Rosemann et al conducted a cross-sectional study among 1021 primary care patients with osteoarthritis in Germany. They found a depression prevalence of 19.76% and 19.16% among males and females respectively(22). Joanna Sale et al carried out a cross-sectional study among 1227 individuals with osteoarthritis to assess the relationship between osteoarthritis and depression. They found a depression prevalence of 21.3%(23). In 2014, Yilmaz H et al conducted a study to determine the prevalence of depression and its relevance to radiological and clinical characteristics in adults with OA. The study included 138 patients that were 65 years and older who were then sex and age matched with 82 healthy controls. They found a depression prevalence of 49.3% among the patients against 12.3% for the controls(24)

A study done in Ibadan hospital, Nigeria in 2015 among 80 patients with knee osteoarthritis found a 28.8% prevalence of depression using the Beck`s depression inventory (BDI). The mean age of the study population was 62.69 years. They also found a negative linear relationship between pain and physical function(25).

2.3 SOCIO-DEMOGRAPHIC FACTORS ASSOCIATED WITH DEPRESSION IN OSTEOARTHRITIS

Research on predictors of developing depression in OA has shown that certain socio- demographic characteristics are associated with development of depression. These include; sex, age, marital status, employment status, substance abuse, BMI and level of education. A retrospective cross-sectional study done in India in 2018, showed increased depression prevalence among females. The study sample size was 212 with 63 years as the mean age. Prevalence of depression among females was 23.8% compared to 15.3% in males(26). In 2016, Moghtadaei et al did a study in Iran which revealed individuals who were married, employed and physically active had lower depression scores(27). A study done by Dexter P et al among 108 individuals with OA of the knee and hip found younger and less educated subjects had relatively more depressive symptoms(28).

2.4 DEPRESSION AND OSTEOARTHRITIS DISEASE SEVERITY

Several studies done world over have linked comorbid depression with poor osteoarthritis disease outcomes. Depression has also been shown to impact negatively on quality of life of these individuals(29). A meta- analysis done on 38 studies found patients with comorbid depression experienced more pain, had frequent hospital visits and reported less optimal outcomes. Depression was also shown to adversely affect surgical outcomes(30). A retrospective study done in New York among 1000 patients with hip osteoarthritis showed 9% of the individuals had mood disorders and they were more physically impaired compared to the patients without mood disorders. These patients also had slower recovery after hip replacement surgery(31). A cross sectional quantitative study in Sao Paulo among 75 women showed more pain and difficulty in daily life activities in the OA group in comparison

to the control group. The study consisted of 75 women 40 of whom had OA. Mean age was 68 years for the OA group and 65 years for the control. The BDI was used to assess for depression(32).

2.5 TREATMENT OF DEPRESSION IN OSTEOARTHRITIS

Depression is a significant comorbidity in patients with OA. A focused collaborative depression care intervention not only reduces depression but improves arthritis related morbidity and quality of life. Early diagnosis with appropriate treatment of depression in these patients has been shown to improve outcomes(33). Use of both pharmacological and non-pharmacological methods has been shown to be effective.

2.5.1 Non pharmacological methods

Non pharmacological methods have been shown to be just as effective as pharmacological methods in treatment of mild and moderate depression. Some of these interventions include; psychotherapy and physical activity programs

Psychotherapy

This is a collaborative form of treatment between a psychologist and a patient, where the psychologist uses scientifically validated procedures to help patients develop healthier and more effective habits. Examples of the psychotherapy techniques include; cognitive behavior therapy (CBT), psychodynamic therapy and supportive psychotherapy. A systematic review of 14 studies, done on treatment of depression in patients with OA, showed CBT and integrated depression management were associated with a reduction of depressed symptoms(34). A randomized controlled trial in 69 adults with OA of the knee and depression showed internet based CBT reduces depressive symptoms and improves pain, stiffness and physical function(35)

Physical activity

Structured exercise has been shown to alleviate depressive symptoms of clinical depression. Exercise is thought to increase release of serotonin, norepinephrine, dopamine and beta endorphins which are all associated with a happier mood. Physical activity also causes destruction from worry and depressed thoughts while enhancing self-efficacy(36). The recommendation is to do at least 30 minutes of aerobic exercise four days a week.

2.5.2 Pharmacological methods

This has been shown to be effective especially for severe depression. It involves the use of antidepressants e.g. selective serotonin re uptake inhibitors (SSRI), monoamine oxidase inhibitors (MAO), serotonin and nor epinephrine reuptake inhibitors (SNRI), and tricyclic antidepressants (TCA). The antidepressants not only alleviate depression but osteoarthritis related joint pain. They have been shown to impact central pain processing mechanisms(37).

2.6 SCREENING TOOL FOR DEPRESSION (PATIENT HEALTH QUESTIONNAIRE 9)

The use of screening tools to assess for presence of depression has increased overtime both in the clinical and research setup. These are usually used as a quick and reliable option in depression assessment. Some of these tools include PHQ-9, Beck's depression inventory, Major depression inventory, Hamilton depression rating scale, Zung self rating depression scale and Geriatric depression scale.

PHQ-9 is a multipurpose tool for screening, monitoring and measuring depression severity. It Incorporates the Diagnostic and statistical manual 4th edition (DSM- IV) depression diagnostic criteria into a brief self reporting tool. It is a self-administered version of the primary care evaluation of mental disorders (PRIME-MD). It has been validated in many studies(38)(39). It is now the most commonly

used version in both research and clinical settings. It is easy to administer and score, takes a short period to administer and is able to assess symptom severity as well.

The PHQ-9 consists of nine items on a 4 point scale i.e. from 0 ("not at all") to 3 ("nearly every day"). It has high sensitivity and specificity for identifying cases of depression and is sensitive to change overtime thus can be used as an outcome measure as well(40). It can be used as a tool for screening, with the recommended cut off score 10 being found to have a specificity and sensitivity of 88% for diagnosis of clinical depression or major depressive disorder(41). It is used to grade depression from mild to severe based on the scores. Mild depression has a score of 10-14, moderate15-19 and severe 20-27. When being used for monitoring, a drop of 5 points is necessary to quantify for a clinically significant response to treatment for depression.

TABLE 2.1: SHOWING SEVERITY SCORES AND TREATMENT ACTION FOR DEPRESSION

PHQ-9 Score	Depression severity	Treatment recommendation
0-4	None or minimal symptoms	No action
5-9	Mild symptoms	Follow up and repeat PHQ-9 later
10	Major depression (MD)	
10-14	Mild MD	Consider psychotherapy/ pharmacotherapy
15-19	Moderate MD	Active treatment with psychotherapy and pharmacotherapy
20-27	Severe MD	Immediate initiation of psychotherapy and pharmacotherapy and refer to a mental health specialist

The PHQ9 has been validated in various regions e.g. Africa, Europe and Asia as a tool for screening for depression in patients with chronic illnesses. In 2009, Omoro SA et al did a study to validate and translate PHQ-9 to a Swahili version. The study included 48 patients with head and neck cancer

attending the ENT clinic at KNH. They found the Swahili version had a good internal consistency of 0.80 and a test-retest reliability of 0.71(42). In 2009, Monahan et al did a study among 347 patients with HIV in western Kenya to validate the PHQ9. They found the PHQ-9 had an internal consistency of 0.78 and a test retest reliability of 0.59 thus concluded the PHQ-9 appears valid for assessing depression(43). Gelaye B et al did a study to validate the PHQ-9 as a screening and diagnostic tool in 2013 at a referral hospital in Ethiopia among medical outpatients. They reported the PHQ-9 had an internal consistency of 0.81 and a test retest reliability of 0.92(44). In 2017, M Englbretcht et al did a study in Germany to validate different standardized questionnaires used in depression screening in rheumatoid arthritis patients. They found the PHQ-9 to have a sensitivity of 80%, specificity of 75% and a test retest reliability of 0.63(45)

2.7 ASSESSMENT OF OSTEOARTHRITIS DISEASE SEVERITY- LEQUESNE ALGOFUNCTIONAL INDEX (LAI)

The Lequesne algofunctional index was developed by Michel Lequesne in the early 80's as an outcome and disease severity measuring tool. The two indices to assess knee and hip osteoarthritis are almost similar with slight differences in structure (46). Each of the indices consists of 3 sections assessing maximum distance walked, pain and discomfort and activities of daily living. The total score for each of the areas assessed is 8 points thus a total maximum score of 24 points. Level of disease severity is then graded as follows: a score of 0 for no limitation, 1-8 mild, 9-16 moderate and 17 and above as severe. This tool has been validated and used in different regions worldwide. It has also been translated into various languages while maintaining its reliability e.g. German(47), French, Chinese, Turkey and Korean.

