

# UNIVERSITY OF NAIROBI COLLEGE OF HEALTH SCIENCES DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS

## THE BURDEN OF DEPRESSION AMONG PATIENTS WITH END STAGE RENAL DISEASE UNDERGOING HEMODIALYSIS AT KENYATTA NATIONAL HOSPITAL, NAIROBI HOSPITAL, AND PARKLANDS KIDNEY CENTER

### DR KEVIN NGURING'A

### H58/6885/2017

A DISSERTATION SUBMITTED IN PART FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF MEDICINE IN INTERNAL MEDICINE

### **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.

Signature	Date
Dr Kevin Nguring'a	

Department of clinical medicine and Therapeutics

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Name of the student	Dr. Kevin Nguring'a	
Registration Number	H58/6885/2017	
College	Health Sciences.	
School	Medicine.	
Department	Clinical Medicine and Therapeutics.	
Course name	Master of Medicine in Internal Medicine.	
Title "THE BURDEN OF DEPRESSION AMONG PATIENTS WITH END STAGE RENAL DISEASE UNDERGOING HEMODIALYSIS AT KENYATTA NATIONAL HOSPITAL, NAIROBI HOSPITAL, AND PARKLANDS KIDNEY CENTER"  I understand what plagiarism is and I am aware of the University's policy in this regard.  I declare that this thesis is my original work and has not been submitted elsewhere for examination, award of a degree or application. Where other people's work or my own work has been used, this has properly been acknowledged and referenced in accordance with University of Nairobi's requirements.		
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### APPROVAL BY SUPERVISOR

This study has been submitted with the approval of	my supervisors namely:
Professor Joshua Kayima MBChB, MMed, FRCP	
Associate professor, Consultant Physician and Neph	hrologist
Department of clinical Medicine and Therapeutics,	school of medicine,
College of health science, University of Nairobi	
Signed	Date
Professor Elijah Ogola MBChB, MMed, FACC	
Associate professor, Consultant Physician and Card	liologist
Department of clinical Medicine and Therapeutics,	school of medicine,
College of health science, University of Nairobi	
Signed	Date
Dr Violet C.A Okech – Helu MBchB, MMed, MPH	I
Consultant Psychiatrist/ Counsellor	
Department of Mental Health	
Kenyatta National Hospital	
Signed	Date

### **DEDICATION**

This work is dedicated to my loving parents' Dr Peter Mwathi and Mrs Elizabeth Wangui Mwathi.

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### LIST OF ABBREVIATION

**ACTH**: Adrenocorticotrophic hormone

**AASK:** African American Study of Kidney Disease and Hypertension Trial

**BMI:** Body Mass Index

**BDNF:** Brain Derived Neurotrophic Factor

**CB CAD:** Coronary Artery Disease

**CBT:** Cognitive Behaviour Therapy

**CHF**: Congestive Heart Failure

**CKD:** Chronic Kidney Disease

**CRH:** Corticotrophin Releasing Hormone

**CRIC:** Chronic Renal Insufficient Cohort

CVA: Cerebrovascular Accident

**DM:** Diabetes

**DSM- IV:** Diagnostic and Statistical Manual IV

eGFR: Estimated Glomerular Filtration Rate

**ESRD:** End Stage Renal

**FSGS:** Focal Segmental GlomeruloSlerosis

HCRIC: Hispanic Chronic Renal Insufficient Cohort

**HD:** Haemodialysis

**HPA:** Hypothalamic Pituitary Adrenal Axis

**HTN:** Hypertension

IL: Interleukin

**KDIGO:** Kidney Disease Improving Global Outcomes

**KNH:** Kenyatta National Hospital

**MAOI:** Monoamine Oxidase Inhibitors

**MD:** Mood disorder

MSPSS: Multidimensional Scale of Perceived Social Support

NH: Nairobi Hospital

PHQ-9: 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

PAD: Peripheral Artery Disease

**RAAS:** Renin Angiotensin Aldosterone System

**TCA:** Tricyclic Antidepressants

WHO: World Health Organization

#### **ABSTRACT**

### **BACKGROUND**

Depression is the commonest psychological disorder in end stage renal disease (ESRD). The presence of depression has been linked with high rates of morbidity and mortality, as well as having an impact on the quality of life. Early diagnosis and treatment of depression in chronic kidney disease (CKD) improves disease outcome. This study sought to assess the prevalence and determinants of depression in patients with ESRD undergoing haemodialysis (HD).

### **OBJECTIVES**

The main objective of this study was to determine the prevalence of depression in ESRD patients undergoing maintenance HD at the Kenyatta national hospital (KNH), Nairobi hospital (NH), and Parklands kidney centre (PKC). The secondary objective was to assess selected determinants of depression amongst this population of patients undergoing maintenance HD.

### **METHODOLOGY**

This was a cross sectional descriptive study carried out at the renal units in KNH, NH and Parklands kidney centre over a period of 2 months. The study population comprised adults aged 18 years and above undergoing maintenance HD at the renal units in KNH, NH and PKC. Patients who met the inclusion criteria and gave written informed consent were enrolled in the study. A study pro forma was used to collect socio demographic data and cardiovascular diseases history coronary artery disease (CAD), cerebrovascular accident (CVA), peripheral arterial disease (PAD). The patient health questionnaire 9 (PHQ - 9) was used to establish presence and severity of depression among participants. The multidimensional scale of perceived social support (MSPSS) was used to assess the level of social support among the study participants.

### DATA MANAGEMENT AND ANALYSIS

The prevalence of depression was calculated as a proportion of patients with any degree of depression and expressed as a percentage. The chi- square test was used to determine the association between presence of depression, and selected determinants. All analyses were conducted using SPSS version 21.0 Chicago Illinois.

### **RESULTS**

This study involved 170 patients undergoing maintenance HD with a mean age of 56.44  $\pm 13.5$  years and a sex ratio (M: F) of 1.2:1. The prevalence of depression was 32.4%, mild depression 24.14%, moderate 7.06% and severe 1.17%. High social support was present for 74.12% of subject who participated, while 23.53% and 2.35% had moderate and low social support respectively. Age (18 - 29 years, p = 0.005), lack of any formal education (p = 0.048), retirement from formal employment (p = 0.036) and lack of social support (p = 0.001) were significantly associated with depression.

### **CONCLUSION**

A substantial proportion of subjects undergoing HD have concomitant depression. The vast majority of these subjects have mild depression. Factors that increased the risk of depression were aged (18 - 29 years), lack of formal education, retirement from formal employment and lack of social support.

The findings of this study highlight the extent to which depression is under recognised and suggest the need for active screening. Carrying out of validated questionnaires to assess for the presence of depression in patients initiating HD may be helpful in early recognition. The quality of life and clinical outcomes in patients diagnosed with ESRD undergoing HD can be greatly improved by early diagnosis and treatment.

### **CHAPTER ONE**

### 1.0 INTRODUCTION

### 1.1 INTRODUCTION

End stage renal disease (ESRD) represents the final stage in the spectrum of chronic kidney disease (CKD); According to kidney disease improving global outcomes (KDIGO) classification an estimated glomerular filtration rate (eGFR) of < 15 ml/min/1.73 indicates ESRD (1). Chronic kidney disease involves the sustained gradual loss of the kidney's ability to perform its normal function, thus leading to the accumulation of metabolic waste normally excreted by the kidneys. The presence of ESRD therefore necessitates the need for renal replacement therapy (RRT), to maintain life and improve the quality of life. The primary signs and symptoms of ESRD are as a result of metabolic or endocrine derangements or disturbance in water or electrolyte balance.

The estimated lifetime risk of developing depression in the general population is estimated to be between 5 – 10 % (2). Worldwide the prevalence of CKD is 10 – 15% (3)(4)(5). The rates of depression are up to 3 times higher than that seen in the general population for CKD/ESRD patients who are not undergoing HD. When this group of patients is compared to those who are suffering from other chronic medical ailments the rates of depression are 2 - 3 times higher (2)(6). The burden of CKD is envisaged to substantially grow owing to a worldwide pandemic of some of the etiological factors associated with CKD e.g. Hypertension (HTN) and Diabetes Mellitus(DM). In Kenya the prevalence of DM is approximately 4.2 %, (7) while that of hypertension is estimated to be 24.5% (18 -69 years) (8). Therefore, with an increasing proportion of the population having risk factors for development of CKD, it is likely therefore that the number of patients requiring RRT in the near future is going to increase.

Depression is a mental disorder characterized by hopelessness, anhedonia, and a constant feeling of sadness for at least 2 weeks, according to the diagnostic and statistical manual of mental disorders (DSM – V). Other symptoms include significant weight loss, slowing down of thoughts, suicidal ideation, feeling of worthlessness, restlessness, insomnia, guilt and reduced concentration. Depression results from a complex interplay between social, biological, and psychological factors. The lifetime prevalence of depression is as high as 20% in the general population, with a female: male ratio of 1.7:1 (9). Globally approximately 350

million people are affected by depression, this has led to depression being the 4<sup>th</sup> leading cause of disability (10). Approximately 800,000 people diagnosed with depression commit suicide globally on an annual basis (10). A study carried out in the year 2002 in a rural district in Kenya showed the prevalence of depression to be approximately 6.1 % (11).

The assessment of depression in patients with CKD is demanding, this is partly due to the fact that there is an overlap between the physical symptoms of uraemia and depression. Patients who have been diagnosed with ESRD show greater than 5 times the rates of developing depression, compared to the general population (12).

End stage renal disease/chronic kidney disease patients who are also depressed tend to be less motivated, have poor disability score and are less compliant to their treatment. The association between depression and mortality has been established in several studies. In a study published by Mapes et al in 2004, the presence of depression was shown to have an independent association with increasing rates of mortality and hospitalization (13). Data compiled from 31 studies comprising of 67,000 patients on chronic maintenance HD, demonstrated a 50 % increase risk of mortality with the existence of depressive symptoms (14). In CKD patients currently not on HD, the presence of depressive symptoms was associated with a higher rate of progression of CKD to ESRD (15).

