PREVALENCE OF DEPRESSION AMONG PATIENTS WITH CHRONIC KIDNEY DISEASE (CKD) AT THE KENYATTA NATIONAL HOSPITAL

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DECLARATION

I declare that this dissertation entitled "PREVALENCE OF DEPRESSION AMONG PATIENTS WITH CHRONIC KIDNEY DISEASE (CKD) AT THE KENYATTA NATIONAL HOSPITAL" is my own work and that it has not been submitted either wholly or in part to this or any other university for the award of any degree.

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SIGNED

DATE...28/10/2021...

DECLARATION BY THE SUPERVISORS

This	dissertation	is	being	submitted	for	the	award	of	the	Master	of	Medicine	in	psychiatry
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DEDICATION

I dedicate this dissertation to my husband Kevin and my daughter Amy. Thank you for your support during this enduring moment. To my parents, thank you for your continued encouragement. To my siblings, thank you for cheering me on.

TABLE OF CONTENTS

LIST OF	F FIGURES AND TABLES	2
LIST OI	F ABBREVIATIONS	3
OPERA'	TIONAL DEFINITIONS	4
ABSTRA	ACT	SS AND TABLES 2 VIATIONS 3 DEFINITIONS 4
CHAPT	ER ONE	6
INTRO	DDUCTION	6
1.1	Background to the study	6
1.2	Problem statement	7
CHAPT	ER TWO	9
2.1	Literature Review	9
2.2	Conceptual framework	12
2.3	Rationale	13
2.4	Research question	13
2.5	Broad objective	13
2.6	Specific Objectives	14
CHAPT	ER THREE	15
3.1	Methodology	15
3.2	Study design:	15
3.3	Study area:	15
3.4	Study population:	15
3.5	Inclusion criteria:	16
3.6	Exclusion criteria:	16
3.7	Sample size:	16

3.8	Study instruments:	17
3.9	Study implementation:	17
3.10 F	Recruitment Procedure:	18
3.11	Quality assurance procedures	18
3.12 N	Methodology flow chart	20
3.13 H	Ethical Consideration	21
3.14 I	Oata management	22
3.15 I	Data analysis	22
3.16	Significance of the study	23
CHAPTER	FOUR	24
4.0 Result	S	24
4.1 Socio-	demographic results	24
4.2 Depre	ssion symptoms	26
4.4 Factor	s associated with depression	31
4.5 Psych	iatric history, Medical history, Substance use and depression	33
CHAPTER	FIVE	35
5.1 Discus	ssion	35
5.11 Socio	o-demographic results	35
5.12 Depr	ession symptoms	36
5.13 Preva	alence of depression	36
5.14 Facto	ors associated with depression	36
5.15 Medi	ical history and depression	37
5.2 Concl	usion	37
5.3 Recon	nmendations	37

REFERENCES	41
APPENDIX A: CONSENT FORM	47
APPENDIX B: SOCIO-DEMOGRAPHIC QUESTIONNAIRE WITH CLINICAL	
CHARACTERISTICS	55
APPENDIX C: BDI – II TOOL	61
APPENDIX D: APPROVAL	75

LIST OF FIGURES AND TABLES

Figure 1: Relationship between Chronic Kidney Disease and Depression (Silva et a	al., 2019) .12	
igure 2: Methodology Flow Chart20		
Table 1: Sociodemographic data	24	
Table 2: Depression symptoms	27	
Table 3: Prevalence of depression	31	
Table 4: Factors associated with depression	326	
Table 5: Psychiatric history, Medical history, Substance use and depression	27	
Table 6: Hypertension and		
depression27		
Table 7: Work Plan	39	
Table 8: Budget Estimates	40	

LIST OF ABBREVIATIONS

APOLI1 Apolipoprotein L1

BDI-II Beck Depression Inventory II

CKD Chronic Kidney Disease

CES-D Center for Epidemiologic Studies – Depression

DALYs Disability Adjusted Life Years

DSM-5 Diagnostic and Statistical Manual for Mental Disorders – fifth edition

e-GFR Estimated Glomerular Filtration Rate

ESRD End Stage Renal Disease

GFR Glomerular Filtration Rate

GDS-15 Geriatric Depression Scale

HADS Hospital Anxiety and Depression Scale

HIV Human Immunodeficiency Virus

ICD-9 International Classification of Disease, ninth revision

KNH Kenyatta National Hospital

MACE Major Adverse Cardiovascular Events

TDQ Taiwanese Depression Questionnaire

QoL Quality of Life

OPERATIONAL DEFINITIONS

Chronic Disease: A health condition that requires ongoing treatment over a long period of time (more than 1 year) or which hinders activities of daily living or both.

Chronic Kidney disease: A longstanding and gradual disease of the kidneys which leads to renal failure. It results in the buildup of waste and fluid in the blood which are usually filtered by kidneys.

End-stage renal disease: The advanced stage of chronic kidney disease when the kidneys completely lose their function and are not able to meet the needs of the body.

Disability adjusted life years DALYs: This is a measure of overall disease burden which is expressed in terms of number of years lost as a result of sickness, disability or early mortality.

Depression: This is a mental health disorder that is characterized by persistent low mood and loss of interest in activities which cause significant impairment to daily functioning.

ABSTRACT

Study background: Depression is a common co-morbidity among patients with Chronic Kidney Disease (CKD). Preceding studies indicates that this condition causes increased mortality and is also linked to poor quality of life. Nevertheless in Kenya, there is a scarcity of data on the prevalence of depression in CKD patients.

Broad objective: The study aimed to establish the occurrence of depression among patients with Chronic Kidney Disease in Kenyatta National Hospital in Kenya.

Study design and site: The study was carried out at the Kenyatta National Hospital in Kenya. It is one of the national referral hospitals in the country, situated in Nairobi, the capital city of Kenya. The study was done at the renal unit and general medical wards of the hospital and was a cross-sectional descriptive study.

Participants and method: The study enrolled 289 patients with CKD who met the inclusion criteria on follow up for kidney transplant and dialysis at the renal unit, those on outpatient follow up at the renal clinic and patients with CKD admitted in the medical wards. The participants were enrolled using systematic random sampling. They were then interviewed using a researcher designed socio-demographic questionnaire with clinical characteristics and the Beck Depression Inventory-II.

Data management: Data was keyed into a password confined Kobo Toolbox Database. IBM Statistics Software Version 21 was used to analyze data and the results reported in narratives, tables and charts.

Results: The research had a sample size of 289 participants. 169(58.5%) of the participants were male while 120 (41.5%) were female. Study participants had a mean age of 45.9 years. The prevalence of depression (borderline clinical depression to extreme depression) was found to be 28.4%. 24.9% of participants had mild mood disturbances and 46.7% did not have depression. The most common symptoms of depression among the participants were loss of energy as reported by 78.5% of them and increased fatigue which was reported by 77.9% of the research participants. Lower education levels (p=0.007) was positively reported to be related to higher depression scores. Moreover, those who were not employed were at a higher risk of depression (p=0.031). There was also noted to be a considerable relationship amid the existence of other physical illnesses and depression (p=0.005). Further investigation on other physical illnesses revealed that hypertension was positively correlated with having depression (p=0.008).

Conclusion: There is a high prevalence of depression among patients with CKD.

Recommendations: Patients should be managed effectively for CKD and any other co-existing comorbidity to improve their health outcomes.

Health care workers managing patients for CKD need to be keen to look for depression in them and manage it to give holistic care.

There is a need to come up with local guidelines on how to effectively manage CKD patients who also have depression in our country Kenya to improve their quality of life.