M. Faucher et al did a study to assess the test retest reliability and contrast validity of modified Lequesne index in knee osteoarthritis. They concluded that modified Lequesne i.e. the French version,

had sufficient psychometric properties to assess osteoarthritis severity(48). In 2007, Xie F et al conducted a study to validate the Singapore, English and Chinese version of the LAI of the knee. They concluded it was a reliable tool that could be used as a global index in health related quality of life(49).

Bae S et al studied the validation and cross cultural adaptation of Korean WOMAC (Western Ontario and Mc Master universities osteoarthritis index) and Lequesne osteoarthritis indices. The test retest reliability for Lequesne was 0.87 and a Cronbach standardized alpha of 0.75(50). A study done in Greece to validate LAI in hip and knee osteoarthritis patients found a Cronbach's alpha of 0.63- 0.74 and 0.74-0.8 for hip and knee osteoarthritis respectively(51). A study done in Turkey in 2010 to assess the reliability and validity of LAI found a test retest reliability of 0.51-0.85 and 0.61- 0.71 for hip and knee osteoarthritis respectively(52)In 2004 Mohammad G et al did a study on the construct validity of translated LAI in Tunisia among knee osteoarthritic patients. They found the inter rater reliability was excellent with interclass correlation coefficient of 0.91. They concluded the translated questionnaire was both valid and reliable(53).

2.8 JUSTIFICATION OF THE STUDY

The prevalence of osteoarthritis has been on the rise in our set up with the increase in life expectancy. From several studies done worldwide among osteoarthritis patients, depression has been shown to have an impact on both disease severity and quality of life. Identifying and treating depression early reduces the magnitude of osteoarthritis disability thus improving physical activity leading to a reduced risk of obesity and lifestyle diseases. Despite knowledge from literature on the prognostic value of early detection and treatment of depression among this population, screening is not routinely done. To the best of our knowledge, such a study had not been done in our local setup. This study aimed to fill in this gap by establishing the prevalence of depression among KHOA patients locally.

2.9 SCOPE OF THE STUDY

This study only assessed KHOA patients in KNH's rheumatology and orthopedic clinics. It involved administration of the PHQ9 to assess presence of depression and LAI to grade the severity of OA among the recruited patients. Data on sociodemographic as well as other factors associated with depression among OA patients was also collected during the study.

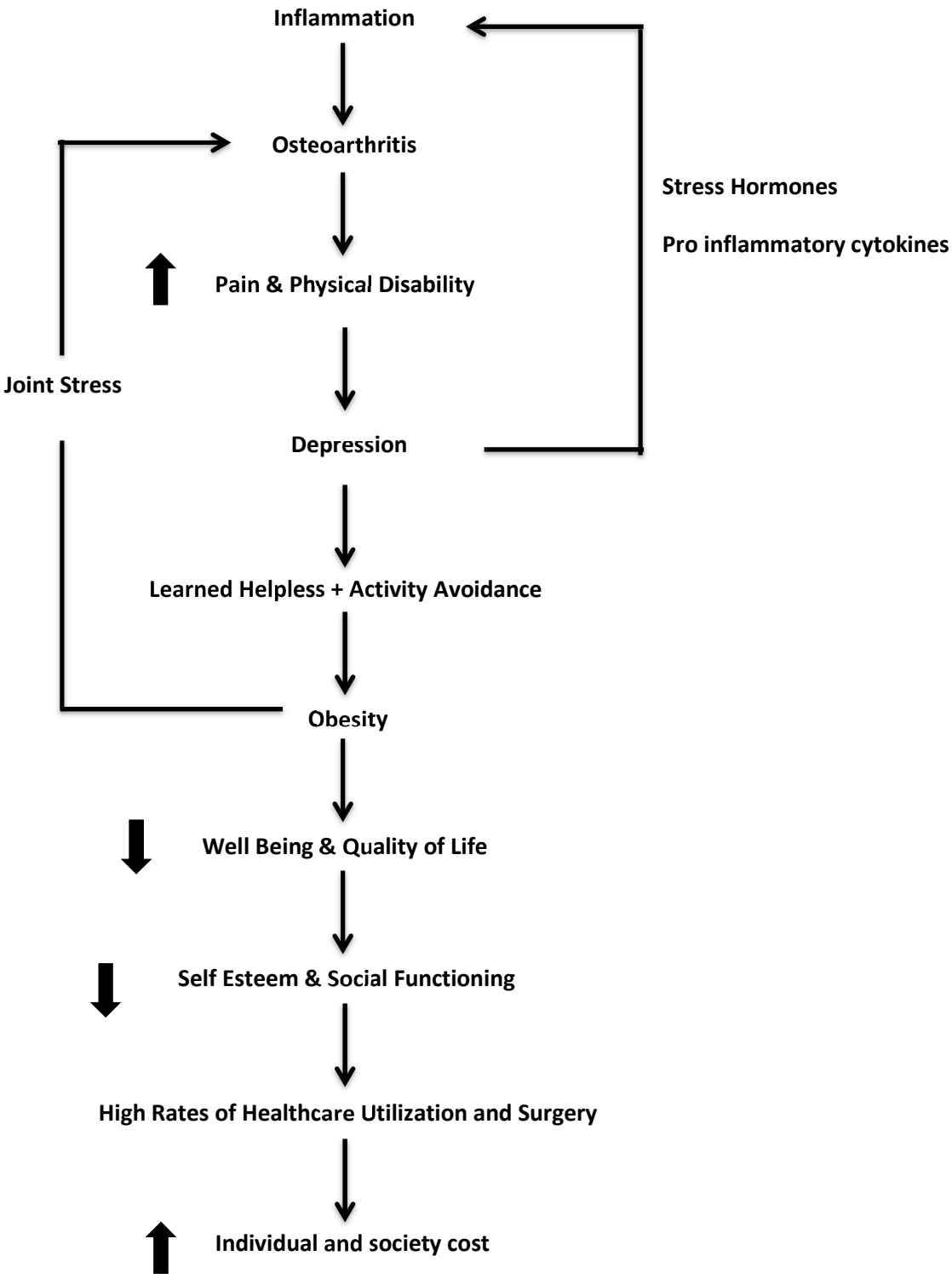
2.10 CONCEPTUAL FRAMEWORK

2.10.1 Narrative

Osteoarthritis and depression seem to have a bidirectional relationship. Chronic joint pain and inflammation leads to up regulation of stress hormones leading to development of depression. The increase in stress hormones further worsens the inflammation within the joints. Depression has also been associated with increase in proinflammatory cytokines which further propagates joint inflammation. Individuals with depression have loss of interest in activities thus exercise avoidance which increases their risk of obesity. Obesity leads to increased joint stress thus worsening the osteoarthritis. This ends up being a vicious cycle leading to worsening of the disease process thus poor quality of life and increased rates of healthcare utilization. Depression is amendable to therapy thus early diagnosis and treatment will reduce the overall disease burden associated with osteoarthritis.

2.10.2 Schematic

FIGURE 2.1: LINK BETWEEN DEPRESSION AND



2.11 RESEARCH QUESTION

What is the burden of depression among ambulatory knee and hip osteoarthritis patients in KNH?

2.12 BROAD OBJECTIVE

To assess the burden of depression among ambulatory knee and hip osteoarthritis patients attending the rheumatology and orthopedic clinics in KNH**.**

2.13 SPECIFIC OBJECTIVES

2.13.1 Primary Objectives

1. To determine the prevalence of depression among ambulatory knee and hip osteoarthritis patients attending the rheumatology and orthopedic clinics at KNH

2. To determine the severity of depression among ambulatory knee and hip osteoarthritis patients attending the rheumatology and orthopedic clinics at KNH

2.13.2 Secondary Objectives

1. To find out factors associated with depression among knee and hip osteoarthritis patients at KNH
2. To determine the association between depression and osteoarthritis disease severity**.**

CHAPTER THREE

3.0 STUDY DESIGN AND METHODOLOGY

3.1 STUDY DESIGN

This was a descriptive cross-sectional study on the burden of depression among ambulatory patients with KHOA in KNH.