In addition to mortality, ESRD patients with depression have other detrimental outcomes including hospitalization, (16)(17) cardiovascular events, (18) cumulative hospital days, (17) emergency department visit, (16) peritonitis, (19) withdrawal from dialysis and suicide (20). High level of depressive symptoms are significantly and independently related with one having a lower quality of life according to the African American Study of Kidney Disease and Hypertension (AASK) cohort study (21). Moreover, ESRD is considerably related with fatigue, (22) pain, (23) pruritus, (24) sleep disturbance and sexual dysfunction (25).

Depression is associated with increasing rates of negative health behaviour such as a sedentary lifestyle, smoking and obesity which contribute to an increase in other lifestyle diseases in these patients i.e. DM and HTN. The interplay between depression and ESRD becomes a vicious cycle leading to high rates of health care utilization with increased economic cost. Depression remains largely underdiagnosed by health care providers in patients with ESRD undergoing HD thus leading to low quality of life and poor patient outcomes. Early diagnosis and intervention of depression can lead to less ESRD related morbidity and mortality.

### **CHAPTER TWO**

### 2.0 LITERATURE REVIEW

### 2.1 BACKGROUND

### 2.1.1 Pathophysiology of End Stage Renal Disease

A typical kidney consists of roughly 1 million nephrons, each of which is involved in contributing to the total glomerular filtration rate (GFR). The biological process of aging initiates various structural and functional adjustments within the kidney. (26) Regardless of the aetiology, once half of all the nephrons are lost, CKD advances in a similar way. Once there is kidney injury (no matter the aetiology), the remaining healthy nephrons undergo a process of physiological adaptation. The adapted nephrons ensure the kidney is able to maintain GFR and tubular function e.g. potassium secretion. The process of physiological adaptation involves the nephrons going through hyper filtration and compensatory hypertrophy. This process of nephron adaptation is referred to as the "final common pathway".

Rapid progressive glomerulonephritis (RPGN) is an example of a condition whose initiating process is abrupt and severe leading to accelerated development of ESRD. However, for a majority of the patients the progression to ESRD is more gradual allowing for a process of physiological adaptation of the nephrons.

The hyper filtration and compensatory hypertrophy of the remaining nephrons though useful, has been hypothesized to represent a serious reason for progressive renal dysfunction. The hyper filtration triggers the activation of renin angiotensin aldosterone system (RAAS) and causes proteinuria. The increasing activity of RAAS, leads to conservation of sodium and water eventually leading to hypertension.

The angiotensin II and protein uptake at the tubules are potent triggers of inflammation and fibrosis of the glomerulus and tubules. These leads to focal segmental glomerulosclerosis (FSGS) and eventually the remaining healthy nephrons become non – functional.

Adapted nephrons enhance the kidneys ability to postpone uraemia, hence delay in some of the clinical manifestation of uraemia. Eventually the adaptive mechanism becomes maladaptive and leads to the demise of the remaining healthy nephrons (27).

### 2.1.2 Pathophysiology of depression

The basic pathophysiology of major depressive disorder is not well understood. Depression results from an interplay of environmental and genetic factors. Several hypotheses postulated to explain the disease process include the Neurotrophic hypothesis, Monoamine hypothesis, and the Neuroendocrine hypothesis (28)(29).

In depression, there is a dysfunction in the regulation of these key neurotransmitters. According to the neurotrophic hypothesis stress suppresses the brain derived neurotrophic factor (BDNF) synthesis in the hippocampus, leading to atrophy of hippocampal neurons and prefrontal cortex. There are several ways in which BDNF concentrations decrease, stress, reduction in hippocampal tissue, direct effects of high cortisol levels, and decreased activity in monoaminergic neurotransmitters. The hippocampus is rich in BDNF which plays a critical role in neuronal growth, arborization, survival and maturation and synaptic plasticity in the adult brain. The changes decrease the ability of the hippocampus to inhibit the release of corticotrophin releasing factor (CRF) by the hypothalamus leading to increase in glucocorticoid release. A cycle of hippocampal atrophy and CRF dysregulation then ensues (28)(30).

The neuroendocrine hypothesis postulates that stress, impaired hippocampal function and increasing pro inflammatory cytokines contribute to the sustained hypothalamic pituitary adrenal axis (HPA) activation. Neuronal damage ensues as a result of calcium entry into activated neurons due to the continued presence of high circulating cortisol levels that have an effect on voltage gated ion channels by facilitating an increase in calcium uptake. The hippocampus may be damaged directly by the effects of glucocorticoid, or via activation of glutamate systems or via BDNF reduction. The hippocampal neurons are directly affected by the direct toxic effect of Corticotrophin releasing hormone (CRH) (28)(30).

The monoamine hypothesis postulates that deficiencies of cortical and limbic serotonin; norepinephrine; and dopamine are responsible for the development of depression (29).

### 2.1.3 The link between end stage renal disease and depression

A bidirectional association has been established between chronic medical disease (e.g. coronary artery disease and depression (30). The mechanisms that link CKD and depression are not well understood. However, it has been postulated to be bidirectional. The mechanisms involved in the development of depression in patients with CKD are thought to be similar as

those seen in other chronic medical diseases, and can be largely divided into behavioural and biological mechanisms (31)(32)(33).

### **Behavioural**

Individuals with CKD and ESRD have a higher frequency of clinic and hospital attendance, enhanced pill burden, and more dietary restrictions. This enhanced burden to the individual related to self-care may lead to major depressive disorder. (34) Functional impairment, (35) and other physical symptoms that are related to having chronic medical disease can also be partly responsible for the development of depression. The presence of comorbid medical ailments such as congestive heart failure (CHF); cerebrovascular accident (CVA); peripheral arterial disease (PAD) can limit one's physical activity and more so in patients with chronic kidney and end stage renal disease. For patients with ESRD, anaemia, and the wear out from HD can forestall a patient from conducting their daily tasks.

Patients with a diagnosis of CKD/ESRD, who are then faced with the reality of imminent dialysis or kidney transplantation are likely to develop depression (31)(36). Depression may be partly responsible for the development of CKD through increasing negative health behaviours such as inactivity, alcohol consumption, inadequate daily fruit/vegetable consumption, smoking and obesity. (31) The increasing negative health behaviours occur more in CKD patients and this, tends to aggravate pre-existing comorbid conditions such as DM, CAD or HTN. This eventually leads to CKD or rapid CKD progression to ESRD (37) (38)(39)(40). Cases of ESRD have been documented to have socio economic difficulties which are associated with the development of major mood disorders (41)(42).

### **Biology**

In chronic medical disease a bidirectional relationship exists linking inflammation and depression (31). Chronic kidney disease progression and mortality are just some of the few poor health outcomes experienced by CKD/ESRD patients due to the high levels of inflammatory markers (43)(44). The increasing pro inflammatory cytokines lead to HPA dysregulation, this leads to the stimulation of the neurosecretory cells located in the hypothalamus leading to CRH secretion. Corticotrophin releasing hormone acts on the anterior pituitary gland leading to secrete of ACTH. The ACTH in turn stimulates the production of cortisol from the zona fasciculata of the adrenal gland leading to an increase in cortisol levels.

Cortisol stimulates tryptophan oxygenase, which leads to reduced tryptophan levels. Tryptophan is required for serotonin synthesis; hence increasing in cortisol levels lead to reduced production of serotonin. A high cortisol level has also been associated with a reduction of dopamine levels in the brain also responsible for development of depression. High cortisol levels are associated with insulin resistance, visceral obesity, obesity, hypertension and dyslipidaemia. These factors play a pivotal role towards development of lifestyle diseases in patients having CKD.

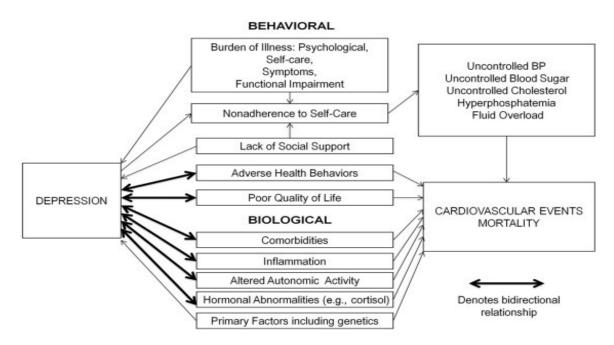


Figure 2.1: Mechanisms of depression and adverse medical outcomes.

### 2.2 PREVALENCE OF DEPRESSION IN CHRONIC KIDNEY DISEASE/END STAGE RENAL DISEASE

The burden of depression in patients diagnosed to have ESRD is high. The estimated lifetime risk of developing depression in the general population is estimated to be between 5% - 10% (2). The rates of depression are up to 3 times higher than that seen in the general population for CKD /ESRD patients who are not undergoing HD. When this group of patients is compared to those who are suffering from other chronic medical ailments the rates of depression are 2-3 times higher (6). Research in the area of ESRD looking at the effects of ethnicity/race and the impact it has towards development of depression has shown conflicting results, some data on this has suggested higher rates of depression among whites while as

other data has shown no correlation between race or ethnicity with one developing depression (45).

In 2012, Lopes AA, analysed data from dialysis outcome and practices patterns study (DOPPS), Lopes established that white patients were more likely to have a physician diagnosed depression as compared to patients of African descent in the USA. (46)

The prevalence of depression in ESRD varies from 14-84 % in patients undergoing HD. The spectrum of depression is wide and ranges from mild to severe, and is captured in various studies (6)(47)(48)(49)(50)(51).