CHAPTER ONE

INTRODUCTION

1.1 Background to the study

Chronic Kidney Disease is a major health concern affecting millions of people globally and its treatment presents a huge burden for these patients as they are required to make changes in life to adapt socially. This adaptation or lack thereof has been associated with increased incidences of depression with a prevalence of 19- 68% for patients who are on hemodialysis (Liu et al., 2017; Shirazian et al., 2017). Further, a double impact of CKD and depression has been reported; where CKD increases the risk of depression while depression reduces the adherence to medication by patients with CKD and leads to low quality of life which is made worse by the high costs associated with its treatment (Bautovich et al., 2014; Kokoszka et al., 2016; Shirazian et al., 2017; Silva Junior et al., 2017). Although renal complications are caused by multiple non-communicable diseases, the renal disease remains one of the most neglected chronic diseases with people suffering from renal disease lacking access to care (Luyckx et al., 2018). Kidney disease increases the risks associated with hypertension, heart disease, Human Immunodeficiency Virus (HIV) and infectious diseases including malaria thereby contributing to the global burden of mortality (Couser et al., 2011).

Approximately 16% of the global population has CKD with those with end-stage renal disease (ESRD) having the most common form of renal replacement (dialysis). While medically there are advancements to improve the life expectancy for patients with CKD, a large pool of proof that exists suggests that this is not the case. Most patients with CKD, due to symptoms that are prevalent and bothersome including impairment, mental and emotional fatigue, physical fatigue, decreased motivation and apathy, have a low quality of life. These factors are a prerequisite to the development of depression which has been found to affect about 25% of hospitalized CKD patients (Farragher et al., 2017; Fischer et al., 2010; Palmer et al., 2013). Further, it is reported that fatigue is associated with 76-96% of patients who have been diagnosed with clinical depression. However,

in most cases, depression is not recognized for patients with CKD and therefore goes untreated (Farragher et al., 2017; Goh & Griva, 2018).

Patients with CKD have prevalent neuropsychiatric disorders including cognitive impairment and depression which worsen the quality of life, lead to long periods of hospitalization and lead to high rates of mortality. Many studies have tried to make sense of the occurrence of CKD with neuropsychiatric disorders and it has been commonly hypothesized that there is a co-occurrence of accumulated uremic toxins and cerebrovascular disease for patients who have CKD (Silva et al., 2019). People with CKD are three times more likely to have depression than the common population (Shirazian et al., 2017)

Research has shown that there is a correlation between the diagnosis of chronic disease and the development of psychiatric disorders. People who have been diagnosed with a chronic disease are 1.4- 4 times likely to develop depression, unlike the general population. Psychological distress in these patients has a prevalence of up to 52% as shown in some studies (Bautovich et al., 2014; Kokoszka et al., 2016; Sfyrkou, 2014). Further, there is a higher likelihood of death for patients with comorbid CKD and depression with a survival rate of 9% compared to a 95% survival rate for patients who do not have depression (Kokoszka et al., 2016). Moreover, factors such as social support may have an impact on psychological changes in an individual having a direct effect on the health of the individual. The social factors, therefore, play a vital part in the disease progression and management (McKercher et al., 2013). This is mainly because psychosocial support determines an individual's psychological adjustment to having the disease. It includes offering knowledge on lifelong treatment for the disease, teaching them the different techniques used in dialysis, empowering them to cope with failures in treatment, complications and side effects (Goh & Griva, 2018; McKercher et al., 2013)

1.2 Problem statement

For patients with renal failure, depression is the most commonly occurring psychiatric disease with a prevalence of up to 21- 39% for end-stage renal disease, with an expected annual raise of 7%

(Amira, 2011; Chiang et al., 2015; Gregg et al., 2020; Saisunantararom et al., 2015; Seidel et al., 2014). Additionally, the frequency of depression amid patients with earlier stages is higher (7-42%) compared to those in ESRD (Loosman et al., 2015). The psychological distress can be attributed to socio-economic difficulties that are experienced by people with CKD including loss of employment, financial constraints, limitation in diet and limitations in social interactions. These, therefore, reduce the standard of life and culminate in a low life expectancy and high mortality in those afflicted (Gerogianni & Babatsikou, 2014; Loosman et al., 2015).

In Africa, the risk for CKD is significant, unfortunately, its treatment is not readily accessible (Kaze et al., 2018). Genetic conditions such as sickle cell disease and the presence of the apolipoprotein L1 (APOLI1) gene contribute to the high rates of renal disease south of the Sahara Desert. This coupled with HIV and its treatment, rise in lifestyle diseases such as diabetes and hypertension and the use of alternative treatment which is a risk factor for kidney disease further exacerbates the risk of CKD. The unavailability of renal treatment in the region hastens the progression to renal failure leading to premature death (Muiru et al., 2020). In Kenya, approximately 4 out of 10 inpatients at the Kenyatta National Hospital have CKD (Mwenda et al., 2019). Worldwide, there is a noteworthy occurrence of depression for adults with renal failure which is three times higher than in the entire population. Depression in patients with CKD is associated with high cases of death and a poor standard of life (Shirazian et al., 2017).

This study aimed to establish the frequency of depression among patients with CKD at Kenyatta National Hospital.

CHAPTER TWO

2.1 Literature Review

Reduced glomerular filtration rates were directly estimated to cause the loss of 18 million years of life, 19 million Disability Adjusted Life Years (DALYs) and 1.2 million deaths globally in 2015. Furthermore, Chronic Kidney Disease is associated with eight to ten times the prevalence of cardiovascular mortality in individuals with co-morbid hypertension and diabetes. In addition, about 2 million people need a renal replacement for the sustenance of life globally. (Couser et al., 2011; Luyckx et al., 2018).

The assessment of kidney disease is done through glomerular filtration rate and the existence of renal damage either by kidney biopsy or proteinuria. CKD is grouped into five stages with the presence of proteinuria leading to poor outcomes. Proteinuria has shown to be a more accurate predictor of the development of kidney failure and heart disease than GFR in studies. Stage 1 and 2 are marked with a projected glomerular filtration rate (eGFR) of 90 ml/min and above or 60 -89 ml/min respectively. Stage 3 has (eGFR 30–59 ml/min) and 4 (eGFR 15–29 ml/min). A cutoff of 60 ml/min between stage 2 and 3 is chosen because it reflects a loss of around 50% of normal renal function (Couser et al., 2011; Sfyrkou, 2014).

The physical and biological changes that result from dialysis treatment for people with renal failure have been reported to cause depression. Further, people with renal failure who are not receiving dialysis treatment are 3 times more likely to have depression unlike the common population (Shirazian et al., 2017). Depression, anxiety, substance use and neurotic stress-related disorders are among the most common psychiatric disorders diagnosed in general hospitals. However, due to the similarity of physical symptoms of long-term medical illnesses and psychiatric disorders, they are not easily identified (Ndetei et al., 2009). This means that for people undergoing peritoneal dialysis, there is a higher rate of hospitalization when it is co-morbid with depression. Although this has a negative life impact, if detected and treated early, there are improved patient outcomes (Amira, 2011).

The Diagnostic and Statistical Manual of Mental Disorders – 5th edition (DSM5) indicates that a diagnosis of major depressive disorder is made following 2 weeks of persistent depressed mood, lack of interest in activities, gaining or losing weight, change in sleep patterns, fatigue, feelings of worthlessness, lack of attention, suicidal ideation or attempt, restlessness and slowdown of thought and movement. At least five of the symptoms ought to be present, causing distress and impaired function. The symptoms should also not be attributed to any medical condition, substance use or any other psychiatric disorder (APA, 2013).