3.2 STUDY SITE

The study was carried out at the rheumatology and orthopedic clinics at the Kenyatta national hospital. KNH is Kenya`s largest public teaching and referral hospital located in Upper hill area in Nairobi. Both the rheumatology and orthopedic clinics offer outpatient services to osteoarthritis patients. The rheumatology clinic runs every Thursday from 2 pm while the orthopedic clinic runs every Tuesday, Wednesday, and Friday from 8am. Majority of the patients with osteoarthritis are on follow up at the orthopedic clinic**.**

3.3 STUDY POPULATION

The study population consisted of patients with knee and hip osteoarthritis on follow up at the orthopedic and rheumatology clinics in KNH.

3.3.1 Case definition

Osteoarthritis

A patient aged 18 years and above with a diagnosis of osteoarthritis as per the American college of rheumatology criteria**.**

Depression

A patient with a PHQ9 score of 10 or more was described as having clinical depression.

3.3.2 Inclusion criteria

Patients 18 years and older diagnosed with either knee or hip osteoarthritis as per the ACR criteria

3.3.4 Exclusion criteria

Patients who do not give informed consent

3.4 SAMPLE SIZE DETERMINATION

The following formula (Daniel, 1999) was used to determine the minimum sample size required for prevalence of depression among patients with knee and hip osteoarthritis;

$$n\frac{=Z^2\ x\ P(1-P)}{d^2}$$

Where

n = Desired sample size

Z = Value from standard normal distribution corresponding to desired confidence level (1.96 for 95% CI)

P = the prevalence of depression in OA ranges from 4 – 61.3% world over. P will be considered as a prevalence of 12.2% from a study done by in Toronto teaching hospital.

d = Desired precision (0.05)

$n\frac{=1.96^2\ x\ 0.122(1-0.122)}{0.05^2} = 164$

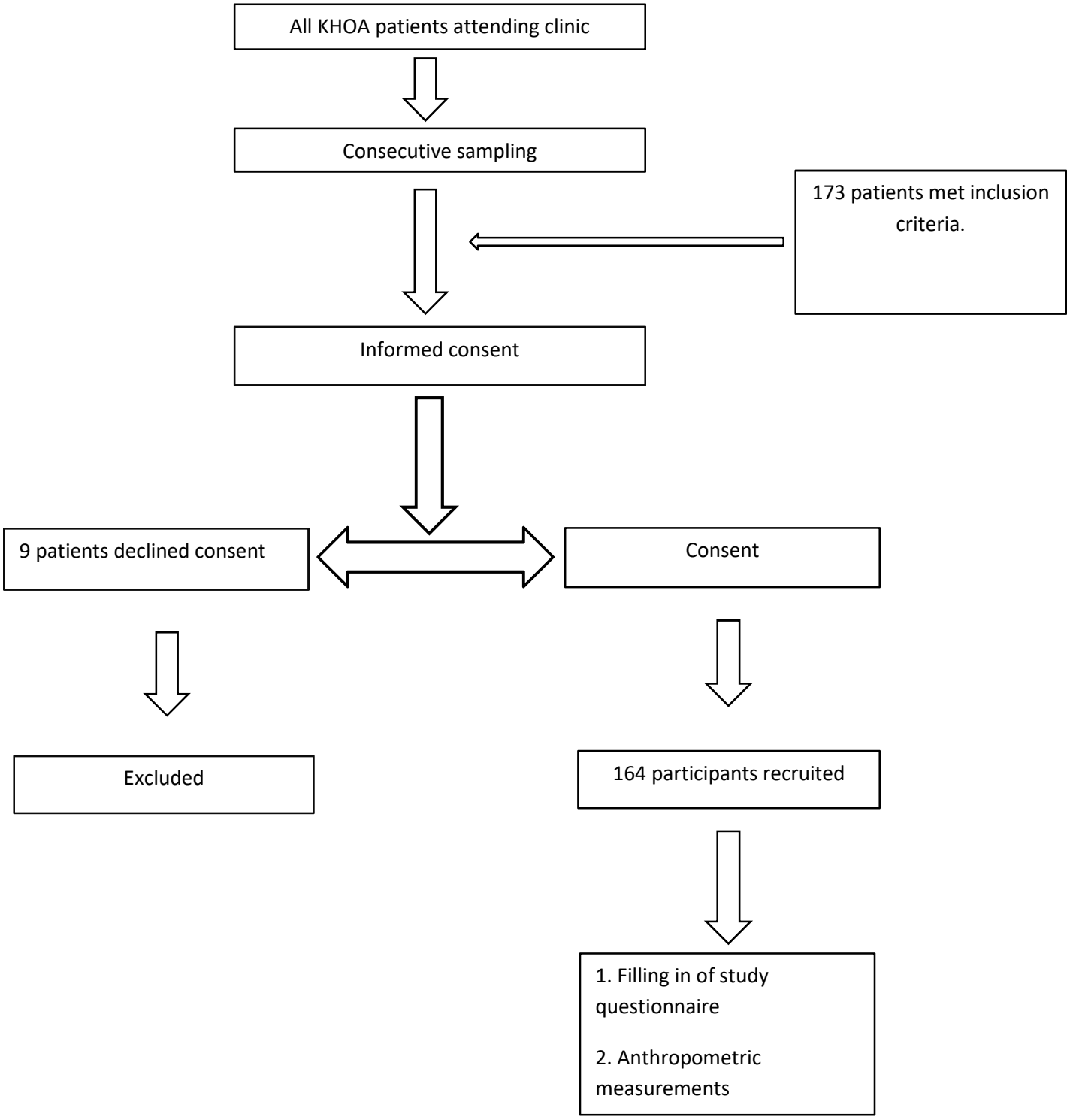
3.5 SAMPLING METHOD

Consecutive sampling technique was used to recruit participants into the study. The principal investigator and the research assistant went to rheumatology and orthopedic clinics on each recruitment day and identified patients with a diagnosis of either knee or hip OA from the files. Each of these patients was approached in order of their arrival time to the clinic and given an opportunity to take part in the study. Patients who gave an informed consent and met the inclusion criteria were recruited into the study. Similar procedure was repeated on each recruitment day until the desired sample size was attained.

3.6 PROCEDURE/ DATA COLLECTION

All patients with either knee or hip osteoarthritis attending the clinics during recruitment days were invited to participate in the study. Those who met the inclusion criteria were explained to the study terms and procedures in a written format (appendix3) and a written informed consent (appendix4) obtained. A study proforma filled in by the patient with the assistance of the PI/ research assistant was used to collect the socio demographic and clinical data. This information was then verified from the patients' medical files. The subjects were given the questionnaire containing the PHQ-9 and the LAI to complete either in English or Kiswahili. Study subjects with difficulty in completing the questionnaire were assisted by either the PI or research assistant. Anthropometric measurements were then taken to determine the participants BMI. The patients' weight was measured using a standard digital weigh scale to the nearest 0.1kg. The height was measured using a stadiometer and values were recorded to the nearest 0.5 centimeters.

FIGURE 3.1: A FLOW CHART OF SUBJECT RECRUITMENT INTO THE STUDY



3.7 STUDY INSTRUMENTS

1. A study proforma was used to collect socio-demographic and clinical data e.g. sex, age, employment status, marital status, level of education, substance abuse and duration of illness.