This variability in prevalence can be explained by a couple of reasons including but not limited to the methodology criteria, and screening tools used. The variability can also be explained by the fact that some of the somatic symptoms of depression as assessed using a questionnaire overlap with those seen in uraemia (lack of sleep, poor appetite, fatigue). In developing nations, the medical priorities are usually centred on patient's survival and little or no attention on the quality of life, therefore the necessary required care tends to be sub optimal due to a lack of the necessary resources and hence may explain the large variability in prevalence (52).

In 2013, Palmer et al, did a systemic review and meta-analysis involving 55982 patients with CKD/ESRD who were identified from 216 studies. The summary prevalence of depression was 39.3 % among ESRD patients undergoing dialysis (6). In 2011, Fischer et al, did a cross sectional analysis that involved 3853 individuals who had mild to moderate CKD enrolled into the CRIC and HCRIC studies. The study found a prevalence of 27.4% using the Beck Depression Inventory (BDI) (53).

In 2007, Cukor et al, a study done at an urban dialysis centre in central Brooklyn USA among 70 patients undergoing HD, found the prevalence of depression to be 29 % using the BDI (54). Boulware and colleagues assessed data from the Choice for healthy outcomes in caring for ESRD (CHOICE) study, a large observation follow up study of incident HD and PD patients from centres across the USA. They found a prevalence of 19 -24%, which is similar to that demonstrated by various studies using BDI (18).

In 2011, Amira et al, in a cross sectional study among participants attending a renal clinic who had chronic kidney disease (stages 3 -5) at a tertiary facility in Nigeria. The prevalence

of depression was 34.5 % among ESRD patients undergoing HD using the Zung depression questionnaire (51).

A study done in capital hospital, Islamabad, Pakistan among 315 patients, found a prevalence of 83.8 % depression amongst patients undergoing HD using the HDRS screening tool (48). In 2015, Ng Hg et al, did a longitudinal study that involved following up 159 patients undergoing HD for a duration of 12 months and found a 39.6 % prevalence of depression (55). In 2009, a descriptive cross sectional survey by Son Y-J in the republic of Korea, among 146 patients undergoing maintenance HD, found the prevalence of depression to be 25.34 % using patient health questionnaire – 9 (PHQ – 9) (56).

### 2.3 SOCIO DEMOGRAPHIC DETERMINANTS ASSOCIATED WITH DEPRESSION IN END STAGE RENAL DISEASE

Various determinants have been identified that can lead to one developing depression in patients diagnosed to have ESRD. In this study, we looked at certain selected determinant i.e. education, duration of dialysis, age, gender, marital status, status in the family, employment status and social support. Lower socio economic status and co morbid conditions have been established to be factors that can be associate with a higher prevalence of depression, in the general population. (41) some of the factors that have been linked to depression include: Young age, white race, female gender, low education level, lack of social support, longer duration of dialysis and co morbid conditions i.e. peripheral artery disease, CVD, CAD, DM (17)(57).

A study done by Fischer et al among 628 subjects showed no association between depression and age (21). A study done by Stasiak et al involving 155 subjects established that the burden of depression and anxiety was greatly impacted by age in patients undergoing HD (58).

A study by Armaly et al among 71 subject undergoing HD found female gender to be associated with a higher burden of depression (59). The higher predominance of depression in female cases may be similar to the one found in the general population. Socio economic as well as biological differences have been partially attributed as some of the reasons this discrepancy exist, to date the issue is still under intense investigation (9).

Several studies have established an association between being married and having a greater risk of developing depression in patients undergoing HD (60)(61). In contrast, a study done in India showed that participants who were single were more likely to have depressive

symptoms as compared to those who were in a relationship (62). However, several studies have found no relationship between once marital status and development of depressive symptoms.

A descriptive study done by a Turkish researcher demonstrated that perceived social support had a direct impact towards development of depression. The researcher established that participants who were more contented with relationship had a lower likelihood of being depressed (63).

A study done by Araujo et al, involving 400 subjects undergoing HD, established that low educational levels as well as employment were greatly associated with one developing depression (64).

The duration of dialysis has been researched as a determinant of depression in several studies and has shown conflicting results. A study by Savitha et al, involving 126 patients undergoing HD, showed the highest risk of developing depression was during the first year after commencement of HD (62).

### 2.4 TREATMENT OF DEPRESSION IN END STAGE RENAL DISEASE

Depression is a significant co morbidity in patients with ESRD; it is however undertreated. In a study involving 928 ESRD participants who had a diagnosis of depression made by a physician and were undergoing chronic maintenance HD only 34.9 % of the patient was receiving anti - depression medication (57). A major reason for low treatment regimen is a lack of random controlled trial that defend or refutes efficacy and safety of various regimens in ESRD patients. However, a focused collaborative depression care intervention not only reduces depression but improves ESRD morbidity and quality of life (65)(66). The use of pharmacological and non – pharmacological methods have been shown to be effective (67) (68).

### 2.4.1 Pharmacological management of depression.

This has been shown to be effective especially for severe depression. It involves the use of anti – depressants e.g. selective serotonin reuptake inhibitor (SSRI), selective norepinephrine reuptake inhibitor (SNRI), monoamine oxidase inhibitor (MAOI), tricyclic antidepressants (TCA). In a systemic review, Nagler et al analysed 11 studies gauging the efficacy of anti – depressants in participants with ESRD (69). The majority evaluated SSRI, and reported a

benefit. Since the reporting of the review by Nagler et al, Palmer et al, reported a systemic analysis of random controlled trials comparing the efficacy of anti – depressant medication versus placebo or psychological training. The analysis included 3 RCT not included in the Nagler. The three RCT, demonstrated undoubtedly that SSRI were useful in improving depressive symptoms (67).

### 2.4.2 Non pharmacological management of depression.

Non pharmacological methods have shown comparable results as those seen in pharmacological methods in the treatment of mild and moderate depression. Some of the approaches include: Cognitive behavioural therapy (CBT); exercise therapy.

### **Psychotherapy**

This is the use of psychological methods intended to modify a person behaviour as well as to overcome challenges encountered in a desired way, particular when based on regular personal interaction. The aim of psychotherapy is to improve the individual's mental health and wellbeing, resolve bothersome behaviours, compulsions, thoughts, beliefs or emotions and help improve social skills as well as relationships. Examples of psychotherapy include: CBT, psychodynamic therapy, supportive psychotherapy.

Patients with ESRD who are subjected to CBT demonstrate some level of improvement in depressive symptoms. In addition to treatment of depression, CBT has shown improvement in sleep quality, adherence to fluid restriction, inflammation, as well as quality of life in patients diagnosed to have ESRD (65)(66)(68).

### **Exercise therapy**

Several studies have gauged the impact of exercise therapy and increasing the number of dialysis session in ESRD patients having depression, the results have been varied. (70) In patients already known to have depression it is not clear whether increased dialysis session or exercise therapy can be beneficial, this due to the fact that they lack the motivation to engaged in these forms of treatment.

### 2.5 SCREENING TOOL FOR SOCIAL SUPPORT: MULTIDIMENSIONAL SCALE OF PERCEIVED SOCIAL SUPPORT (MSPSS)

The first publication of MSPSS was done in 1988 in the journal of personality assessment, it was developed by Gregory Zimet and colleagues. The MSPSS is a brief research tool designed to measure perceived social support across three parameters: significant other; family and friend (71).

The MSPSS consists of 12 parts with 4 of the 12 parts used to assess social support across the three sources. The subscale items are divided into: significant other (1, 2, 5, and 10); family (3, 4, 8, and 11) and friends (6, 7, 9 and 12). The total score for each assessed item is 7 points, thus a total maximum score of 28 points for each sub scale. The total score for each of the 3 subscale is then divided by 4. The mean scale score then divides the participants into 3 comparable groups. The level of perceived social support is then graded as follows: a score 1 - 2.9 low support; 3 - 5 moderate support; 5.1 - 7.0 high support.

The MSPSS has been demonstrated to have good internal and test retest reliability, good validity and fairly stable factorial structure, from a number of studies (72)(73)(74)(75). The MSPSS has been translated into several languages including: Urdu; Hebrew; Chinese; French; Italian.

In 2010, NG Cg et al, studied the validation of the MSPSS in the Malaysian population, the tool showed a good internal consistency, with a Cronbach's alpha co efficiency of 0.89, parallel from reliability 0.94 and test retest reliability of 0.77 (74).

In 2011, Wong Pakaran et al, studied the reliability and validity of the MSPSS, Thai version. The internal consistency of the scale was found to be good with a Cronbach's alpha co efficiency of 0.91 for the student group and 0.83 for the post graduate. A test retest was found to be 0.84 (73).

In 2014, Robert C Stewart et al, studied the validation of the MSPSS in Malawi. The internal consistency was demonstrated to be good with a Cronbach's alpha co efficient of 0.90, it also demonstrated construct validity (75).

Pushkarev et al, in 2018, studied the Russian MSPSS version to establish the validity and reliability of the tool. The study demonstrated a high internal consistency; Cronbach's alpha

co efficiency in the group of patients with stable angina was 0.91 versus 0.90 in the group with acute coronary syndrome (72).

### 2.6 SCREENING TOOL FOR DEPRESSION (PATIENT HEALTH QUESTIONNAIRE 9)

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

The PHQ - 9 is a multifunctional tool used to assess severity as well as screen and monitor for depression. The tool blends 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). PHQ - 9 has been validated in many studies (76)(77). In research as well as clinical areas the PHQ – 9 is the most commonly used tool. 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 over time thus can be used as an outcome measure as well (78).

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 major depressive disorder or clinical depression (79).