Globally, there is a prevalence of 25% of major depressive disorder for individuals with long term kidney impairment compared to 7% prevalence for the general population (Gregg et al., 2020). In a study done in the USA for Major Depressive Episode (MDE) and renal disease, at baseline, there was a prevalence of 21% for Major Depressive Episode (MDE). After one year follow up, the prevalence for MDE was 61% with death, dialysis initiation and hospitalization occurring more for those with MDE (Hedayati et al., 2010). A consequent study on health outcomes for individuals with hypertension and CKD showed that there was 1.5 times more likelihood for death from cardiovascular disease and hospitalization for patients with depression compared to those who did not have depression. The study showed unfavourable cardiovascular outcomes in those with depression (Fischer et al., 2011).

Other studies in Europe have evidence of the existing correlation between CKD and depression as well as other psychiatric conditions such as anxiety. Moreover, depression has been linked to poor health outcomes such as death and dialysis for patients with CKD (Chiang et al., 2015; Loosman et al., 2015). According to Loosman et al., (2015), there was a 34% incidence of depression among patients with CKD in the Netherlands, 31% occurrence of anxiety and 23% prevalence for both depression and anxiety.

In Asia, a study using the Taiwanese Depression Questionnaire found a prevalence of depression of 21% at the beginning and 31% when the study ended (Chiang et al., 2015). These results were similar to studies done in China where the prevalence of depression was between 23%- 29% for

patients on hemodialysis (Liu et al., 2017; Wang et al., 2019). Another study on the correlation between depression and occurrence of death, the Major Adverse Cardiovascular Events (MACE) and severe infections in patients commencing dialysis found that death occurred in 45% of those with depressive symptoms compared to about 40% of those without depression. Further, those with depression also had a 46% rate of severe infections compared to 40% of those without depression. Individuals on dialysis who have depressive symptoms are at a higher risk of infections and death (Wu et al., 2019). However, a study in Malaysia found relatively higher prevalence rates of depression for people on hemodialysis. At baseline, patients had a prevalence of depression of 71% which rose to 78% after 3 months and 84% after 6 months. The study focused on patients with comorbid CKD and hypertension (Khan et al., 2019).

The incidence of symptoms of depression in Asia was almost similar to the results of studies done in the Middle East. Studies conducted found a prevalence of depression for patients undergoing treatment for CKD of between 21% and 28% and the prevalence for anxiety was 23%. (Hawamdeh et al., 2017; Turkistani et al., 2014). Furthermore, the burden of the disease occurs not just for the patients but also the caregivers with a potential for the low quality of life for both. There is however limited evidence on the burden of disease for caregivers of patients with CKD. Hawamdeh et al., (2017) found that the prevalence of depression among the caregivers of patients with CKD was 31% for mild depression, and 8% for severe depression which was the same as the incidence of severe depression for CKD patients in the study.

Although there are very few studies done in Africa exploring the occurrence of depression among patients with CKD, a study done in Nigeria on stages 3-5 of renal disease found a prevalence of 23%, which is similar to most of the studies done globally, compared to 2% for the general population (Amira, 2011). Research conducted in Ghana found an incidence of 45% of depression amid patients with CKD with a 19% low overall standard of life based on the World Health Organization Quality of Life (WHOQOL) instrument (Ganu et al., 2018).

2.2 Conceptual framework

Psychiatric conditions such as anxiety disorders and depression occur commonly in patients with CKD. These patients tend to have comorbidities such as hypertension and diabetes as well as psychosocial and economic factors which make them vulnerable to developing depression. These factors not only worsen their standard of life but also cause long periods of hospitalization and high mortality (Chiang et al., 2015; Loosman et al., 2015; Silva, Miranda, Rocha, & Teixeira, 2019).

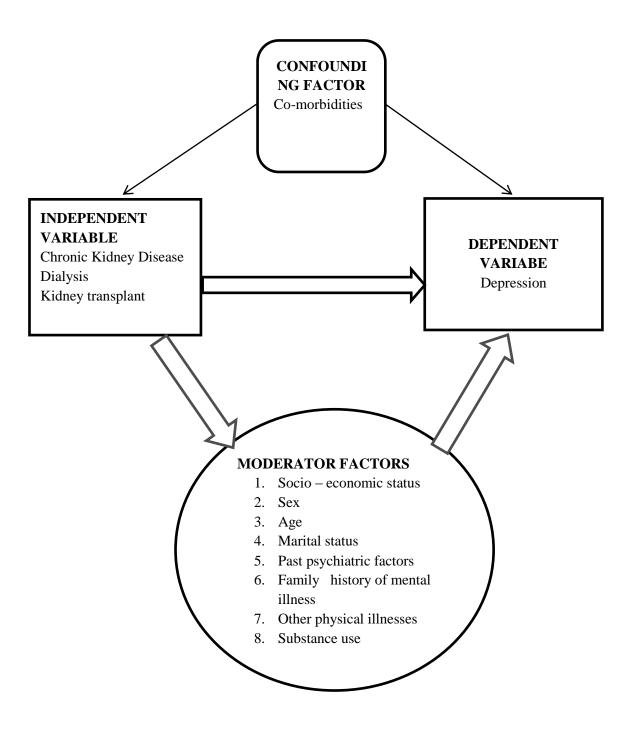


Figure 1: Relationship between Chronic Kidney Disease and Depression (Silva et al., 2019)

2.3 Rationale

Anxiety and depression are the most widespread comorbid psychiatric disorders in patients with long-term conditions (Ndetei et al., 2009). Globally, due to the high number of comorbidities, financial strain and lifelong treatment, patients with a diagnosis of CKD have been known to have depression. The rates of patients with depression in CKD surpasses the numbers of people who have been diagnosed with other terminal diseases (Ahlawat et al., 2018; Chan et al., 2017). Numerous studies have been done globally on depression prevalence in renal disease; unfortunately, local data on the same is not substantial. In Kenya, there is very scarce data on the relationship between depression and CKD. This makes this study worthwhile as it has provided additional motivation for clinicians to continually assess for and treat psychiatric illnesses in all patients at all hospital levels to give them holistic care.

This study is beneficial in that it has provided local data which will assist in establishing guidelines on the management of patients with comorbid depression and CKD thus reducing the risk of morbidity and mortality. It has also painted a picture of how commonly CKD and depression occur together in our setting and increased awareness in clinicians to look for and treat depression in patients with CKD and thus enhance their quality of life.

2.4 Research question

- 1. What is the prevalence of depression among CKD patients at Kenyatta National Hospital?
- 2. What are the socio-demographic and clinical characteristics of CKD patients with a diagnosis of depression?
- 3. What is the association between CKD and depression?

2.5 Broad Objective

To establish the prevalence of depression and related risks among patients with CKD at KNH

2.6 Specific Objectives

- 1. To establish the frequency of depression among patients with CKD at KNH.
- 2. To describe the relationship connecting socio-demographic and clinical characteristics and depression among CKD patients.
- 3. To elicit the association between CKD and depression.

CHAPTER THREE

3.1 Methodology

3.2 Study design:

The researcher conducted a cross-sectional descriptive study.

3.3 Study area:

Kenyatta National Hospital

This study was done at Kenyatta National Hospital, the largest Teaching and Referral hospital in Kenya. This facility started to operate in 1901 with an initial bed capacity of 40, the land on which the hospital lies is approximately 45.7 hectares and inside the Kenyatta National Hospital complex are situated the University of Nairobi School of Medicine, The Kenya Medical Training College, Kenya Medical Research Institute and the National Laboratory Service. The hospital has a total of 50 wards, 22 out-patient clinics, 24 theatres (16 specialized) and the Accident and Emergency Department. It has 8 adult medical wards situated on the seventh and eighth floors. On average the medical wards host around 400 patients in total. Patients with renal issues and who require admission are admitted to any of the medical wards. This facility has a total of 209 beds for the private wing out of a possible 1800 bed capacity. The Hospital accommodates between 2,500 and 3,000 patients in its wards on any given day. The Hospital takes care of over 80,000 inpatients and over 500,000 outpatients on average every year with a renal unit that was opened in 1984. Within this unit, dialysis is done daily. There is a renal transplant clinic every Tuesday and a renal clinic run every Friday morning at the clinic no. 24. About 50 patients are dialyzed every day and on Friday mornings at the clinic, an average of 60 patients is seen.