2. Patient health questionnaire-9was used for screening of depression.

3. The LAI was used to determine the severity of osteoarthritis

4. A standard digital weighing scale for weight measurement and a stadiometer was used to measure height.

3.8 DEFINITION OF STUDY VARIABLES

i. Depression

A patient with a PHQ-9 score of more than or equal to 10 was described as having clinical depression

ii. Severity of depression

Based on the PHQ-9 score, clinical depression was categorized into mild (10-14), moderate (15-19) and severe (20-27)

iii. Osteoarthritis disease severity

This was measured using the total score obtained from the LAI. A score of 0-8 was defined as mild disease, a score of 9-16 was defined as moderate disease and a score of 17-24 was defined as severe disease.

iv. Body mass index

This was calculated and expressed in Kg/m2. Study participants were categorized as underweight (less than 18.5), normal (18.5-24.9), overweight (25-29.9) and obese (more than or =30)

3.9 QUALITY ASSURANCE

The phq-9 is a tool used for screening, diagnosis and assessing the severity of depression and has been validated for use in chronic medical conditions such as osteoarthritis. The questionnaire has also been validated for use worldwide and in our local setup. It has been translated to several languages while maintaining its sensitivity thus very reliable. The LAI has been in use over several years and has been validated for use in osteoarthritis. It has also been translated into different languages while still maintaining its sensitivity. This therefore means the study tools were not only valid but highly reliable. The tools were also very user friendly and easy to fill in which minimized errors.

The study assistant was adequately trained by the PI on the data collection process prior to the onset of the study thus was well vast with the research tools and all clarifications were made beforehand. This minimized errors during the data collection hence reliable data. Data verification was done by the PI at the end of each data collection day.

3.10 ETHICAL CONSIDERATION

Approval and permission were obtained from the department of clinical medicine and therapeutics of the University of Nairobi and KNH research and ethics committee before commencement of data collection. The purpose of the study was explained to all subjects and written informed consent obtained. Patients' confidentiality was maintained by assigning codes to the questionnaires and computerized data. Data collection forms were stored in a lockable cabinet accessible only to the principal investigator.

BMI and PHQ-9 scores were communicated to the patient as well as their primary physician. Patients found to have comorbid depression were referred to the department of mental health for further evaluation and management by a psychiatrist. Privacy was upheld during the data collection process to ensure participants felt comfortable when answering questions that seemed personal. The PI/ research assistant used an isolated cubicle in the clinics when assisting participants to fill in the questionnaire. Participants answered questions at will without being coerced and were free to withdraw from the study at any point without being discriminated. The data collected was not used for any other purpose other than meeting the objectives of this study.

3.11 DATA MANAGEMENT AND ANALYSIS

All data from the study proforma was coded, entered and managed in Microsoft access data base. Data cleaning was conducted at the conclusion of data entry and errors were resolved using the questionnaires. Data analysis was performed using the SPSS Chicago Illinois version 21. Study population was defined using clinical and sociodemographic characteristics. Continuous variables were summarized as mean and standard deviation. Categorical variables e.g. age, sex, employment status, marital status and level of education were presented as proportions. Prevalence and severity of depression was calculated and presented as a percentage with 95% confidence interval. Factors associated with depression were analyzed using chi- square tests. The statistical test was tested at 5% level of significance. A p value of less or equal to 0.05 was interpreted as significant. Results presentation was done using tables and figures where appropriate.

CHAPTER FOUR

4.0 RESULTS

The study was carried out between 20th May 2019 and 30th June 2019 at KNH orthopedic and rheumatology clinic. A total of 173 patients with either knee or hip OA were approached to participate in the study 9 of whom declined to give consent sighting time effort as the reason for declining. Out of the 164 participants, 80(48.8%) had knee OA while 84(51.2 %) had hip OA.

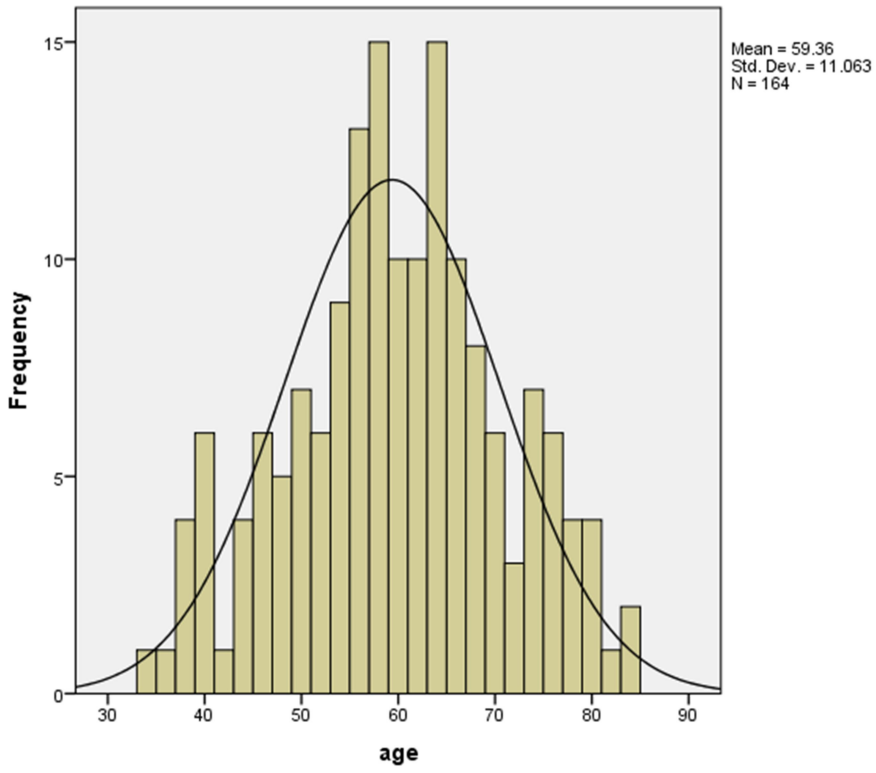
4.1 STUDY POPULATION CHARACTERISTICS

A total of 164 patients participated in the study of whom 60 (36.6%) were males and 104 (63.4%) were females. The male: female ratio was 1: 1.7. The mean age of participants was 59.4±11.1 years. 79.9% were married with the remainder being either single or widowed. 93.9% had some formal education and 74(45.1%) of the participants were employed.

TABLE 4.1: PATIENT SOCIODEMOGRAPHIC CHARACTERISTICS

n = 164	Frequency (%)
Age (years)	
Mean 59.4 ± 11.1	
Median 59.0(15)	
< 60	84(51.2)
≥ 60	80(48.8)
Gender	
M:F 1:1.7 Male	60(36.6)
Female	104(63.40
Education	
Primary	71(43.3)
Secondary	13(7.9)
Tertiary	70(42.7)
None	10(6.1)
Marital status	
Married	131(79.9)
Single	2(1.2)
Widowed	31(18.9)
Employment status	
Yes	74(45.1)
No	90(54.9)

FIGURE 4.1: AGE DISTRIBUTION OF THE STUDY POPULATION



4.2 CLINICAL CHARACTERISTICS OF THE STUDY POPULATION

127(77.4%) of the study participants had been living with OA for < 5 years from the time of diagnosis while the rest had lived with the disease for 5- 10 years. 82(50%) participants were overweight, 73(44.5%) were obese while the rest had normal BMI. 43(26.2%) participants were using recreational substances majority being alcohol i.e. 37(86%) . 114(69.5%) participants had moderate OA, 31(18.9%) severe OA and 19(11.6%) had mild OA.

TABLE 4.2: CLINICAL CHARACTERISTICS OF STUDY PARTICIPANTS

n = 164	Frequency (%)
OA duration	
< 5 years	127(77.4)
5 -10 years	37(22.6)
Substance use	
Yes	43(26.2)
No	121(73.8)
BMI	
Mean 29.8±3.2	
18.5-24.9	9(5.5)
25.0-29.9	82(50)
>=30.0	73(44.5)
OA disease severity(LAI score)	
Mean 12.6±3.9	
Mild: 0-8	19(11.6)
Moderate: 9-16	114(69.5)
Severe: 17-24	31(18.90

4.3 PREVALENCE AND SEVERITY OF DEPRESSION IN KHOA

Out of the total study population 28(17.1%) had clinical depression with a PHQ 9 score of ≥ 10. Among these 21(75%) had mild depression with a PHQ 9 score of between 10-14, 5(17.9%) had moderate with a score of between 15-19 while 2(7.1%) has severe depression with a score between 20-27