The tool has the ability 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. A drop of 5 points on the PHQ – 9 severity scoring systems signifies a clinical response to treatment of 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 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. (80)

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. They concluded the PHQ-9 appears valid for assessing depression. (81)

Gelaye B et <sup>i</sup>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. (82)

### 2.7 PROBLEM STATEMENT

ESRD is the final common pathway in the spectrum of CKD. It has been shown to be a leading cause of disability leading to an increase in economic burden both at an individual and societal level as well as loss of productivity years. The prevalence of depression in Kenya has been steadily increasing over the years as evidence by a report done in 2017 by WHO which showed that 1.9 million Kenyans are suffering from depression (27). Individuals with CKD/ESRD exhibit a higher risk of developing depression as compared to the general

population or patients with other chronic medical ailments. ESRD patients who are also depressed have been shown to have poorer disease outcomes. Despite depression being a treatable illness whose early diagnosis and treatment can lead to reduction in morbidity and mortality, it remains largely underdiagnosed by health care providers.

### 2.8 JUSTIFICATION OF THE STUDY

ESRD is increasingly being diagnosed in Kenya and with an even higher increase in non-communicable disease e.g. HTN and DM the number of patients diagnosed with CKD/ESRD will therefore gradually increase. With a growing number of patients being diagnosed to have CKD/ESRD, the rate of depression is therefore expected to increase. In Kenya, unpublished data from Kenya Renal Association, revealed a tremendous increase in health facilities offering HD across the country from 10 to 102 between the year 2006 and 2018. The gradual increase in the number of HD units has led to an increase in the number of patients on chronic HD from 300 to 2400 in the same period. The prevalence of depression has been documented to be between the range of 14 – 84 % in ESRD patients undergoing HD according to several studies. Despite knowledge from literature on the prognostic value of early detection and treatment of depression among this population, screening is not routinely done. A study to establish the burden of depression in ESRD had not been done in Kenya. This study aimed at filling in the gaps that currently exist in our set up by establishing the prevalence of depression and looking at selected determinants associated with depression among ESRD participant undergoing HD.

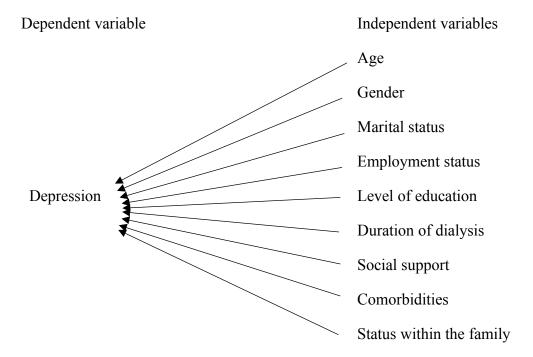
### 2.9 CONCEPTUAL FRAMEWORK

### 2.9.1 Narrative

ESRD and depression seem to have a bidirectional relationship, the mechanism of depression in CKD are very much alike to those identified in other chronic medical ailments. Several factors can lead to the development of depression. In this study we have identified some socio demographic determinants that could influence depression namely: age, gender, marital status, employment status, level of education, duration of dialysis, comorbidities (coronary artery disease, peripheral artery disease, and cerebrovascular accident), and status within the family.

### 2.9.2 Schematic

Figure 2.2: Shows the relationship between dependent variable and independent variables.



### 2.10 RESEARCH QUESTION

What is the burden and determinants of depression among ESRD patients undergoing HD?

### 2.11 OBJECTIVES

### 2.11.1 BROAD OBJECTIVE

To assess the burden and determinants of depression in ESRD patients undergoing HD

### 2.11.2 SPECIFIC OBJECTIVES

### 2.11.3 PRIMARY OBJECTIVES

- 1. To determine the prevalence of depression in patients with ESRD undergoing HD
- 2. To determine the severity of depression in patients with ESRD undergoing HD

### 2.11.4 SECONDARY OBJECTIVES

1. To explore selected predictors of depression in patients with ESRD undergoing HD.

### **CHAPTER THREE**

### 3.0 STUDY DESIGN AND METHODOLOGY

### 3.1 Study design

This was a descriptive cross-sectional study.

### 3.2 Study sites

This study was carried out at the renal units of KNH, NH and PKC. KNH is the largest referral and teaching hospital situated in the capital city of Kenya, Nairobi. It serves as the teaching hospital for UoN medical school. The bed capacity of KNH is 1800 beds with over 6000 staff members. It has 50 wards, 22 outpatient clinics and 24 theatres. There are about 110 patients with ESRD undergoing HD at KNH renal unit. The renal unit is run 24 hours and patients dialyze each day between 5AM and 11PM. Approximately 25 to 30 patients are dialyzed at the renal unit every day. The NH is one of the nation's top private hospitals with a bed capacity of 400, it has over 2000 staff members. In the renal unit at NH there are a total of 100 patients dialyzed in a week with a maximum of thirty patients in a day. The PKC is a private outpatient dialysis centre that dialyses a total of 70 patients in a week.

### 3.3 Study population

These were ambulatory adult patients with ESRD undergoing maintenance HD at the renal units in KNH, NH and PKC.

### 3.3.1 Case definition

A patient with a diagnosis of ESRD and on maintenance HD.

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

### 3.3.2 Inclusion criteria

1. Patients aged 18 years and above who had ESRD and were undergoing maintenance HD.

### 3.3.3 Exclusion criteria

- 1. Patients who did not give informed consent.
- 2. Patients who had any form of cognitive impairment.

### 3.4 sample size

Finite formulae with correction was used to determine the minimum sample size required for prevalence of depression among ESRD patients undergoing maintenance HD.

$$n = \frac{Nz^2 pq}{E^2(N-1) + z^2 pq}$$

where

n =Desired sample size

N = population size (estimated number of patients seeking dialysis services at KNH, NH, and PKC 280).

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

p = prevalence of depression in ESRD patients undergoing maintenance HD ranges from 14 - 84 worldwide. P will be considered as prevalence of 39.3 from a meta-analysis by Palmer et al, 2013 (6).

$$q=1-p$$

E =desired precision (0.05)

$$n = \frac{280 \times 1.96^{2} \times 0.39 \times 0.61}{0.05^{2} (280 - 1) + (1.96 \text{ i.i.} \times 0.39 \times 0.61) = 158 \text{ i.}}$$

158 participants were considered to be the desired sample size for this study.

### 3.5 Sampling Method

Recruitment occurred between 0800 hours to 1800 hours every day of the week. The sampling frame was from all booked patients for HD in each of the three renal units. The principal investigator and trained medical research assistants perused the clinic booking register a day before the clinic and extracted the medical files. On the recruitment day the principal investigator and a trained medical research assistant approached each patient in order of their arrival time to the dialysis unit, each eligible patient was given an opportunity to take part in the study. Participants 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 achieved. Participants already recruited into the study were subsequently eliminated during the next data collection day. Consecutive sampling was used to sample participants to the study.

### 3.6 Data collection procedure

Patients who were on maintenance HD 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 (appendix 1) and any question raised were answered. Those who agreed to participate in the study were given the written informed consent form (appendix 1) to sign and consequently recruited to the study. A study pro forma filled in by the patient with the assistance of the PI/ research assistant was used to collect socio demographic and comorbidity data.

This information was then verified from the patients' medical file. The PHQ -9 and MSPSS was administered in either English or Swahili depending on the participants' preference. Study participants with difficulty in completing the questionnaire were assisted by either the PI or research assistant. Once data had been collected, it was kept safely in a locker only accessible to the researcher

### 3.7 Research Instruments

To collect data, the following data collection instruments were used.

- 1. Instruments: 1. Patient Health Questionnaire (PHQ 9)
  - 2. The Multidimensional scale of perceived social support (MSPSS)

### 3.7.1 Patient Health Questionnaire – 9 (PHQ 9)

The questionnaire was administered to the patient and assistance offered by the principal investigator and/ or medical research assistants when necessary. Once a questionnaire was completed the total sum was added up and used to classified our participants as either mild, moderate and severe depression. Those who had moderate and severe depression were linked to a psychiatrist for management.

### 3.7.2 Multidimensional scale of perceived social support (MSPSS)

The questionnaire was administered to the patient and assistance offered by the principal investigator and/ or medical research assistants when necessary. Once a questionnaire was completed the total sum was added up and used to classified our participants as either having low, moderate and high social support.

### 3.8 DEFINITION OF STUDY VARIABLES

### 3.8.1 Dependent variable

1. Depression

A patient with a PHQ -9 score of 10 or more was described as having clinical depression. The severity of depression was graded as follows, depending on the PHQ -9 scores: mild (10 -14), moderate (15 -19) and severe (20 -27)

### 3.8.2 Independent variables

- 1. Age: Described in years as at of the last birthday.
- 2. Gender: Described as either female/ male.
- 3. Marital status: This was categorized as either single, married, separated, divorced or widowed.
- 4. Employment status: The status of an economically active individual with respect to his/her employment. This was assessed by inquiring whether the activity one was involved in lead to a source of gainful income, or if one had retired from gainful employment that in turn had led to a decline in once source of income. It was categorized as either employed, non employed or retired.
- 5. Level of education: This was categorized as either having no formal education or having primary, secondary or tertiary.
- 6. Duration of dialysis: This was described in months/ years from the start of maintenance HD.
- 7. Level of perceived social support: This was graded as follows: a score 1 2.9 low support; 3-5 moderate support; 5.1 7.0 high support.

- 8. Comorbidities: This included a history of ever having been diagnosed with cerebrovascular accident, coronary artery disease, or peripheral arterial disease.
- 9. Status within the family: This concept referred to the position occupied within the family by each one of its members. It refers to the social status ascribe to each individual in the family based on individual's effort. This was assessed by inquiring who was the provider of the family or gave leadership on family matters. It was categorized as either head of the family, dependant and neither head of the family/dependant.

### 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 conditions such as DM. The questionnaire has also been validated for use worldwide and also in our local set up. The MSPSS has been in use over several years and has been validated for use in assessing the level of perceived social support. It has been translated into different languages while maintaining its validity and sensitivity.