3.4 Study population:

Participants for this study were renal patients admitted to the medical wards, CKD Patients attending the renal outpatient clinic and patients on follow up for dialysis and kidney transplant at the renal unit in KNH.

3.5 Inclusion Criteria:

- 1. Those over the age of 18 years.
- 2. Those who gave informed permission to take part in the study.
- 3. Those with a diagnosis of CKD.
- 4. Those admitted in any of the medical wards and attending the renal outpatient clinic or on follow up for dialysis and kidney transplant at the renal unit.

3.6 Exclusion criteria:

- 1. Those who were unable to give informed approval to be part of the study.
- 2. Those who were too sick to complete the questionnaire.

3.7 Sample Size:

Naing et al., (2006) formula was used to calculate the study sample size.

$$N = \underline{Z^2 P(1-P)}$$

 d^2

Where;

Where:

N =the desired sample size

Z = 1.96 the critical value on a standard normal distribution corresponding to a 95% confidence level.

P = 25%, the estimated proportion of patients who have a diagnosis of major depressive disorder in Chronic Kidney Disease globally.

d =the degree of precision set at 0.05(5%)

 $N = (1.96)^2 \times 0.25(1-0.25)$

 $(0.05)^2$

N = 288 patients

3.8 Study instruments:

1. Socio-demographic Questionnaire

This is a researcher premeditated questionnaire that captured data classification and appropriate demographic variables like sex, age, marital status, religion, educational level, occupation and the approximate amount of income. It also captured past psychiatric factors, substance use history, mental illness history of the family and other co-morbidities.

2. Beck Depression Inventory-II (BDI-II)

Depression was assessed using the BDI-II (Beck, Steer and Brown, 1996). This is a 21-item scale that measures the symptomatology of depression. Every question on the BDI-II is scored from 0- 3 where the higher number indicates symptom severity. From the 21 items on the questionnaire, their range of scores is between 0- 63. The clinical cut-off points include; mild mood disturbance (11-16), borderline clinical depression (17-20), moderate depression (21-30), severe depression (31-40) and extreme depression (40-63). It has high internal consistency, and Cronbach's α = .92 (Beck et al., 1996). The BDI -II has been applied in Kenya and other nations (Kojima et al., 2002; Musyimi et al., 2017; Ndetei et al., 2009)

3.9 Study implementation:

A total of five days of the week from Monday to Friday were set aside to interview patients for three months starting 01/03/2021 to 31/05/2021.

Monday, Tuesday and Thursday, the researcher sat at the renal unit at KNH daily from 8:00 am to 5:00 pm and interviewed those on follow up for dialysis and kidney transplant who met the inclusion criteria. On Wednesday, the researcher interviewed patients in the ward, between 8:00 am

to 5:00 pm who met the inclusion criteria. On Friday, the researcher sat at Renal Clinic No.24 and interviewed those who met the inclusion criteria.

3.10 Recruitment Procedure:

The study employed a systematic random sampling method with substitution to recruit individuals who came for follow-up as well as those admitted in the wards. The first recruitment procedure involved the researcher interviewing every third patient who came for clinic, dialysis and kidney transplant follow up at the renal unit at KNH. Any patient who did not qualify or declined to participate was replaced with the next one on the list who qualified. The second recruitment procedure involved CKD patients in the wards. The researcher interviewed every third patient that was admitted in the wards, and who met the inclusion criteria. Any selected patient who declined to participate was replaced with the next patient on the list who qualified. The study was conducted at the renal unit and general medical wards in Kenyatta National Hospital. To ensure privacy and confidentiality, the interviews were done in one of the consultation rooms at the unit. In the wards, the interviews were done at the bedside of the patients.

Due to COVID-19, data collected at the follow-up clinic and in the ward was in adherence to the set public health directives, policies and recommendations. During face-to-face visits, appropriate infection prevention control measures including temperature checks, washing and sanitizing of hands, wearing of a 3-ply face mask and social distancing of 1.5 meters during the interviews was observed.

3.11 Quality assurance procedures

To ensure that this dissertation adhered to set standards:

- The proposal for the research was defended at the Department of Psychiatry, University of Nairobi.
- ii. The research proposal was assessed by the University of Nairobi Ethics and Research Committee/Kenyatta National Hospital for quality assurance purposes and ensuring that the researcher understood fully their study area.

- iii. The researcher is a postgraduate student with training on methods of research and tools of data collection necessary for the study. Moreover, the researcher worked under the supervision of the University of Nairobi Supervisors.
- iv. Emphasis was put on explaining the consent form to ascertain that the participants understood the contents of the questionnaire and the purpose of the study.
- v. During the process of data collection, each participant was issued with a unique study code to ensure that no identifying information of the patient was used on the data collection forms.
- vi. Research results will be submitted for peer review to the Department of Psychiatry and the UoN/KNH-Ethics & Research Committee.

3.12 Methodology flow chart

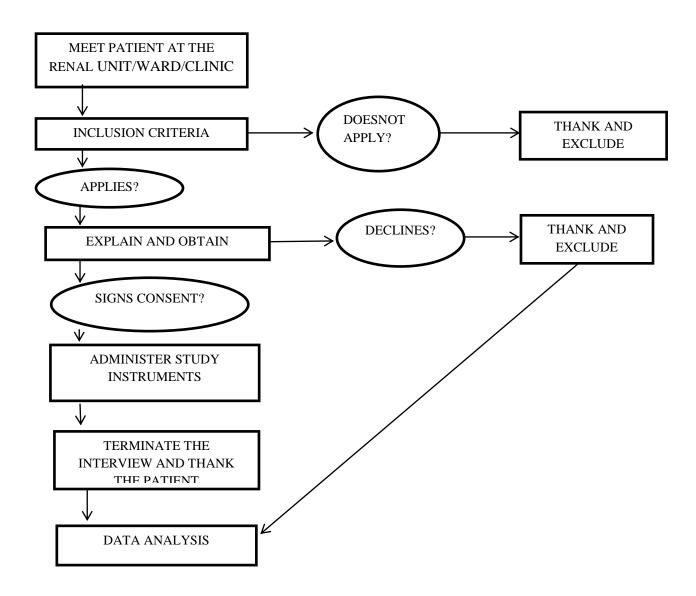


Figure 2: Methodology Flow Chart

3.13 Ethical Consideration

The researcher sought consent from the Department of Psychiatry, UoN/KNH-ERC before carrying out the study. The official informed permission was sought from individual participants after they were explained the purpose of the study. It was also stressed to the participants that there was no material gain from the study, though it was hoped that the data collected will aid in coming up with appropriate guidelines for better management of depression in CKD. Consent forms were included together with the interview questionnaires that contained study explanation, study purpose, voluntary participation, risk, benefits and any inconveniences that might be caused by the study. It also included the right of the participants to withdraw from the interview at any point without any loss of benefits.

Before seeking consent from the participants, the following was explained:

- 1. Consent: Verbal consent explanation was done in either Swahili or English language based on the choice of the participant. It also had an explanation of the type of the study, confidentiality, the possible dangers and benefits on the individual and voluntary participation. Each participant was informed that they were free to withdraw from the study at any given time. The study did not offer any incentives for participation. Every participant was required to give official approval for the study. The informed permission clarified that participation in the study was voluntary and information collected would be used solely for this study and not otherwise.
- 2. Confidentiality: The study questionnaires used unique serial numbers which were given to each participant. Secondly, consent forms collected from participants only required name initials and signature from the participant. Additionally, these were kept separately from the interview questionnaires and were kept under lock and key, with access to the data only limited to the researcher. Soft copies of data were kept in a password protected Microsoft database to safeguard participants' confidentiality.
- 3. **Risks:** There were no anticipated risks from the study to the participants. The only cost for the participants was the time taken to undertake the interview. However, some of the

questions asked in the course of the study were very personal and had the potential to make patients uncomfortable. This was minimized by encouraging and assuring the patients of utmost confidentiality.