The mean age of the participants with depression was 60.0±12.3

Fig 4.2 Prevalence of depression in KHOA patients

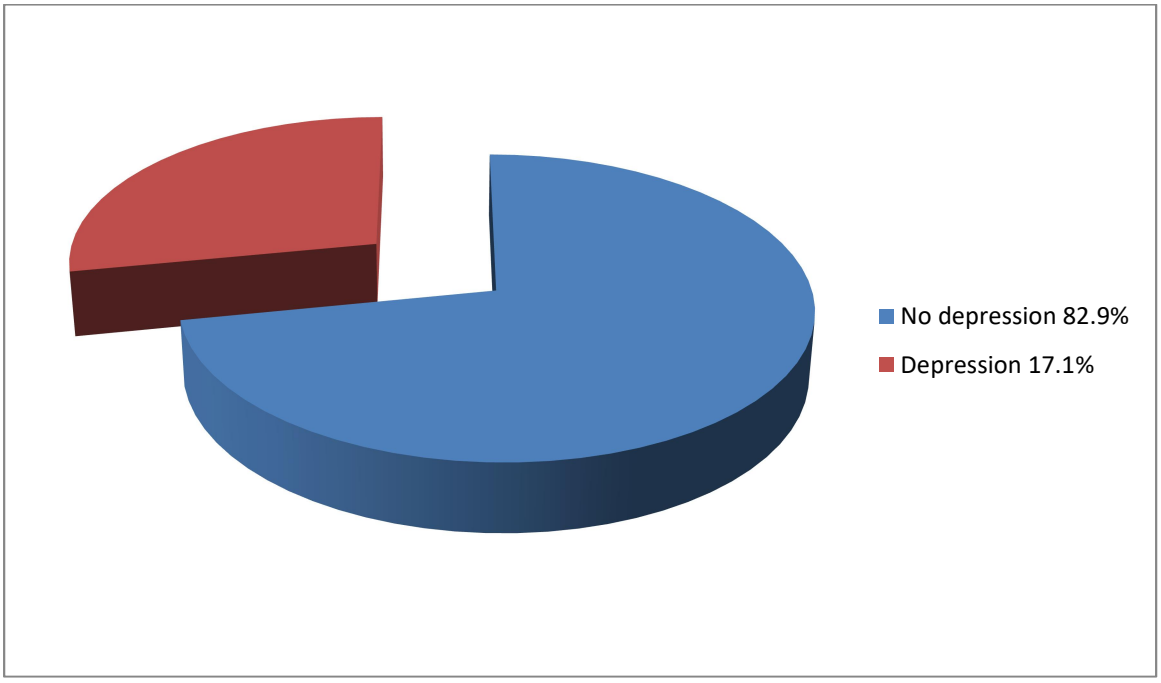
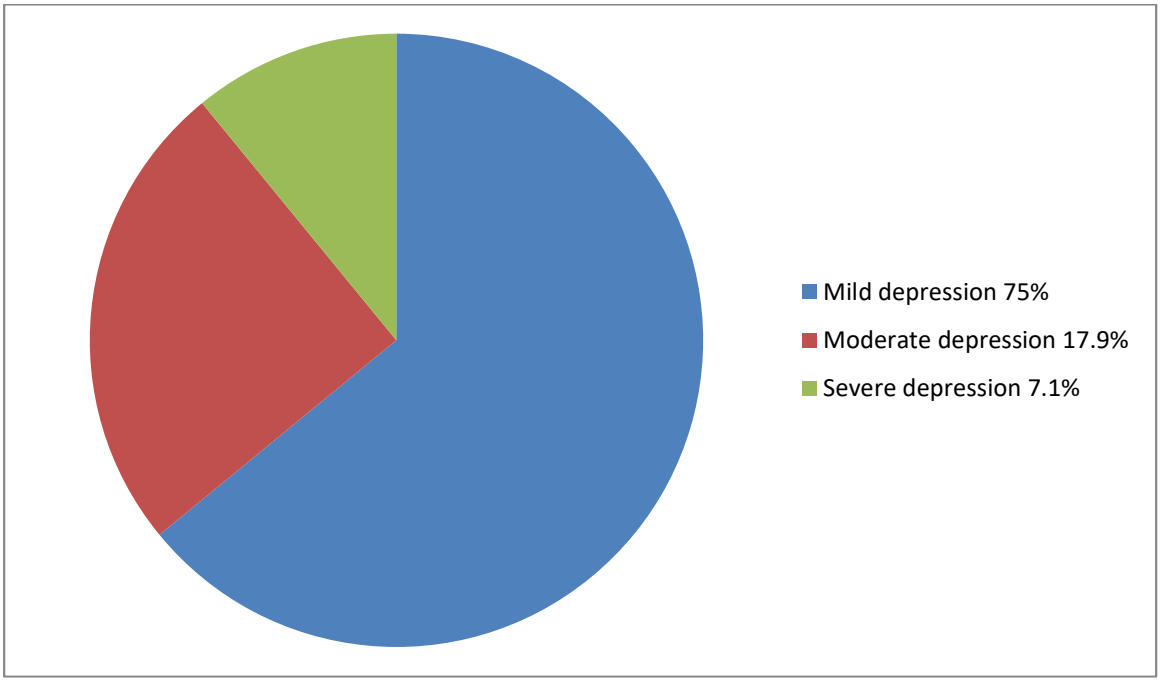


FIGURE 4.3 SEVERITY OF DEPRESSION IN KHOA PATIENTS



4.4 FACTORS ASSOCIATED WITH DEPRESSION IN KHOA

As shown in table 4.3, the proportion of depressed individuals was slightly higher among the elderly i.e. ≥ 60 years however this was not significant. The proportion of females depressed was higher than that of males i.e. 19.2% versus 13.3% respectively. The proportion of depressed patients was higher among the uneducated compared to the educated i.e. 20% versus 16.9%. Married participants had a lower proportion (16%) of depressed compared to the widowed/single participants (21.2%).The study participants who were employed had a lower proportion (9.6%) of depression compared to the unemployed (23.1%). Individuals who had OA for > 5 years had a higher proportion (27%) of depression than those who had OA for < 5 years (14.2%).

The participants who were using recreational substances of abuse had a lower proportion (14%) of depression than those who were not (18.2%). All the participants who had depression were either obese or overweight.

Table 4.3: Factors associated with depression in KHOA patients

	Depressed	No Depression	Total	OR (95% CI)	p-value
Age					
<60	13(15.5)	71(84.5)	84 (100)	0.8(0.4-1.8)	0.578
≥60	15(18.8)	65 (81.3)	80(100)		
Gender					
Male	8 (13.3)	52 (86.7)	60 (100)	0.6 (0.3-1.6)	0.334
Female	20 (19.2)	84 (80.8)	104 (100)		
Education					
None	2 (20.0)	8 (80.0)	10 (100)	1.2 (0.2-6.1)	0.680
Educated	26 (16.9)	128 (83.1)	154 (100)		
Marital status					
Married	21 (16.0)	110 (84.0)	131 (100)	0.7 (0.3-1.8)	0.480
Widowed/Single	7 (21.2)	26 (78.8)	33 (100)		
Employment status					
Yes	7 (9.6)	66 (90.4)	74 (100)	0.4 (0.2-0.9)	**0.023**
No	21 (23.1)	70 (76.9)	90 (100)		
OA duration					
< 5 years	18 (14.2)	109 (85.8)	127 (100)	0.4 (0.2-1.1)	0.067
5 - ≤ 10 years	10 (27.0)	27 (73.0)	37 (100)		
Substance abuse					
Yes	6 (14.0)	37 (86.0)	43 (100)	0.7 (0.3-1.9)	0.527
No	22 (18.2)	99 (81.8)	121 (100)		
BMI					
18.5-24.9	0 (0.0)	9 (100.0)	9 (100)	-	0.360
25.0-29.9	10 (12.2)	72 (87.8)	82 (100)	0.5 (0.2-1.1)	0.097
≥ 30.0	18 (24.7)	55 (75.3)	73 (100)	2.6 (1.1-6.2)	**0.021**