The study assistant was adequately trained by the PI on the data collection process as well as the research instruments prior to the onset of data collection. This minimized errors during the data collection process hence reliable data. The process of 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, University of Nairobi, KNH research and ethics committee, NH ethics committee and the in charge of PKC before commencement of data collection.

The aim of the study was clearly explained to eligible participants in a language suitable to them prior to seeking an informed consent. Only those participants who agreed and signed a consent were included into the study. To ensure we maintained confidentiality all the information we gathered from the participants enrolled into the study was assigned an anonymous study number. This was the only identification appearing on the study questionnaire. Participants were duly informed of their right to withdraw from the study at any point without any discrimination. Privacy was upheld during the process of data

collection to ensure participants felt comfortable when answering the questions that were of personal nature.

Information obtained in this study was considered to be important in the management of the patient. Participants diagnosed to have comorbid depression were linked up with a mental health facility or a clinician of choice for further evaluation and management.

All the information collected onto the data collection tool was put in a secure location only accessible to the principal investigator. The information was used for the purpose of this study and will not be shared with any other persons and may be used for future studies. It will be stored for a duration of 5 years after completion of the study in the event of any need for verification, clarification purposes or further analysis. Upon the lapse of 5 years, the coded questionnaires will be destroyed.

# 3.11 Data management and Analysis

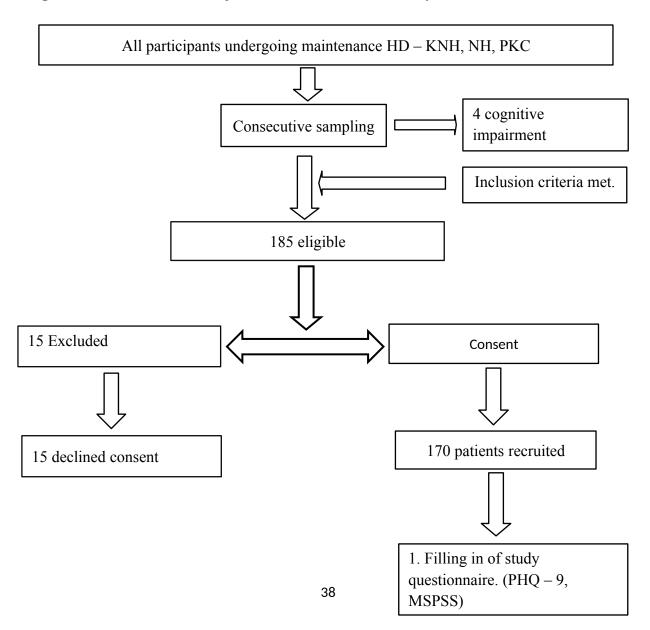
All data from the study pro forma was verified by the principal investigator and coded. Data from the study proforma was keyed in a password protected Microsoft access 2016 data base. Data verification was carried out to flag any erroneous entries and subsequently resolved using the study questionnaires. Data analysis was performed using the SPSS Chicago Illinois version 21. Study population was defined using sociodemographic and comorbid characteristics. Continuous variables were summarized as mean and standard deviation. Categorical variables e.g. age, sex, employment status, level of education were presented as proportions. Prevalence and severity of depression were calculated and presented as a percentage with 95 % confidence interval. The selected determinants associated with depression were analysed using chi – square tests. The statistical 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

A hundred and eight five patients on maintenance HD were enrolled to take part in the study, 15 patients declined to give consent sighting various reason for declining. The major reason for a majority of those declining was having been recruited to multiple other ongoing studies, while 4 patients were excluded due to cognitive impairment based on an expert opinion. A hundred and seventy patients were recruited into the study from KNH, NH, and PKC with a distribution of 70, 65 and 35 patients respectively.

Figure 4.1: Flow chart of subject recruitment into the study



### 4.1 STUDY POPULATION CHARACTERISTICS

A hundred and seventy participants participated in the study of whom 94 (55.3%) were males. The mean age of the respondents was  $56.4 \pm 13.5$  years, while the median age was 57.0 (IQR=19.0) years. Participants aged above 50 years accounted for 67.6%, while as 72.9% were married, 32.4% were employed, a further 30% had retired from formal employment, 97.6% had attained primary, secondary or tertiary levels of education, indicating a high literacy level.

This study population had 52.9% of participants having ever consumed alcohol, 27.6% had a history of cigarette smoking, 2.4% reported a history of using other substances of abuse i.e. bhangi. The respondents had a high percentage of risk factor for cardiovascular disease with 41.8% having diabetes and 84.7 % having a history of hypertension.

This study population had 9 (5.3%) participants having ever been diagnosed with depression, and of those who were diagnosed with depression only 6 (3.5%) had ever been put on any form of treatment. Out of the 9 participants who had ever been diagnosed with depression 2 were known depressive patients prior to developing ESRD.

TABLE 4.1: PARTICIPANTS SOCIO DEMOGRAPHIC CHARACTERISTICS

Variable	Categories	Frequency	Percentage (%)
Age (yrs.)	18 - 29	3	1.8
	30 - 39	14	8.2
	40 - 49	38	22.4
	50 - 59	43	25.3
	60 - 69	41	24.1
	≥ 70	31	18.2
Gender	Male	94	55.3
	Female	76	44.7
Marital status	Single	14	8.2
	Married	124	72.9
	Separated	3	1.8
	Divorced	6	3.5
	Widowed	23	13.5
<b>Employment status</b>	Employed	55	32.4
	Unemployed	64	37.6
	Retired	51	30.0
Level of education	None	4	2.4
	Primary	31	18.2
	Secondary	54	31.8
	Tertiary	81	47.6
History of alcohol	Yes	90	52.9
use	No	80	47.1
History of smoking/	Yes	47	27.6
tobacco use	No	123	72.4
History of DM	Yes	71	41.8
History of HTN	No	99	58.2
History of HTN	Yes	144	84.7
Have you ever been	No Yes	26 9	15.3 5.3
•			
diagnosed with MD	No	161	94.7

#### 4:2 PREVALENCE AND SEVERITY OF DEPRESSION

Out of the study population 55 (32.4%) had clinical depression with a PHQ - 9 score =/> 10. Among these 41 (74%) had mild depression with a PHQ - 9 score of between 10 - 14, 12 (22%) had moderate depression with a score of between 15 - 19 while 2 (4%) had severe depression with a score of between 20 - 27. The mean age of those with depression was 53.0  $\pm$  14.3 years, and the mean depression score was 12.5.

FIGURE 4.2: PREVALENCE OF DEPRESSION IN ESRD PARTICIPANTS UNDERGOING MAINTENANCE HAEMODIALYSIS

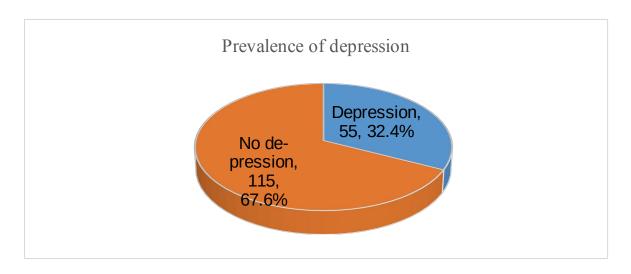
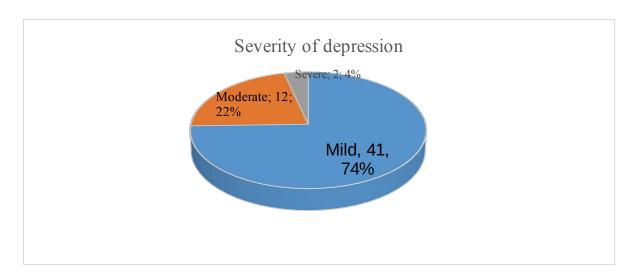


FIGURE 4.3: SEVERITY OF DEPRESSION IN ESRD PARTICIPANTS UNDERGOING MAINTENANCE HAEMODIALYSIS



# 4:3 FACTORS ASSOCIATED WITH DEPRESSION IN PARTICIPANTS UNDERGOING HAEMODIALYSIS

As shown in table 4.2, the age group between (18 - 29) years showed a trend to develop depression compared to the other age groups (p<0.005).

Participants who had retired were more likely to suffer from depression than those who were unemployed or employed (p<0.036). The group of participants who had no form of formal education were more likely to suffer from depression as compared to those who had any form of formal education (p<0.048). The group that admitted having high social support was less likely to suffer from depression than the ones with moderate or low social support (p<0.001).

The proportion of female who were depressed was higher than of males i.e. 38.2% versus 27.7% respectively, however this was not statistically significant (p<0.146). However, this study failed to show any association of depression with marital status, duration of dialysis, comorbidities and status within the family.