4. **Benefits:** The study did not have any direct or monetary benefits to the participants. However, the outcomes of this study have provided local data that will assist in the creation of guidelines and inform policy on optimal management of Chronic Kidney Disease patients who have comorbid depression. Patients who were assessed to have depression were counseled on the spot and those who required further treatment were referred to the Counselor at the renal unit and Psychiatric consultation and follow up at the Department of Mental Health in KNH.

3.14 Data management

The researcher checked data every day for completeness and later transported the hard data in a sealed envelope via private vehicle from the hospital to the researcher's data entry site where the hard data was kept in a lockable cabinet. Data was keyed into a password protected Kobo Toolbox. The consent forms from the study participants were stored in a lockable cabinet in the Principal Investigator's office at the time of collection and after analysis. Upon completion of data collection, hard copy consent forms were evaluated with the entered data to confirm synchrony.

3.15 Data analysis

Descriptive statistics was done in areas where separate variables were put in form of a summary with frequencies and percentages. Continuous variables were summarized by the use of measures of central tendency and dispersion like median, mean, mode, standard deviation and inter-quartile ranges. Reliability and validity analysis was conducted to determine the ability of the tool to reproduce the same results and accuracy of the instrument in measuring depression in patients with Chronic Kidney Disease. As the main variable of interest, factors associated with depression were recognized by the use of Chi-squared tests and Fisher's exact tests for nominal variables and T-tests for continuous variables. Some of these factors included age, socio-economic status, pre-existing

medical conditions, mental health history among others. Throughout the multivariate analysis, we attuned for confounders and effect modifiers in the model to establish independent factors related to depression by use of binary stepwise backward logistic regression. All analysis was done by use of IBM Statistics Software Version 21 and presented using tables, graphs and in prose.

3.16 Significance of the study

This study has painted a picture of how commonly CKD and depression occur together in our setting, it provides a basis to prompt health care workers to be keen and alert when dealing with CKD patients to also look for depression and manage it.

It has also added to the much needed local data on the co-occurrence of depression and Chronic Kidney Disease in Kenya.

It is useful for the creation of guidelines and policies for the management of depression in patients with CKD.

CHAPTER FOUR

4.0 Results

4.1 Socio-demographic Results

As shown in Table 1 below, two hundred and eighty-nine participants were enrolled on the study. The response rate was 100% with the mean age of participants recorded at 45.9 years. 23 (8%) of the participants were 18-24 years, 56 (19.4%) were 25-35 years, 110 (38.1%) were 36-50 years, while 100 (34.6%) were above 50 years.

Table 1: Socio-demographic Data

		N	%
	18-24	23	8.0
A	25-35	56	19.4
Age category	36-50	110	38.1
	Above 50 years	100	34.6
Sex	Male	169	58.5
Sex	Female	120	41.5
	Single	66	23.0
	Married	206	71.8
Marital status	Separated	11	3.8
	Widowed	4	1.4
	Cohabiting	0	.0
	Lack of formal education	5	1.7
Level of Education	Primary	71	24.6
Level of Education	Secondary	141	48.8
	Tertiary	72	24.9
Occupation	Student	19	6.6

	Formal employment	54	18.7
	Informal employment	38	13.1
	Businessperson	96	33.2
	Unemployed	82	28.4
	More than one category	0	.0
	Less than 6000	141	49.0
	6000-10000	42	14.6
Income	10000-40000	65	22.6
	40000-100000	34	11.8
	>100000	6	2.1
	Catholic	106	36.8
D. I	Protestant	167	58.0
Religion	Muslim	13	4.5
	Others	2	.7

Additionally, as shown in Table 1 above, 169 (58.5%) of the participants were male while 120 (41.5%) were female. Almost three-quarters 206 (71.8%) were married, 66 (23%) were single, 11(3.8%) were separated and 4(1.4%) were widowed. 5 (1.7%) participants had no formal education, 71 (24.6%) had attained education up to the Primary school level and 141 (48.8%) had attained education up to secondary school level. 72 (24.9%) had attained education up to the tertiary level. A total of 92 (31.8%) participants were employed. 96 (33.2%) of the participants were in business and those who were unemployed were 82 (28.4%). 19 (6.6%) participants were students. Almost half of the participants 141 (49%) were earning less than KES 6,000, 42 (14.6%) were earning approximately KES 6000 – 10000, 65 (22.6%) were earning KES 10000-40000, 34(11.8%) were earning KES 40000-100000 and only 6 (2.1%) were earning more than KES

100000. The most common religion was Christian with 106 (36.8%) being catholic and 167 (58.0%) being protestant. There were only 13 (4.5%) Muslims.

4.2 Depression symptoms

As demonstrated in Table 2 below, 168 (58.1%) did not report any sadness, 204 (70.6%) did not report any discouragement about the future, 219 (75.8%) did not report feeling like a failure, 118 (40.8%) reported no changes in things that gave them pleasure, 207 (71.6%) didn't report feeling guilty, 230 (79.6%) did not feel like they were being punished, 230 (79.9%) did not report self-dislike, 233 (80.6%) did not report self-criticalness, 265 (91.7%) did not report suicidal thoughts, 209 (72.3%) reported that they did not feel like crying more than before, 160 (55.4%) did not report unusual agitation, 192 (66.4%) did not report any loss of interest in other people or activities, 213 (72.7%) said they felt they were decisive, 247 (85.5%) did not report worthlessness, 62 (21.5%) reported no loss in energy, 106 (36.7%) did not report any changes in sleep patterns, 153 (52.9%) did not report increased irritability, 119 (41.3%) did not report changes in appetite, 160 (55.4%) reported no changes in concentration levels, 64 (22.1%) did not detect increased fatigue while 99 (35.7%) did not report any changes in sexual interest. The average score was 12.8 (std dev 8.7) with the most common symptoms of depression being the loss of energy (78.5%) and increased fatigue (77.9%).

Table 2: Depression symptoms

		N	%
	I do not feel sad	168	58.1
Sadness	I feel sad much of the time	106	36.7
Sauliess	I am sad all the time	12	4.2
	I am so sad or unhappy that I can't stand it	3	1.0
	I am not discouraged about my future	204	70.6
Pessimis	I feel more discouraged about my future than I used to	72	24.9
m	I do not expect things to work out for me	8	2.8
	I feel my future is hopeless and will only get worse	5	1.7
	I do not feel like a failure	219	75.8
Past	I have failed more than I should have	29	10.0
failure	As I look back, I see a lot of failures	34	11.8
	I feel I am a total failure as a person	7	2.4
	I get as much pleasure as I ever did from the things I enjoy	118	40.8
Loss of	I don't enjoy things as much as I used to	101	34.9
pleasure	I get very little pleasure from the things I used to enjoy	63	21.8
	I can't get any pleasure from the things I used to enjoy	7	2.4
	I don't feel particularly guilty	207	71.6
Guilty	I feel guilty over many things I have done or should have done	67	23.2
feelings	I feel quite guilty most of the time	14	4.8
	I feel guilty all of the time	1	.3
D '1	I don't feel I am being punished	230	79.6
Punishme	I feel I may be punished	35	12.1
nt	I expect to be punished	1	.3
Feelings	I feel I am being punished	23	8.0