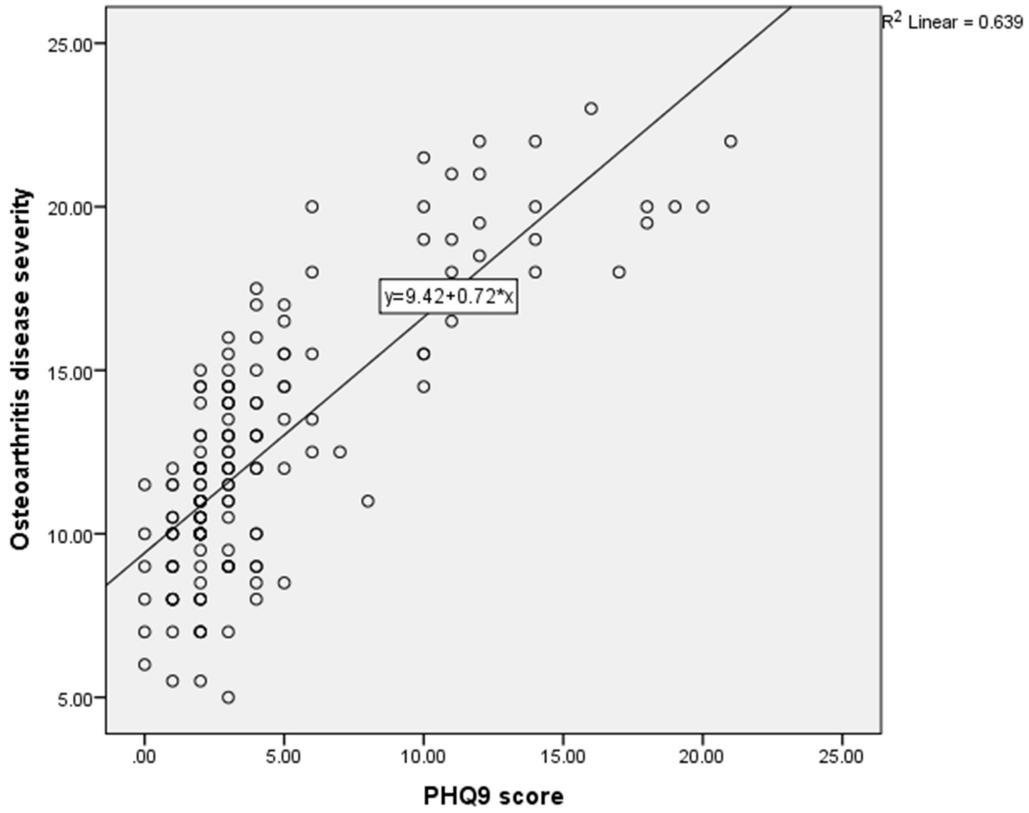
4.5 DEPRESSION AND KHOA DISEASE SEVERITY

As shown in the table 4.4, there was a strong positive correlation between KHOA disease severity and PHQ 9 Score ($r = 0.799$, $p < .0001$).

TABLE 4.4: CORRELATION BETWEEN DEPRESSION AND KHOA DISEASE SEVERITY

	Osteoarthritis disease severity	PHQ-9 score
Osteoarthritis disease severity	1	0.799*
Sig. (2-tailed)		< 0.001

FIGURE 4.4: CORRELATION BETWEEN DEPRESSION AND KHOA DISEASE SEVERITY



CHAPTER FIVE

5.0 DISCUSSION

The purpose of this study was to determine the burden of depression among ambulatory KHOA patients at KNH. The study revealed the prevalence of depression among these patients was 17.1% using the PHQ-9. Majority of these (74.9%) had mild depression. Such patients would benefit from non-pharmacological methods for treating depression.

The overall prevalence in our study was similar to other studies done worldwide. A study done in Germany by T. rosemann et al found a depression prevalence of 19.4% in OA. This study used a similar depression assessment tool as our study i.e. the PHQ-9. A multicenter study done in Spain revealed a depression prevalence of 17.4% in OA using the hospital anxiety and depression scale (HADS)(20). A study done by Joanna et al found a prevalence of 21.3% in Canada using the Centre for epidemiological studies depression scale(23). Despite the different tools used in all these studies, there was similarity in the prevalence of depression. This could be due to the fact that having the same underlying condition predisposes patients to similar disabilities and psychosocial stressors.

The prevalence of depression in this study was lower than that done by Yilmaz et al in 2014 which showed a prevalence of 49.3%(24). The study by Yilmaz et al only included patients who were older than 65 years. This could have contributed to the higher prevalence since older patients tend to have lived with OA longer thus have severe form of the disease which increases the likelihood of developing depression. Older patients also tend to have co morbidities and challenges associated with post retirement all of which might increase likelihood of depression(54). Our study also showed a slight increase in the proportion of depression among the elderly.

A study done in Nigeria among patients with knee OA showed a slightly higher prevalence of depression (28.8%) compared to our study (25). This difference could be attributed to the fact that the Nigerian study used purposive sampling technique for recruitment which has an increased risk of selection bias compared to consecutive sampling which was used in our study(55).

This study also analyzed the frequency of depression based on sociodemographic and clinical parameters e.g. age, sex, marital status, level of education, duration of OA and BMI. The mean age of the study population was 60.0±12.3 which was similar to the mean age of the overall study population (59.4±11.1). The proportion of depression was slightly higher in females (19.2%) compared to males (13.3%) however this was not significant (p= 0.334). This could be explained by the fact that most of the participants were in the peri menopausal age. This is usually associated with hormonal changes that have been shown to increase risk of depression independent of other factors(56). A study done by Amir et al showed increased rate of depression among females with knee OA(57). Rosemann et al found no significant sex difference in a study on predictors of depression in OA(18). Participants who were unemployed had a higher proportion of depression (23.1%, p= 0.023). This is in keeping with a study done by Dextar et al which also found lack of employment is a predictor for depression in OA(28). Lack of employment could lead to loss of social contact and income which increase the likelihood of developing depression. Amir et al also demonstrated that lack of employment increases likelihood of developing depression(57).

Study participants who had no formal education had a slightly higher proportion of depression (20%) compared to the educated (16.9%) however this was not significant. A study done by Amir et al on knee OA patients also showed increased risk of depression among the uneducated. This could be because educated individuals tend to be more knowledgeable thus more actively involved in their management plan with better compliance to treatment thus better disease outcomes.

Widowed/single participants had a higher proportion (21.2%, p=0.480) of depression compared to the married (16%, p=0.48) however not significant. This was similar to a study done by Moghtadaei et al which revealed individuals who were married had lower depression scores(27). This could be explained by the fact that loss of a life partner is an additional social stressor and has been shown to increase the likelihood of one developing depression and other mental illnesses(58)

Obese participants had an increased proportion of depression (24.7%, p=0.021) compared to the overweight (12.2%, p=0.097). Among the participants who had normal weight, none had depression. These findings are similar to a study done by Rosemann et al on predictors of depression in OA which also found having a high BMI was associated with a higher PHQ 9 score(22). This could be explained by the fact that depression has been shown to be a barrier to physical activity hence weight gain(59). This together with poor feeding habits in depressed individuals increases the likelihood of obesity. Participants who had OA for a longer duration had a higher proportion of depression (27%) compared to those with a shorter duration of the disease (14.2%) however not significant. The use of recreational substances of abuse was not significantly associated with depression

The relationship between KHOA disease severity and depression was also analyzed. Study participants with higher LAI scores also had higher PHQ 9 scores with a strong positive correlation, r =0.799, p< .0001. These finding was similar to a study carried out by Marks et al which revealed OA patients with mood disorders were more physically impaired(31). A meta- analysis done by Sharma et al also showed OA patients with comorbid depression had worse OA symptoms(30). T. Rosemann et al conducted a study on knee OA patients in Germany and found individuals who were depressed had worse WOMAC scores and increased radiological disease severity(22). OA is associated with chronic joint pain that is both physically and emotionally stressful thus severe forms of the disease increase the likelihood of

developing depression. Depression also impacts OA negatively as a barrier to physical activity. Exercise alleviates joint pain and improves joint mobility in OA.

5.2 CONCLUSION

The prevalence of depression is relatively high among ambulatory KHOA patients at KNH orthopedic and rheumatology clinic. Patients who were unemployed and obese had an increased proportion of depression and this was statistically significant. Our study also revealed there was a strong positive correlation between KHOA disease severity and depression.

5.3 RECOMMENDATION

We recommend routine screening of all KHOA patients for depression using simple screening tools e.g. PHQ-9 with appropriate referral.

There is need to do a larger multicenter study to look at the burden of depression in KHOA and design effective interventional programs.