TABLE 4.2: SELECTED DETERMINANTS ASSOCIATED WITH DEPRESSION IN END STAGE RENAL DISEASE PARTICIPANT UNDERGOING HAEMODIALYSIS

Variable	Total	Depressio n	No depression	OR (95% CI)	P value
Age (yrs.)					
18 - 29	3	3 (100.0)	0(0.0)	-	0.005
30 - 39	14	7 (50.0)	7 (50.0)	3.4 (0.89 -13.04)	0.066
40 - 49	38	12 (31.6)	26 (68.4)	1.6 (0.54 -4.73)	0.405
50 - 59	43	15 (34.9)	28 (65.1)	1.8 (0.63 -5.14)	0.253
60 - 69	41	11 (26.8)	30 (73.2)	1.3 (0.44 - 3.86)	0.680
≥ 70	31	7 (22.6)	24 (77.4)	Ref	
Gender					
Male	94	26 (27.7)	68 (72.3)	Ref	
Female	76	29 (38.2)	47 (61.8)	0.6 (0.3-1.2)	0.146
Marital status					
Single	14	7 (50.0)	7 (50.0)	Ref	
Divorced	6	0(0.0)	6 (100.0)	-	1.000
Married	124	38 (30.6)	86 (69.4)	0.4 (0.1-1.3)	0.151
Widowed	23	8 (34.8)	15 (65.2)	0.5 (0.1-2.1)	0.363
Separated	3	2 (66.7)	1 (33.3)	2.0 (0.1-27.4)	0.604
<b>Employment status</b>					
Employed	55	21 (38.2)	34 (61.8)	Ref	
Not employed	64	24 (37.5)	40 (62.5)	1.0 (0.48 -2.10)	0.939
Retired	51	10 (19.6)	41 (80.4)	0.4 (0.17 -0.96)	0.036
<b>Level of Education</b>					
None	4	3 (75.0)	1 (25.0)	7.6 (0.75 -76.89)	0.048
Primary	31	10 (32.3)	21 (67.7)	1.2 (0.49 -2.94)	0.688
Secondary	54	19 (35.2)	35 (64.8)	1.4 (0.67 -2.93)	0.404
College	81	23 (28.4)	58 (71.6)	Ref	
<b>Duration of dialysis(yrs.)</b>					
<6 months	23	10 (43.5)	13 (56.5)	Ref	
06 months – 1 year	44	17 (38.6)	27 (61.4)	0.8 (0.3-2.3)	0.701
1 year – 5 years	77	18 (23.4)	59 (76.6)	0.4 (0.1-1.1)	0.064
>5 years	26	10 (38.5)	16 (61.5)	0.8 (0.3-2.5)	0.722

Social support					
Low	4	4 (100.0)	0(0.0)	-	0.001
Moderate	40	21 (52.5)	19 (47.5)	3.5 (1.66 - 7.36)	0.001
High	126	30 (23.8)	96 (76.2)	Ref	
History of cardiovascular					
diseases (CAD, CVA, PAD)					
Yes	17	7 (41.2)	10 (58.8)	1.5 (0.54 -4.18)	0.412
No	153	48 (31.4)	105 (68.6)	Ref	
Status within the family					
Head of family	100	28 (28.0)	72 (72.0)	Ref	
Dependent	65	25 (38.5)	40 (61.5)	1.6 (0.82 -3.11)	0.160
Neither head of	5	2 (40.0)	3 (60.0)	1.7 (0.27 -10.72)	0.562
family/dependent					

#### **CHAPTER FIVE**

#### 5.0 DISCUSSION

Initiation of HD can pose enormous challenges to patients, this challenges ultimately have an impact on their psychological well-being and quality of life. The aim of this study was to determine the burden of depression among ESRD patients undergoing maintenance HD at KNH, NH and PKC. This study determined the prevalence of depression among patients with ESRD undergoing HD to be 32.4% using the PHQ - 9 questionnaire. The distribution of these participants according to severity of depression was 3.6% severe, 21.8% moderate and 74.5% mild depression. There were 55.3% male participants, and the mean age of those with depression was  $53.0 \pm 14.3$  years.

The overall prevalence in our study was similar to other studies worldwide. A study done in Nigeria by Amira et al, found a prevalence of 34.5% among patients undergoing HD using the Zung depression questionnaire (51). The mean age of those undergoing HD was  $42.0 \pm 15.0$  years, no other socio demographic categorization was done. A study done in Brooklynn USA by Cukor et al, found a 29% prevalence of depression among ESRD patients undergoing HD using the BDI screening tool (54). This study had 52.9% female, 88.6% black respondent, and a mean age  $53.3 \pm 15.0$  years. A large observation study by Boulware and colleagues assessed data from the choice for healthy outcomes in caring for ESRD (CHOICE) study and found the prevalence of depression to be between 19 - 24% (18). A meta-analysis by Palmer et al, found a summary prevalence of 39% among ESRD undergoing HD (6). Despite the different tools used in all these studies, there was similarity in the prevalence of depression. This could be due to the tools used are consistent or 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 shazia et al which showed a prevalence of 76.1% using the HDRS screening tool (49). This study had 69.3% male participants and a mean age of  $48.43 \pm 12.69$  years. A study done by Bhatti et al showed a prevalence of 83.8% using the HDRS screening tool (48). This study had 51.96% male participants and a mean age of  $46.83 \pm 17.65$  years. The large variability in prevalence could be as a result of the study criteria, methodology and the use of different screening tools to diagnose depression.

The severity spectrum in our study varies from other studies done worldwide. A study done by shazia et al found 31.8% had mild depression, 13.6% had moderate depression and 30.7% had severe depression using the HDRS screening tool (49). This study had 69.3% male participants and a mean age of  $48.43 \pm 12.69$  years. A study by nelson at al showed 28.1% had mild depression, 39.7% had moderate depression and 15.7% had severe depression using the BDI screening tool (50). This study population had 78% male participants and the mean age of  $52.89 \pm 11.02$  years. This difference could be as a result of the study criteria, methodology and the use of different screening tools to diagnose depression.

A study by shazia et al, found no correlation between age and one developing depression (49). A study by Sanathan et al found that older individuals have higher depression rates (62). A study by Fischer et al, found that younger patients experience more depressive symptoms than older patients (53). Our results are consistent with the latter findings, that young patients (18 – 29 years) are more likely to suffer from depression as compared to older patients.

Education status can be postulated in addition to undergoing HD to contribute to a patient suffering from depression. In India ESRD patients undergoing HD who had low levels of education were shown to exhibit more depressive symptoms, several other studies have shown this relationship (50)(60). In our study the findings corroborate these findings and demonstrate that patients with no level of formal education were more likely to suffer from depression as compared to patients who had any form of formal education. This could be explained by the fact that lack of education makes one not follow instruction concerning their health i.e. poor dietary habits, lack of compliance to medication and poor health seeking behaviour.

The social economic status can be an important determinant of depression in patients undergoing HD, this in our study can be deduced from one's employment status. We know that ESRD brings a series of losses to the patient and requires some adaptation, including the difficulty of integration into the labour market, due to the physical condition caused by the disease and the dynamics of dialysis treatment. A study by Andrade et al, reported a higher percentage of depressed patients among those who were unemployed and those without monthly income, several other studies have shown this relationship (53)(83). In our study, there were more patients who were not involved in some productive economic activities, but no significant association was seen between this group of patients and development of depression. However, we observed a significant association between retirement and one developing depression. This could be explained by the loss of social links created during employment, decline in social status within the society after retirement, and a reduction in income. This aspect deserves to be better evaluated in future studies.

Turkish researchers carried out a study looking at the relationship between depression and perceived social support in ESRD patients undergoing HD. According to the study patients who had high social support were less likely to be diagnosed with depression (63). Many other studies carried out in different geographical locations and ethnic groups have established comparable result. Our result established that patients with high social support were less likely to develop depression as compared to those with moderate or low social support. Psychological issues in resource constrained setting are likely to be neglected especially in patient with ESRD undergoing HD. The knowledge that social support can have an impact on depression in patients undergoing HD presents an opportunity for early medical intervention. It would therefore be reasonable for the medical team involved in the care of this patients to recognise and stress upon the importance of social support. Physician ought to identify patients with low social support, and offer alternative options (e.g. group therapy) to help improve the quality of life especially in patients on HD. (84).

A study by shazia et al, showed a relationship between gender and one developing depression in patients who were undergoing HD. In this study female were more likely to develop depression as compared to their male counterparts (49). Armaly et al, also demonstrated a similar pattern with females having more depression than males (59). The study we carried out showed no association between gender and depression.

Marital status can be an important predictor of depression in patients undergoing HD. A study done among HD patient showed being married conferred one with an greater risk of developing depression (60). In contrast a study done in India showed that participants who were single had more depressive symptoms than the rest of the participants (62). Our results do not demonstrate any association between one developing depression and their marital status. This variability may be explained by the fact that different cultures may have multiple sources of support and don't necessarily rely on the spouses.

Duration of dialysis has been researched as a determinant of depression in several studies and has shown conflicting results. A study, carried out in India demonstrated that the first year after commencing HD was linked with a higher risk of developing depression (62). Our finding is in contrast to this studies, we did not establish any link between duration of dialysis and our participants developing depression. However, this link is still possible if screening of patients is done while commencing HD and then subsequently followed up over time.

A history of cardiovascular disease can be postulated in addition to undergoing HD to contribute to a patient suffering from depression, this can ultimately have an impact on once quality of life (53). Individually this medical conditions have been associated with one developing depression. Having multiple chronic illness is expected to put an undue socio economic burden on the patient. This multiplicity of issues could facilitate in the development of depression. However, this study did not demonstrate any significant association between having a history of cardiovascular disease and developing depression.

The status within a family set up of a patient diagnosed with ESRD undergoing HD may have an impact on one developing depression. This may be as a result of the financial implication involved in managing a chronic medical condition or self-reproach for not being able to meet the needs of the family, however our study failed to demonstrated any significant link with status within the family.

Despite the high incidence of depressive symptoms, only 9 patients had ever been diagnosed with depression. This study highlights the extent of how under recognised depression is and hence the need for active screening for this disorder in ESRD patients undergoing HD. In our study about 6 patients who had ever been diagnosed with depression were ever put on treatment. A number of studies have looked at the use of antidepressant medication in patients diagnosed to have depression and undergoing HD and shown low levels of compliance among patients; approximately between 10% and 50 % (21)(53)(57)(85). The

low uptake to treatment may be as a result of misdiagnosis of depression in ESRD, concern about drug toxicity in the setting of reduced kidney function as well as drug to drug interaction due to the high pill burden, drug side effects, patient non adherence to treatment, and treatment with non pharmacological treatments such as psychotherapy (65)(85). Several studies indicate that treatment with antidepressant, Sertraline for 3 months, not only reduced the symptoms but also improved the quality of life (86).