	I feel the same about myself as ever	230	79.9
Self-	I have lost confidence in myself	29	10.1
Dislike	I am disappointed in myself	17	5.9
	I dislike myself	12	4.2
Self-	I don't criticize or blame myself more than usual	233	80.6
Criticalne	I am more critical of myself than I used to be	33	11.4
	I criticize myself for all of my faults	15	5.2
SS	I blame myself for everything bad that happens	8	2.8
Suicidal	I don't have any thoughts of killing myself	265	91.7
Thoughts	I have thoughts of killing myself, but I would not carry them out	22	7.6
	I would like to kill myself	1	.3
or Wishes	I would kill myself if I had the chance	1	.3
	I don't cry any more than I used to	209	72.3
Cavina	I cry more than I used to	51	17.6
Crying	I cry over every little thing	7	2.4
	I feel like crying, but I can't	22	7.6
	I am no more restless or wound up than usual	160	55.4
	I feel more restless or wound up than usual	93	32.2
Agitation	I am so restless or agitated, it's hard to stay still	29	10.0
	I am so restless or agitated that I have to keep moving or doing	7	2.4
	something	7	2.4
	I have not lost interest in other people or activities	192	66.4
Loss of	I am less interested in other people or things than before	71	24.6
Interest	I have lost most of my interest in other people or things	22	7.6
	It's hard to get interested in anything	4	1.4
Indecisive	I make decisions about as well as ever	213	73.7

ness	I find it more difficult to make decisions than usual	54	18.7
	I have much greater difficulty in making decisions than I used to	17	5.9
	I have trouble making any decisions	5	1.7
	I do not feel I am worthless	247	85.5
Worthless	I don't consider myself as worthwhile and useful as I used to	22	7.6
ness	I feel more worthless as compared to others	13	4.5
	I feel utterly worthless	7	2.4
Loss of	I have as much energy as ever	62	21.5
energy	I have energy than I used to have	133	46.0
	I don't have enough energy to do very much	87	30.1
	I don't have enough energy to do anything	7	2.4
Changes in	I have not experienced any change in my sleeping	106	36.7
sleeping	I sleep somewhat more than usual	34	11.8
pattern	I sleep somewhat less than usual	80	27.7
	I sleep a lot more than usual	17	5.9
	I sleep a lot less than usual	44	15.2
	I sleep most of the day	1	.3
	I wake up 1-2 hours early and can't get back to sleep	7	2.4
Irritability	I am not more irritable than usual	153	52.9
	I am more irritable than usual	82	28.4
	I am much more irritable than usual	46	15.9
	I am irritable all the time	8	2.8

Changes in	I have not experie	enced any change	in my appetite		119	41.3				
appetite	My appetite is so	mewhat less than	usual		90	31.3				
	My appetite is m	uch less than befo	ore		55	19.1				
	My appetite is m	uch greater than u	sual		16	5.6				
	I have no appetite	e at all			6	2.1				
	I crave food all th	crave food all the time								
Concentrati	I can concentrate	can concentrate as well as ever								
on	I can't concentra	te as well as usual			92	31.8				
difficulty	It's hard to keep	my mind on anyth	ning for very long		35	12.1				
	I find I can't con		2	.7						
Tiredness	I am no more tire	64	22.1							
or fatigue	I get more tired o	or fatigued more e	asily than usual		144	49.8				
	I am too tired or	fatigued to do a lo	ot of the things I u	sed to do	69	23.9				
	I am too tired or	fatigued to do mo	st of the things I u	ised to do	12	4.2				
Loss of	I have not noticed	d any recent chang	ge in my interest i	n sex	99	35.7				
interest in	I am less interest	ed in sex than I us	sed to be		93	33.6				
sex	I am much less in	nterested in sex no)W		50	18.1				
	I have lost interes	st in sex complete	ly		35	12.6				
	Mean	Standard	Median	Percentile 25	Percer	tile 75				
		Deviation								
Total Score	12.8	8.7	11.0	7.0	18	3.0				

4.3 Prevalence of Depression

As shown in Table 3 below, 135 (46.7%) reported no depression, 72 (24.9%) had mild mood disturbances, 33 (11.4%) had borderline clinical depression, 37 (12.8%) had moderate depression, 8 (2.8%) had severe depression and 4 (1.4%) had extreme depression. In summary, the prevalence of depression (borderline clinical depression to extreme depression) was 82 (28.4%).

Table 3: Prevalence of Depression

		N	%
	No depression	135	46.7
	Mild mood disturbances	72	24.9
Level of depression	Borderline clinical depression	33	11.4
Level of depression	Moderate depression	37	12.8
	Severe depression	8	2.8
	Extreme depression	4	1.4
	No depression to Mild mood disturbances	207	71.6
Depression	Borderline clinical depression to extreme depression	82	28.4

4.4 Factors associated with depression

As shown in Table 4 below, depression scores appeared to be higher in; females (p=0.09), those separated (p=0.379), those with low income (0.474), and in Muslims and other religions (0.709), but the differences were not statistically significant. However, lower education (p=0.007) and being unemployed (p=0.031) appeared to be associated with higher depression scores and were statistically significant.

Table 4: Factors associated with depression

		Total	Score				
		Mean Standard Deviation		p-value			
Sex	Male	12.0	8.3	0.090			
Sex	Female	13.8	9.0	0.090			
	Single	12.7	9.3				
	Married	12.7	8.5				
Marital status	Separated	16.9	9.6	0.379			
	Widowed	9.5	5.7				
	Cohabiting						
	No formal education	20.2	2.6				
Education level	Primary	15.1	9.2	0.007			
Education level	Secondary	11.5	8.2	0.007			
	Tertiary	12.4	8.7				
	Student	8.7					
	Formal employment	12.9	9.8				
Occupation	Informal employment	12.8	7.5	0.031			
Occupation	Businessperson	11.7	8.2	0.031			
	Unemployed	14.9	9.2				
	More than one category						
	Less than 6000	13.0	8.5				
	6000-10000	12.4	7.5				
Income	10000-40000	13.8	9.8	0.474			
	40000-100000	10.4	8.0				
	>100000	12.0	12.0				

	Catholic	12.2	9.1	
Daligion	Protestant	13.0	8.1	0.706
Religion	Muslim	14.7	12.3	0.706
	Others	15.5	7.8	

4.5 Psychiatric history, Medical history, Substance use and depression

As shown in Table 5 below, 11 (3.8%) of the participants had a family history of mental illnesses and 5 (1.7%) had a history of mental illness. Additionally, 201 (69.8%) had another physical illness and 20 (7.2%) were using alcohol and other substances.

There was a statistically significant relationship between the presence of other physical illnesses and depression (p=0.005). However, there was no statistically significant association between depression and having had a history of mental illness in the family. There was also no statistically significant connection between depression and having a history of mental illness or use of substances.

Table 5: Psychiatric history, Medical history, Substance use and depression

					Depre	ession		
						Borde	erline	
				No dep	ression	clinic	cal to	
				to mile	l mood	extr	eme	
		Hist	disturbance		depression			
		N	%	N	%	N	%	p-value
History of	Yes	11	3.8	8	72.7	3	27.3	
mental illness in	No	278	96.2	199	71.6	79	28.4	0.934

History of a	Yes	5	1.7	3	60.0	2	40.0	0.561
mental illness	No	284	98.3	204	71.8	80	28.2	0.301
Had any other	Yes	201	69.8	134	66.7	67	33.3	0.005
physical illness?	No	87	30.2	72	82.8	15	17.2	0.003
Uses any	Yes	20	7.2	12	60.0	8	40.0	
substances e.g.,	No	259	92.8	188	72.6	71	27.4	0.229
cigarettes	110	239	72.6	100	72.0	/1	21.4	

Further investigations on other illnesses found that depression was associated with having hypertension (p=0.008). This means that hypertensive people were likely to report borderline to extreme depression as in table 6 below.