There is need of involving a multidisciplinary team in management of OA patients for holistic patient care. This could include the primary physicians, nutritionists and psychologists.

5.4 STUDY LIMITATIONS

1. This was a single center study thus results are not generalizable to the rest of the country.

2. The study was only well powered to look at the prevalence of depression and not the associated factors

3. Recall bias in filling in the questionnaire.

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APPENDICIES

APPENDIX 1: SCREENING PROFORMA

Study No.: …….

Age: …….

Date of Birth: ……

Gender: Female ☐ Male ☐

Are you willing to participate in the study burden of depression among ambulatory knee and hip osteoarthritis patients at Kenyatta National Hospital?

YES ☐

NO ☐

APPENDIX 2: PARTICIPANT INFORMATION AND CONSENT FORM

THE BURDEN OF DEPRESSION AMONG AMBULATORY KNEE AND HIP OSTEOARTHRITIC PATIENTS AT THE KENYATTA NATIONAL HOSPITAL

Principal Investigator

Dr. Bosire Hannah Moraa - **UoN**

Co-Investigators

Prof. Omondi Oyoo - **UoN**

Dr. Eugene Genga - **UoN**

Dr. Violet Okech- Helu- **KNH**

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

WHAT IS THIS STUDY ABOUT?

The researchers listed above are interviewing individuals who have knee or hip osteoarthritis. The purpose of the interview is to find out if you are suffering from depression. Participants in this research study will be asked questions about their socio demographic data, osteoarthritis disease severity and symptoms of depression. Participants will also have the choice to undergo weight and height measurements to determine their BMI There will be approximately one hundred and Sixty four participants in this study. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last about 20 to 30 minutes.

After the interview has finished**,** your weight and height will be measured. This will be used to calculate your BMI

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: missing data on the study questionnaire.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

You may feel some discomfort when answering some of the questions as we try to ascertain if you are depressed. The interviewer will be as empathetic as possible and help you through it however you are free not to answer if you so wish without being victimized at all.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving a referral to a psychologist should you be found to be depressed thus start early therapy to prevent further complications that may come with it.
The information you provide will help us better understand the burden of depression in osteoarthritis. This information is a contribution to science and will help in future management of other patients.
There shall however be no monetary/ non-monetary compensation for participating in the study

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: **Yes** ☐ **No** ☐

I agree to provide contact information for follow-up: Yes ☐ No ☐

Participant printed name: _____

Participant signature / Thumb stamp _____ **Date** _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name _____ **Date** _____

Signature: _____

Role in the study _____

Contact information

Dr. Hannah Moraa Bosire

Telephone number 0736403563

KIAMBATISHO CHA PILI: FOMU YA HABARI KWA WANAOSHIRIKI NA IDHINI

MZIGO WA UGONJWA WA UZUNI MIONGONI MWA WAGONJWA WANAOUGUA OSTE OARTHRITIS KWENYE GOTI NA MAKALIO

Mtafiti mkuu

Dr. Bosire Hannah Moraa - **UoN**

Watafiti wenza

Prof. Omondi Oyoo - **UoN**

Dr. Eugene Genga - **UoN**

Dr. Violet Okech- Helu - **KNH**

Utangulizi:

Ningependa kuwafahamisha kuhusu utafiti huu unaofanywa na watafiti ambao wametajwa hapo juu. U muhimu wa fomu hii ni kukujulisha yale unatakiwa kujua kabla ya kuamua kushiriki au kutoshiriki kati ka utafiti huu. Unaweza kuuliza maswali yoyote kuhusu umuhimu wa utafiti huu , faida na hasara zake k ama zipo, haki zako ikiwa utajitolea kushiriki na chochote ambacho hujaelewa.

Utakapoelewa utahitajika kutia sahihi kwenye fomu hii.

Unapaswa kuelewa kuwa;

i. Haifai kulazimishwa kushiriki ila kwa uamuzi wako mwenyewe.
ii. Unaweza kujitoa kwenye utafiti huu wakati wowote ule bila kutoa sababu.
iii. Matibabu yako yataendelea kama kawaida hata utakapo kataa kushiriki katika utafiti huu.

Tutakupatia fomu nyingine ili uweze kuiweka.

Je, niendelee? Ndio/La

Utafiti huu umeidhinishwa na KNH-university ya Nairobi ethics &Research committee protocol no. ___

Utafiti huu unahusu nini?

Watafiti waliotajwa hapo juu wanauliza maswali watu ambao wanaugua ugonjwa wa arthritis ya goti a ma Makalio. Umuhimu wa haya maswali ni kufanya uchunguzi kuhusu mzigo wa huzuni miongoni mwa wagonjwa hawa. Watakaoshiriki katika utafiti huu wataulizwa maswali kuhusu ugonjwa wao wa arthriti s na jinsi imewaathiri , demografia za kijamii na dalili za ugonjwa wa huzuni. Watakaoshiriki wanaweza kuamua iwapo watapimwa kwa mambo kama vile urefu na kilo.

Watakuwepo washiriki mia moja sitini na nne katika utafiti huu. Tunakuomba uweze kujitolea kushiriki katika utafiti huu.

YATAKAYO FUATA IWAPO UTAAMUA KUSHIRIKI KATIKA UTAFITI HUU.

Ukikubali kushiriki katika utafiti huu:

Utaweza kuulizwa maswali kwa siri na kwa kipindi cha dakika 20- 30. Maswali haya yanahusu mambo kama vile dalili za ugonjwa wa huzuni na demografia za kijamii

Tutakuomba nambari yako ya simu ambayo itatumika tu na wale wanaohusika katika utafiti huu pekee. Sababu zinazoweza kufanya sisi kukupigia simu ni kama vile fomu kutojazwa vikamilifu.

JE KUNA HATARI ZINAZOHUSIANA NA UTAFITI HUU.

Utafiti wa aina hii uko na uwezo wa kuleta usumbufu wa Kisaikolojia, soshiolojia, hisia na hatari zingin ezo. Juhudi za kupunguza hatari hizi zinapaswa kuwekwa. Moja wapo ya hatari ni kupoteza usiri wako l akini tunaahidi kuwa tutaziweka habari zako kuwa siri . Pia, huenda ukahisi usumbufu unapojibu maswa li. Kama kuna swali ambalo hutaki kulijibu uko na uhuru wa kukosa kulijibu.

JE, KUNA UMUHIMU WA KUSHIRIKI KWENYE UTAFITI HUU.

Unaweza kupata huduma kama kuelekezwa kwa daktari wa kisaikolojia ikiwa utapatikana kuwa na ugon jwa wa huzuni

Pia habari utakatoa zitasaidia kuelewa vyema mzigo wa ugonjwa wa huzuni miongoni mwa wagonjwa wa osteoarthritis hivyo kuboresha matibabu yao katika siku zijazo.

Je Uko na Maswali Mengine?

Iwapo kuna maswali yoyote kuhusu kushiriki katika utafiti huu,tafadhali piga simu au tuma ujumbe kwa nambari iliyo mwisho wa ukurasa huu. Iwapo uko na maswali zaidi kuhusu haki zako kama mshirika kw enye utafiti huu, wasiliana na karani/mwenyekiti KNH-University ya Nairobi Ethics &Research commit ee.Telephone no. Ext.44102 Email.uonknh_etc@kuomba.ac.ke.

Je, kuna uamuzi mwingine?

Uamuzi wa kuhusishwa kwenye utafiti huu ni wako mwenyewe. Unaweza kujiunga na kujitoa kwenye u tafiti huu wakati wowote ule bila ya kupoteza faida zozote za kimatibabu.

Consent form

Participant statement

Nimesoma fomu hii. Nimepata fursa ya kujadili utafitii huu. Maswali yangu yamejibiwa kwa lugha nina yoielewa. Nimeelewa faida na hatari zinazotokana na utafiti huu. Nimeelewa kuwa kushiriki kwangu sio kwa lazima na ninaweza kujitoa wakati wowote ule.

Nakubali kushiriki kwenye utafiti huu. Naelewa kua juhudi zimewekwa kuhakikishwa habari nitakazozit oa zitakua ni siri.

Kwa kutia sahihi sijapoteza haki zangu kama muhusika.