This study has some implications on health care service delivery in our set up. First, this study shows that depression is a common and substantial mental health problem which is often not diagnosed in ESRD patients undergoing HD. Therefore, it's important to include screening as part of the essential health package before initiating HD. The study also creates a platform for further studies exploring the predictors and mitigating factors in depression among ESRD undergoing HD.

This study had several limitations, we relied on a history of cardiovascular disease to obtain this particular predictor of depression in relation to ESRD patients undergoing HD. The analysis of the selected predictors is not definitive because they lack the statistical power, and hence are only exploratory in nature.

#### 5.1 CONCLUSION

A high percentage of patients undergoing HD suffer from depression. The vast majority of this patients have mild depression. This study highlights the extent of how under recognised depression is and perhaps suggests the need for active screening for this disorder. The quality of life and clinical outcomes in patients diagnosed with ESRD undergoing HD can be greatly improved by early diagnosis and treatment.

### **5.2 RECOMMENDATION**

- 1. We recommend routine screening of all ESRD patients for depression before commencement of HD using simple screening tools e.g. PHQ 9 with appropriate referral.
- 2. There is need of involving a multidisciplinary team in management of ESRD patients on HD. This could include the primary physician, psychologist and psychiatrist.
- 3. There is need for research in areas revolving around mechanisms of depression and preventing and treating depression.

#### **5.3 STUDY STRENGTH**

- 1. To the best of our knowledge this is the first study which has studied the prevalence of depression in ESRD patients undergoing HD in Kenya.
- 2. The use of well validated tools i.e. PHQ 9 and MSPSS to assess depression and social support respectively.
- 3. The collection of data from multiple study centres with varying participants in term of social economic status.

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#### APPENDIX 1: PARTICIPANT INFORMED CONSENT FORM

**Title of the study:** The burden of depression among end stage renal disease patients undergoing haemodialysis at Kenyatta national hospital, Nairobi hospital, and Parklands kidney centre.

#### Introduction

My names are Dr Kevin Nguring'a, I am a post graduate student in the department of internal medicine at the university of Nairobi. The purpose of this consent form is to provide you with all the necessary information to enable you make an informed choice to be a participant in this study. This process is called informed consent. Once you have understood the purpose of the study and agree to be part of the study, I will request you to sign your name on this form.

## Aim of the study

The intention of this study is to determine the proportion of patients undergoing haemodialysis who have depression and what are the unique factors that leads to development of depression among ESRD patients undergoing haemodialysis.

# Procedure to be followed in the study

Your decision to participation in this study is absolutely voluntary and should you accept to participate we will ask you some questions from a questionnaire.

The interview will take approximately 30 minutes and will be conducted in a private room to allow privacy and comfort. The interview shall be conducted by a trained interviewer to assist you in areas that you might not be conversant with.

## **Benefits of participating**

You may benefit from this study by receiving a referral to a psychologist should you be found to be depressed thus start early therapy to avert further complication that may come with a diagnosis of depression. The data we shall obtained from this study will help inform sound scientific clinical decision making in future management of patients who have ESRD undergoing HD.

# Risks of participating

There is no harm involved in participating in this study. That said any study has the potential to introduce psychological, social, emotional and physical risks.

# Compensation

There is no monetary or non-monetary compensation for taking part in this study.

# **Confidentiality**

All the response obtained as well as your result shall remain confidential. 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. Any publication arising from this study will not identify you in person.

# Right to withdrawal

You may decline to take part in this study or drop out at will and at any time during the study. This will not in any way lead to loss of benefits or denial of treatment at the facility.

## **Participation**

Participation in this study is absolutely voluntary and at any given time you are allowed to withdraw or refuse to participate without any victimization on your part.

Questions about the research

If you have any questions or concerns about participating in this study, kindly contact me on

this telephone number 0724766251.

For more information about your rights as a research participant you may contact the

secretary or chairperson, Kenyatta National Hospital University of Nairobi ethics and

research committee.

Telephone Number: 2726300

Participant name

Ext: 44102

Email: uonknh erc@uonbi.ac.ke

I have read this consent form or had the information read out to me in a way I understood. I have had the opportunity to ask questions about it and any question I have asked have been answered to my satisfaction. 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 withdrawal at any

time. I understand that all efforts will be made to ensure that my personal information is kept

confidential. I consent voluntary to participate in this research study.

Participant signature/Thumb stam	np
Date	
Investigators statement	
I, the undersigned have fully exploresearch study to the participant r	lained the relevant details including implications of this named above.
Investigators signature	
Date	

# KIAMBATISHO CHA KWANZA: FOMU YA HABARI KWA WANAOSHIRIKI NA IDHINI

**Kichwa cha utafiti:** Mzigo wa unyogovu kati ya wagonjwa wa magonjwa ya figo ya hatua ya mwisho wanaofanyiwa hemodialysis katika hospitali ya kitaifa ya Kenyatta, hospitali ya Nairobi, na kituo cha figo cha Parklands.

## Utangulizi

Majina yangu ni Dkt Kevin Nguring'a, mimi ni mwanafunzi wa kuhitimu katika idara ya dawa za ndani katika chuo kikuu cha Nairobi. Madhumuni ya fomu hii ya idhini ni kukupa habari zote muhimu kukuwezesha kufanya uchaguzi sahihi kuwa mshiriki katika utafiti huu. Utaratibu huu unaitwa idhini iliyo na habari. Mara tu umeelewa madhumuni ya utafiti na ukubali kuwa sehemu ya masomo, nitakuomba utie saini jina lako kwenye fomu hii.

## Lengo la utafiti

Madhumuni ya utafiti huu ni kuamua idadi ya wagonjwa wanaopata hemodialysis ambao wana unyogovu na ni nini sababu za kipekee zinazoongoza kwa maendeleo ya unyogovu kati ya wagonjwa wa ESRD wanaopatikana hemodialysis.

#### Utaratibu wa kufuatiwa katika utafiti

Uamuzi wako wa kushiriki katika utafiti huu ni wa hiari kabisa na ikiwa utakubali kushiriki tutakuuliza maswali kadhaa kutoka kwa dodoso.

Mahojiano yatachukua takriban dakika 30 na yataendeshwa katika chumba cha kibinafsi ili kuruhusu faragha na faraja. Mahojiano yataendeshwa na mwhojiwa aliyefunzwa ili

kukusaidia katika maeneo ambayo unaweza kutozungumza nao.

Faida ya kushiriki

Unaweza kufaidika na utafiti huu kwa kupokea rejelea kwa mwanasaikolojia unapaswa

kupatikana kuwa huzuni hivyo kuanza tiba mapema ili kuzuia matatizo zaidi ambayo inaweza

kuja na kugundua unyogovu. Takwimu tutakayopatikana kutoka kwenye utafiti huu itasaidia

kuwajulisha maamuzi ya kisayansi ya kliniki katika usimamizi wa wagonjwa wa baadaye.

Hatari za kushiriki

Hakuna madhara yanayohusika katika kushiriki katika utafiti huu. Amesema kuwa utafiti

wowote una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihisia na kimwili.

**Fidia** 

Hakuna fidia ya kifedha au isiyo ya kifedha kwa kushiriki katika utafiti huu.

Usiri

Majibu yote yaliyopatikana pamoja na matokeo yako yatabaki siri. Tutatumia nambari ya

nambari ili kukutambua kwenye darasani ya kompyuta iliyohifadhiwa ya nenosiri na

itachukua rekodi zote za karatasi kwenye baraza la mawaziri lililofungwa. Kichapisho

chochote kinachotokana na utafiti huu hakitakutambulisha wewe mwenyewe.

Haki ya uondoaji

Unaweza kushuka kushiriki katika utafiti huu au kuacha kwa mapenzi na wakati wowote

wakati wa utafiti. Hii si kwa njia yoyote itasababisha kupoteza faida au kukataa matibabu

katika kituo hicho.

Kushiriki

Kushiriki katika utafiti huu ni kikamilifu kwa hiari na wakati wowote unaruhusiwa kufuta au

kukataa kushiriki bila unyanyasaji wowote kwa sehemu yako.

Maswali kuhusu utafiti

Ikiwa una maswali yoyote au wasiwasi juu ya kushiriki katika utafiti huu, nishughulikie kwa

nia nambari hii ya simu 0724766251.

Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti unaweza kuwasiliana na katibu

au mwenyekiti, Chuo Kikuu cha Kenyatta National Hospital cha Nairobi na kamati ya utafiti.

Nambari ya simu: 2726300 Mpana: 44102

Barua pepe: uonknh erc@uonbi.ac.ke

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Nimeisoma fomu hii ya idhini au nilisoma habari kwa njia niliyoelewa. Nimekuwa na fursa ya kuuliza maswali kuhusu hilo na swali lolote nililoomba limejibu limejibiwa kwa kuridhika kwangu. Hatari na faida zimeelezwa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni hiari na kwamba nipate kuchagua kuchagua uondoaji wakati wowote. Ninaelewa kwamba jitihada zote zitafanywa ili kuhakikisha kuwa maelezo yangu binafsi yanawekwa siri. Ninakubali hiari kushiriki katika utafiti huu wa utafiti.