Table 6: Hypertension and depression

			Depre	ession			
		No depression	clinical to				
		distur	bance	extreme d			
		N	%	N	%	p-value	
Hypertensiv	No	96	80.0	24	20.0	0.000	
e	Yes	111	65.7	58	0.008		

CHAPTER FIVE

5.1 Discussion

5.11 Socio-demographic results

Two hundred and eight-nine participants were interviewed with the enrollment mean age of participants standing at 45.9 years. This can be explained by the fact that the risk of developing non-communicable diseases increases with age (Dixon, 2016). Most of the participants were male even though the Kenya Demographic and Health Survey 2014 showed that females are likely to report having been diagnosed with hypertension by a health care provider up to 3 times more than men (Dixon, 2016). This high number of male respondents compared to the females may be because men tend to have poor health-seeking behaviour and they often go to the hospital when they already have complications as CKD is a complication of hypertension. Other studies were done in the USA, Asia, the Middle East and Africa and they also had higher samples of males than females (Hedayati et al., 2009; Chiang et al., 2015; Khan et al., 2019; Hawamdeh et al., 2017; Turkistani et al., 2014; Amira, 2011).

Most participants were Christians. Additionally, there were more Protestants than Catholics. This can be explained by the fact that the most recent national census in Kenya done in 2019 showed that 85.5 % of the population are Christians and that among them 33.4% are Protestants, 20.4% are affiliated with Evangelical churches and 20.6% are Catholic (KNBS, 2019).

The majority of the participants had completed secondary education. A significant number of them were either employed or business owners. Slightly more than a quarter were unemployed. Of those who were employed or in business, the majority were earning below 6,000.

5.12 Depression Symptoms

The most common symptoms of depression reported by the participants were fatigue (77.9%) and loss of energy (78.5%). While these are symptoms of depression they are also very common symptoms of CKD itself (Ndetei et al., 2009). That explains why most of the participants reported them in this study.

5.13 Prevalence of Depression

The prevalence of depression was found to be 28.4%. This is similar to studies done in the USA, Europe, Asia, Middle East and one study done in Africa (Hedayati et al., 2010; Fischer et al., 2011; Loosman et al., 2015; Liu et al., 2017; Chiang et al., 2015; Turkistani et al., 2014; Amira, 2011) despite the use of different research tools.

In Asia, a study done in Malaysia found a much higher incidence of depression in CKD patients of 71-84%. This study used HADS as the screening tool for depression and the tool was administered to hypertensive CKD patients on dialysis on three different visits. With every dialysis visit, the prevalence of depression got higher in that sample population (Khan et al., 2019). Similarly, another study done in the Middle East found an equally high prevalence of 70% using the Hamilton rating scale for depression (HAM-D) (Hawamdeh et al., 2017).

A study was done in Ghana and established a 44% frequency of depression which is higher than what this study found. The screening tool used in that study was the PHQ 9 while this study used the BDI II (Ganu et al., 2018).

5.14 Factors associated with Depression

In the study, being unemployed (p=0.031) was reported to be related to high depression risk. This is has been shown in other studies as well. For instance, a study done in Saudi Arabia found that depression was higher in patients on hemodialysis with a lower socioeconomic status. This association can be explained by the fact that treatment for CKD is very expensive and causes a lot of economic strain on these patients and their families (Hawamdeh et al., 2017).

The connection between lower education level and having depression was statistically significant (p=0.007). This is similar to what has been demonstrated in other studies including a study in Ghana by (Ganu et al., 2018). Knowledge of one's chronic illness has been reported to be associated with better coping mechanisms in those who are educated as opposed to those who are not educated.

5.15 Medical History and Depression

This study shows that having a physical illness together with Chronic Kidney Disease is associated with having depression (p=0.005). Having hypertension particularly was linked to a higher chance of having depression (p=0.008). This has also been demonstrated in other studies globally (Bahall et al., 2020; Jahrami et al., 2020).

5.2 Conclusion

There is a high occurrence of depression among patients with CKD. Further, lower education, unemployment and having another illness such as hypertension are significantly associated with depression.

5.3 Recommendations

- 1. Patients should be managed effectively for CKD and any other co-existing comorbidity to improve their health outcomes.
- 2. Health care workers managing patients for CKD need to be keen to look for depression in them and manage it to give holistic care.
- 3. There is a need to come up with local guidelines on how to effectively manage CKD patients who also have depression in our country to better their standard of life.
- 4. There is need for a follow up study on the most efficacious treatment for depression among patients with Chronic Kidney Disease in our local set up in Kenya.

5.4 Strengths and Limitations of the study

A strength of this study is the fact that it was carried out at a National Teaching and Referral hospital in Kenya and so the patients recruited were from all over the country. Patients were diverse and so the results give a picture of the situation in the country.

Another strength of the study is the fact that there were many patients and the target sample size was achieved with ease.

One limitation of the study is that the other physical illnesses reported by the patients in the study other than hypertension were not analysed.

Table 7: Work Plan

Activity	Jun-	Jul-	Aug-	Sep-	Oct-	Nov-	Dec-	Jan-	Feb-	Mar-	Apr-	May-
	20	20	20	20	20	20	20	21	21	21	21	21
Proposal												
writing and												
presentation												
Submission												
proposal and												
ethical												
review												
Review												
period												
Response to												
review												
comments (if												
any)												
Data												
collection												
and entry												
Data analysis												
Thesis write												
up												
Submission												
of the final												
thesis												

Table 8: Budget Estimates

	Quantity	Days	Unit cost in (Total cost in
			Ksh)	(Ksh)
Stationery	25	N/A	500	12500
Ethics Payment	1	1	2500	2500
Pens	30	N/A	20	600
Transport	2	90	50	4500
Airtime	1	90	100	9000
Data Entry	1	10	1000	10000
Data Analysis	1	10	5000	50000
Total			<u> </u>	89100
Contingency (10	8910			
GRAND TOTAL	98010			

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APPENDIX A: CONSENT FORM

Introduction:

I would like to tell you about a study being conducted by the above researcher. 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.

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 researcher is interviewing individuals who have a

diagnosis of Chronic Kidney Disease. The purpose of the interview is to find out whether or not the

individual also has depression. Participants in this research study will be asked questions about

their general feelings and interest in activities.

There will be approximately 288 participants in this study randomly chosen. 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 approximately 20 minutes. The interview will cover topics such as your socio-demographics, every day general feelings and interest in activities. If as a participant you are found to have depression at the end of the interview, you will be given treatment at the renal unit either through counseling or medicine or both. You will also be referred appropriately for continued care if necessary.

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.

ARE THERE ANY BENEFITS BEING IN THIS STUDY? There will be no monetary gain from participating in this study, however if found to have depression you will be given treatment at the renal unit either through counseling or medicine. You may also be referred to the department of mental health at Kenyatta National Hospital for continued care if necessary.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

No. You are not required to pay anything to participate in this study.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

No. There will not be any monetary compensation for participating in this study. However, any charges incurred purposely to participate in the study e.g. telephone charges will be reimbursed.

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.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

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.

1 agree to participate in this research study:	Yes No	
Participant name initials:		
Participant signature / Thumb stamp	Date	

Researcher's statement

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

Researcher: DR. ANGELINE MUTINDI, MMED PSYCHIATRY, UNIVERSITY OF NAIROBI. For more information contact me through my phone number: 0716165560 and e-mail address: angelinekioko@gmail.com

You could also contact my supervisors:

- 1. DR. TERESIA MUTAVI, BA (CUEA), MA (NAIROBI), HND Counseling (KIPC), PhD, PSW (NAIROBI), LECTURER, DEPARTMENT OF PSYCHIATRY (UNIVERSITY OF NAIROBI) through her phone number: 0722391236.
- 2. DR. PIUS KIGAMWA, MBChB, MMED (Psych) (Nairobi), SENIOR LECTURER, DEPARTMENT OF PSYCHIATRY (UNIVERSITY OF NAIROBI) through his phone number: 0722521261.