Nakubali kushiriki katika utafiti huu Ndio ☐ La ☐

Nakubali kupeana nambari yangu ya simu ili kuwezesha mawasiliano. Ndio ☐ La ☐

Jina la mshirika

Sahihi ya mshirika /alama ya kidole_____tarehe

Kauli ya utafiti

Mimi niliyetia sahihi kwenye karatasi hii nimeeleza kwa kina mambo yote ambayo mshiriki aliyetajwa h apo juu anapaswa kuelewa na amekubali kushiriki katika utafiti huu bila kulazimishwa.

Jina la mtafiti_____ tarehe_____

Sahihi

Jukumu kwenye utafiti_____

Kwa maelezo zaidi wasiliana na

Dr. Hannah Moraa Bosire

Nambari ya simu 0736403563

APPENDIX 3: STUDY PROFORMA

Tick where applicable

How long have you had Osteoarthritis?

< **5 yrs.** ☐

5- 10 yrs. ☐

>10 yrs. ☐

2. What is your gender? **Male** ☐ **Female** ☐

3. What is your Date of Birth? **Year** ☐

4. What is your highest level of education you achieved?

None at all ☐

Primary School ☐

High School ☐

College/ University ☐

5. What is your marital status?

Single ☐ Divorced ☐ Married ☐ Widowed ☐ Separated ☐

6. Employment statement: Employed ☐ Not employed ☐

7. Do you use Alcohol/ cigarettes/ bhang/ miraa/ Injectable drugs? Yes ☐ No ☐

8. Weight =

9. Height =

10. BMI =

KIAMBATISHO CHA TATU: PROFOMA YA UTAFITI

Weka alama ya pata( ) inapohitajika

1. Umeugua ugonjwa wa Osteoarthritis kwa muda gani?

<5(miaka) ☐

<5-10(miaka) ☐

>10(miaka) ☐

2. Je, wewe ni wa jinsia gani? Kiume ☐ Kike ☐

3. Mwaka wako wa kuzaliwa ni gani? Mwaka ☐

4. Je,kiwango chako cha juu cha elimu ni gani?

Hamna kabisa ☐ Shule ya msingi ☐ Shule ya sekondari ☐

Chuo Kikuku/Shule ya Sahanati ☐

5. Habari kuhusu ndoa

Hujaolewa ☐ Talaka/ mjane ☐ Umeolewa ☐ Mmetengana ☐

6. Kauli ya ajira: Umeajiriwa ☐ Haujaajiriwa ☐

7. Je unatumia vileo/sigara/bangi/miraa/dawa za sindano Ndio ☐ La ☐

8. Uzito =

9. Urefu =

10. BMI =

APPENDIX 4: LEQUESNE ALGOFUNCTIONAL INDEX FOR KNEE AND HIP OSTEOARTHRITIS

PAIN OR DISCOMFORT	
Pain or discomfort during nocturnal bed rest	
None	0
Only on movement or in certain positions	1
Without movement	2
Duration of morning stiffness or pain after getting up	
None	0
< 15 minutes	1
≥ 15 minutes	2
Remaining standing for 30 minutes increases pain	
No	0
Yes	1
Pain on walking	
None	0
Only after walking some distance	1
Early after stating	2
Pain or discomfort	
No	0
For the hip: in sitting position for 2 hours	1
For the knee: after getting up from sitting without use of arms	
MAXIMUM DISTANCE WALKED	
Unlimited	0
> 1km but limited	1
About 1 km (about 15 minutes)	2
About 500- 900 meters	3
From 300- 500 meters	4
From 100-300 meters	5
<100 meters	6
1 walking stick or crutch	+1
2 walking stick or crutch	+2

ACTIVITIES OF DAILY LIVING	
Easily=0, mild difficulty=0.5, moderate difficulty=1, marked difficulty=1.5 and impossible=2	
Hip	**0-2**
Can you put on socks by bending forward	
Can you pick up an object from the floor	
Can you go up and down a standard flight of stairs/ hill	

Can you get into and out of a car/ motorbike

Knee **0-2**

Able to climb up a standard flight of stairs/ hill
Able to climb down a standard flight of stairs/ hill
Able to squat or bend at the knee
Able to walk on uneven ground

TOTAL (0-24)

KIAMBATISHO CHA NNE: LEQUESNE ALGOFUNCTIONAL INDEX FOR KNEE AND HIP OSTEOARTHRITIS

Maumivu au Usumbufu	
Maumivu au Usumbufu unapopumzika kitandani	
Hakuna	0
Wakati tu ninaposonga au baadhi ya sehemu	1
Bila kusonga	2
Muda wa ugumu au maumivu unapoamka asubuhi	
Hakuna	0
< Dakika 15	1
≥Dakika 15	2
Kuendelea kusimama kwa dakika 30 kunaongeza maumivu	
La	0
Ndio	1
Maumivu unapotembea	
Hakuna	0
Baada tu ya kutembea umbali fulani	1
Pindi tu ninapoanza kutembea	2
Maumivu au usumbufu	
Hakuna	0
Kwenye makalio:Ninapoketi kwa muda wa masaa mawili	1
Kwenye goti: Baada ya kusimama bila kutumia mikono	
MUDA MREFU SANA UMETEMBEA	
Bila ugumu wowote	0
> 1km lakini kwa ugumu	1
About 1 km (kwa dakika kama 15)	2
Mita kama 500- 900	3
Mita kama 300- 500	4
Mita 100-300	5
Chini ya mita100	6
Kwa kijiti kimoja cha kutembelea(mkongojo)	+1
Kwa vijiti viwili vya kutembelea	+2
SHUGHULI ZA MAISHA YA KILA SIKU	
Rahisi=0,ngumu kidogo=0.5, ngumu kiasi=1, ngumu zaidi=1.5 na haiwezekani=2	
Makalio	**0-2**
Je, unaweza kuvalia sokisi ukiwa umeinama kwenda mbele?	
Je, unaweza okota kitu sakafuni?	
Je, unaweza panda ukishuka kwenye ngazi?	
Je, unaweza kuingia na kutoka kwenye gari?	

Goti **0-2**

Je, unaweza kupanda ngazi?
Je, unaweza kushuka ngazi?
Je, unaweza kuchuchumaa au kukunja goti?
Je, unaweza kutembea kwenye barabara mbovu?

JUMLA (0-24)

APPENDIX 5: PATIENT HEALTH QUESTIONNAIRE – 9

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔ to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
⑤	⑤	⑤	⑤

KIAMBATISHO CHA TANO: KIDODOSI JUU YA AFYA YA MGONJWA - 9

KIDODOSI JUU YA AFYA YA MGONJWA -9 (PHQ-9)

Katika kipindi cha wiki mbili zilizopita ni mara ngapi umesumbuliwa na matatizo haya yafuatayo? *(Tumia "✔ ili kuashiria jibu lako)*	**Haijatoke zea kabisa**	**Siku kadhaa**	**Zaidi ya nusu ya siku hizo**	**Takriban kila siku**
1. Kutokuwa na hamu au raha ya kufanya kitu	0	1	2	3
2. Kujisikia tabu sana au kukata tamaa	0	1	2	3
3. Matatizo ya kupata usingizi au kuweza kulala au kulala sana	0	1	2	3
4. Kujisikia kuchoka au kutokuwa na nguvu	0	1	2	3
5. Kutokuwa na hamu ya kula au kula sana	0	1	2	3
6. Kujisikia vibaya-au kujiona kuwa umeshindwa kabisa au umejiangusha au kuikatisha tama familia yako	0	1	2	3
7. Matatizo ya kuwa makini kwa mfano unaposoma gazeti au kuangalia TV	0	1	2	3
8. Kutembea au kuongea taratibu sana mpaka watu wakawa wameona tofauti? Au kinyume chake kwamba hutulizani na unahangaika sana kuliko ilivyo kawaida	0	1	2	3
9. Mawazo kuwa ni afadhali zaidi ufe au ujidhuru kwa namna fulani	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

Kama ulitia alama matatizo yoyote, matatizo hayo yamefanye iwe vigumu kivipi kwako kufanya kazi yako, kushughulikia vitu nyumbani, au kutangamana na watu wengine?

Sio ngumu hata kidogo ⑤	**Ngumu kiasi** ⑤	**Ngumu sana** ⑤	**Ngumu zaidi** ⑤