Jina la kuchapishwa la mshiriki	
Mshiriki wa saini ya kitambulisho	
Tarehe	
Taarifa ya wachunguzi	
Mimi, aliyechaguliwa ameeleza kikamilif utafiti huu wa utafiti kwa mshiriki aitwaye	u maelezo muhimu ikiwa ni pamoja na matokeo ya hapo juu.
Wachunguzi saini	
Tarehe	

# APPENDIX 2: STUDY PROFORMA

Tick where applicable
1. How long have you been undergoing haemodialysis
< 6 Months
6 Months – 1 Year
1 Year – 5 Years
> 5 Years
2. What is your gender? Male Female
3. How old are you?
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 Retired
7. History of alcohol consumption? Yes No
8. History of cigarette smoking/ tobacco use?  Yes  No
9. Any history of other substance abuse other than the once mentioned above?
Yes No No
10. If the answer to the above question is yes what are this substance?
11. History of Diabetes? Yes No
12. History of hypertension? Yes No No
13. Have you ever been diagnosed with depression? Yes No No
14. If yes to the above question were you put on any form of treatment?
Yes No No
15. History of Coronary artery disease? Yes No No
16. History of cerebrovascular accident? Yes No No
17. History of peripheral artery disease? Yes No No
18. Status in the family
a) Head of the family

b) Dependent
KIAMBIATISHO CHA PILI: PROFORMA YA UTAFITI
Weka alama ya pata( ) inapohitajika
1. Je! Una muda gani tangu kuanza kuochwa figo kwa machine (hemodialysis) ?
< 6 Miezi
Miezi 6 - Mwaka 1
Mwaka 1 - Miaka 5
> Miaka 5
2. Je, wewe ni wa jinsia gani? Kiume Kike
3. una miaka mingapi? Miaka
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
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6. Kaulı ya ajıra: Umeajırıwa	Haujaajiriwa	Ms	staafu	
7. Historia ya matumizi ya pombe?		Ndio	, [	La 📖
8. Historia ya kuvuta sigara ?		Ndio		La
9. Historia yoyote ya unyanyasaji wa v	vileo vingine	ambazo hazija	elezwa hapo ju	ıu
Ndio La				
10. Kama jibu lako kwa maswali ya ju	ıu ni ndiyo ni	vileo ngani un	atumia ?	
11. Historia ya ugonjwa wa kisukari ?	Ndio	La		
12 Historia ya shinikizo la damu ?	Ndio	La		
13 Umewahi patikana na ugonjwa wa	unyogovu ?	Ndio	La	
14. Kama ndiyo kwa swali hapo juu u	liwekwa juu y	a aina yoyote	ya matibabu ?	
Ndio La				
15. Historia ya maradhi ya moyo ?		Ndio	La	
16. Historia ya ajali ya cerebrovascula	ur ?	Ndio	La	
17. Historia ya ugwonjwa wa ateri ya	pembeni ?	Ndio	La	
18 Hali katika familia?				
Kichwa				
Tegemezi				

# APPENDIX 3: MULTIDIMENSIONAL SCALE OF PERCEIVED SOCIAL SUPPORT

	Very						Very
	Strongly	Strongly	Mildly		Mildly	Strongly	Strongly
	Disagree	Disagree	Disagree	Neutral	Agree	Agree	Agree
1.There is a special person who	1	2	3	4	5	6	7
is around when I am in need. SO							
2.There is a special person with whom	1	2	3	4	5	6	7
I can share my joys and sorrows. SO							
3. My family really tries to help me. Fam	1	2	3	4	5	6	7
4. I get the emotional help and support	1	2	3	4	5	6	7
I need from my family. Fam							
5. I have a special person who is a	1	2	3	4	5	6	7
real source of comfort to me. SO							
6. My friends really try to help me. Fri	1	2	3	4	5	6	7
7. I can count on my friends when	1	2	3	4	5	6	7
things go wrong. Fri							
8. I can talk about my problems	1	2	3	4	5	6	7
with my family. Fam							
9. I have friends with whom I can	1	2	3	4	5	6	7
share my joys and sorrows. Fri							

10. There is a special person in my	1	2	3	4	5	6	7
life who cares about my feelings. SO							
11. My family is willing to help	1	2	3	4	5	6	7
me make decisions. Fam							
12. I can talk about my problems	1	2	3	4	5	6	7
with my friends. Fri							

# KIAMBATISHO CHA TATU: KIWANGO CHA MULTIDIMENSIONAL YA KIJAMII INAVYOJULIKANA

	Sana ha		awakubaliana		kukubaliana		kukubaliana	
	Sana	Sana			kwa	sana	sana sana	
	hawakubal	i hawakubal	i l	katikati		kukubalia	ana	
1. Kuna mtu maalum ambaye yuko	1	2	3	4	5	6	7	
karibu wakati ninamhitaji. SO								
2. Kuna mtu maalum ambaye	1	2	3	4	5	6	7	
Ninaweza kushiriki fuaha na								
huzuni zangu. SO								
3. Familia yangu kweli hujaribu	1	2	3	4	5	6	7	
kunisaidia. Fam								
4. Ninapata msaada wa kihisia na	1	2	3	4	5	6	7	
msaada Kutoka kwa familia yangu. F	am							
5. Nina mtu maalum ambaye ni	1	2	3	4	5	6	7	
Chanzo halisi cha faraja kwangu. SO								
6. Marafiki zangu wanajaribu	1	2	3	4	5	6	7	
kunisaidia. Fri								
7. Ninaweza kutegemea marafiki wang	gu 1	2	3	4	5	6	7	
Wakati vitu vimeenda mrama. Fri								
8. Ninaweza kuzunumza juu ya	1	2	3	4	5	6	7	
Matatizo yangu na familia. Fam								

9. Nina rafiki ambaye ninaweza kushiriki	1	2	3	4	5	6	7
Naye wakati wa furaha na huzuni. Fri							
10. Kuna mtu maalum katika maisha	1	2	3	4	5	6	7
yangu ambaye hujali hisia zangu. SO							
11. Familia yangu iko tayari kunisadia	1	2	3	4	5	6	7
Kufanya uamzi. Fam							
12. Ninaweza kuzungumza juu ya	1	2	3	4	5	6	7
Matatizo yangu na rafiki zangu. Fri							

# APPENDIX 4: PATIENT HEALTH QUESTIONNAIRE – 9

# PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the <u>last 2 weeks</u> , ho by any of the following pour control of the following pour at the following pour		Not at all	Several days	More than half the days	N early every day
1. Little interest or pleasure	e in doing things	0	1	2	3
2. Feeling down, depresse	d, 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 li	ttle energy	0	1	2	3
5. Poor appetite or overeat	ing	0	1	2	3
6. Feeling bad about yours have let yourself or your	elf — or that you are a failure or family down	0	1	2	3
7. Trouble concentrating or newspaper or watching	n things, such as reading the television	0	1	2	3
noticed? Or the opposit	lowly that other people could have e — being so fidgety or restless ing around a lot more than usual	0	1	2	3
9. Thoughts that you would yourself in some way	l be better off dead or of hurting	0	1	2	3
	For office cou	DING 0 +	+	+	
			=	Total Score	
If you checked off <u>any</u> pr work, take care of things	oblems, how <u>difficult</u> have these at home, or get along with other	problems m	ade it for	you to do y	our/
Not difficult at all  S	Somewhat difficult ⑤	Very difficult ⑤		Extrem e difficul ⑤	•

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

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

Katika kipindi cha <u>wiki mbili zilizopita</u> ni mara ngapi umesumbuliwa na matatizo haya yafuatayo? (Tumia "✔" ili kuashiria jibu lako)	H aijatoke zea kabisa	Siku kadhaa	Zaidi y a nusu y a siku h iz o	Takribar 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
<b>4.</b> Kujisikia kuchoka au kutokuwa na nguvu	0	1	2	3
5. Kutokuwa na hamu ya kula au kula sana	0	1	2	3
<ol><li>Kujisikia vibaya-au kujiona kuwa umeshindwa kabisa au umejiangusha au kuikatisha tama familia yako</li></ol>	0	1	2	3
<ol><li>Matatizo ya kuwa makini kwa mfano unaposoma gazeti au kuangalia TV</li></ol>	0	1	2	3
<ol><li>Kutembea au kuongea taratibu sana mpaka watu wakawa wameona tofauti? Au kinyume chake kwamba hutulizani na unahangaika sana kuliko ilivyo kawaida</li></ol>	0	1	2	3
9. Mawazo kuwa ni afadhali zaidi ufe au ujidhuru kwa namna fulani	0	1	2	3
FOR OFFICE CODING	g <u>0</u> +_	+	+	
			= Total Scor	e:

Kama ulitia alama matatizo <u>vovote</u>, matatizo hayo yamefanye iwe <u>viqumu</u> kivipi kwako kufanya kazi yako, kushughulikia vitu nyumbani, au kutangamana na watu wengine?

Sio ng u m u	Ngumu	Ngumu	Ngumu
hata kid o g o	k ia s i	s a n a	zaidi
(5)	(3)	(5)	(5)



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

KNH-UON ERC

Email: uonknh\_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH\_ERC https://twitter.com/UONKNH\_ERC

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KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202 Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi

4th November, 2019

APPROVED

O 4 NOV 2019

KHH/UON-ERC

Ref: KNH-ERC/A/414

Dr. Kevin Nguring'a Reg. No. H58/6885/2017 Dept. of Clinical Medicine and Therapeutics School of Medicine College of Health Sciences University of Nairobi

Dear Dr. Nguring'a

RESEARCH PROPOSAL: THE BURDEN OF DEPRESSION AMONG END STAGE RENAL DISEASE PATIENTS UNDERGOING HEMODIALYSIS AT KENYATTA NATIONAL HOSPITAL, NAIROBI HOSPITAL AND PARKLANDS KIDNEY CENTRE (P566/07/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 4th November 2019 – 3rd November 2020.

This approval is subject to compliance with the following requirements:

- a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- 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 potification.
- 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
- 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. Submission of an <u>executive summary</u> 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.

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

The Principal, College of Health Sciences, UoN

The Director, CS, KNH

The Chairperson, KNH- UoN ERC

The Assistant Director, Health Information, KNH The Dean, School of Medicine, UoN

The Chair, Dept. of Clinical Medicine and Therapeutics, UoN

Supervisor: Prof. Joshua Kayima (Dept. of Clinical Medicine and Therapeutics, UoN),
Prof. Elijah Ogola (Dept. of Clinical Medicine and Therapeutics, UoN),
Dr. Violet C.A. Okech-Helu (Dept. of Mental Health, KNH)