FOMU YA HABARI YA MSHRIKI NA IDHINI

Kiingilio:

Ningetaka kukuambia kuhusu somo inayofanywa na mtafiti huyu. Sababu ya fomu hii ya idhini ni kukupa habari ambayo utahitaji kukusaidia kuchagua kama utakuwa mshirika katika somo hili. Sikia ukiwa huru kuuliza maswali kuhusu kusudi la utafiti huu, nini kitakachofanyika ukishiriki katika somo hili, hatari na faida ambayo yanawezakana, haki zako kama mtu wa kujitolea, na kitu chochote kingine kuhusu utafiti huu ama kitu chochote katika fomu ambayo hayaeleweki. Wakati tushajibu maswali yako yote hadi ukatosheka unaweza chagua kama utaendela na somo hili au la. Mchakato huu unaitwa 'idhini iliyopashwa'. Mwishoni ukielewa na kuitika kukuwa katika somo hili, nitakuomba utie sahihi ya jina lako katika fomu hii. Unafaa kuelewa kanuni ya jumla ambazo huu tumika na washiriki wote katika utafiti wa kimatibabu: i) Chaguo lako la kushiriki ni la kuitolea pekee ii) Unaweza kujiondoa kutoka kwa somo hili wakati wote bila kupatiana sababu ya kujiondoa iii) Kukataa kwa kushiriki kwa utafiti huu haitaadhiri huduma ambayo unaipata katika kituo hiki cha afya au vingine.

Ninaweza endelea? NDIO/LA

Somo	hili	imehakikishwa	na	Hospitali	Kuu	cha	Kenyatta-Chuo	Kikuu	cha	Nairobi	Maadili	na
Utafiti	na k	xamati ya itifaki	No).								

SOMO HILI NI KUHUSU NINI? Mtafiti huyu anahoji watu walio na Ugonjwa Sugu ya Figo. Kusudi la kuhoji ni kutambua kama mtu huyo ana huzuni. Washiriki walio katika somo hili la utafiti wataulizwa maswali kuhusu hisi na hamu za shughuli zao za jumla. Kutakuwa na takriban washiriki 288 katika somo ambao wamechaguliwa bila. Tunaulizia idhini yako kuhusu fikira zako za kushiriki katika somo hili.

NINI KITAFANYIKA UKIAMUA KUSHIRIKI KATIKA SOMO HILI?

Ukiamua kushiriki katika somo hili, mambo yafuatayo yatatendeka: Utahojiwa na mhoji aliyefunzwa katika pahali pa kibinafsi ambapo utajihisi ukiwa huru kujibu maswali. Mahojiano yataendelea hadi takriban dakika 20. Mahojiano ayo yataangazia mada kama vile demografia ya

kijamii, hisi zako za kijumla za kila siku na hamu katika shughuli. Wewe kama mshiriki ukupatikana kama una huzuni katika mwisho wa mahojian, utapewa matibabu katika kitengo cha figo labda kupitia ushauri ama dawa ama yote mawili. Pia utapelekwa ipasavyo kuendelea na matibabu kama itahtajika.

KUNA HATARI YOYOTE, MADHARA AU HARMS USUMBUFU INAYOHUSIANA NA SOMO HILI?

Utafiti wa kimatibabu ina uwezo wa kukujulisha kuhusu hamu za kisaikolojia, kijamii, kihisia na kimwili. Nguvu inafaa kuwekwa ili kupunguza hamu. Hamu moja ilinayowezekana katika somo hili ni kupoteza usiri wako. Tutajaribu tuwezayo kuweka kila kitu unatuambia kwa usiri iwezekanavyo. Tutatumia nambari ya kodi kukutambulisha katika kompuyta iliyolindwa kwa nywila na tutaweka kila rekodi yako ya karatasi katika chumba kidogo cha faili iliyofungwa. Lakini, hakuna mfumo wa kulinda usiri wako ili kukuwa salama kabisa, kwa hivyo inwezekana kuwa mtu atajua ulikuwa katika somo na kujua habari kukuhusu.

Pia, kujibu maswali katika mahojiano haya yanaweza kukupa wasiwasi. Kama kuna maswali utaki kujibu, unaweza kuyaruka. Unahaki kukataa mahojiano ama swali lolote unachoulizwa katika mahojiano.

KUNA FAIDA ZOZOTE ZINAKUWA KATIKA UTAFITI HUU?

Hakuna faida ya moja kwa moja kwako kwa kushiriki katika utafiti huu. Walakini, tunatumahi kuwa, katika usoni za kibinafsi, watu wengine wanaweza kufaidika na utafiti huu kwa sababu itaturuhusu kujifunza zaidi juu ya kuenea kwa wasiwasi, unyongovu na PTSD kati ya watu waliokatwa miguu. Kushiriki katika utafiti huu hautakugharimu chochote isipokuwa dakika zako 40 au zaidi zako.

JE, UTAGHARIMIKA KWA KUSHIRIKI KATIKA UTAFITI HUU?

Kushiriki katita utafiti huu hakutakugharimu chochote isipokuwa muda wako wa takiban dakika arobaini.

UTAPATA PESA ZOZOTE KWA KUSHIRIKI KATIKA UTAFITI HUU?

Hakuna malipo yoyote utakayopata kwa kushiriki katika utafiti huu.

USIRI

Habari unayotoa itashughulikiwa kwa siri na wanachama tu walioidhinishwa wa timu ya utafiti. Utapewa kitambulisho cha kipekee cha kusoma na hakuna majina yatakayopewa kuandika kwenye fomu za mahojiano. Jina lako au habari nyingine ya kibinafsi hautatumika katika ripoti zozote au kushirikishwa na mtu mwingine yeyote. Tutatumia habari hiyo kwa madhumuni ya utafiti tu pekee.

NINI UKIWA NA MASWALI BAADAYE?

Ikiwa una maswali zaidi au wasiwasi juu ya kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe mfupi kwa watafiti walio hapa chini. Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti , unaweza kuwasiliana na Katibu / Mwenyekiti Barua pepe: uonherc@uonbi.ac.ke, au nambari ya simu 2726300 ext 44102. Watafiti watakulipa

CHAGUO ZAKO ZINGINE NI NINI?

Uamuzi wako wa kushiriki katika utafiti ni wa hiari. Uko huru kukataa kushiriki katika utafiti na unaweza kujiondoa kutoka kwa utafitiwakati wowote bila udhalimu na upotezaji wa aida yoyote

FOMU YA RIDHARA

Taarifa ya mshiriki

Nimesoma fomu hii idhini au habari hiyo imesomwa kwangu. Nimepate nafasi ya kujadili utafiti huu na mshauri wa masomo nimajibiwa maswali yangu kwa lugha ambayo inayoeleweka. Nimeelezwa hatari na faida za kushiriki. Ninaelewa kuwa kushiriki kwangu katika utafiti huu ni kwa hiari na kwamba ninaweza ujiondoa wakati wowote. Ninakubali kwa hiari kushiriki katika utafiti huu.

Ninaelewa kuwa juhudi zote zitafanywa kutunza habari k	uhusu kitambulisho changu kuwa siri
(Saini Thumb Uchapa wa Mshiriki)	(tarehe)
(Jina la mshiriki)	

Taarifa ya mtafiti

Mimi kama mtafiti, nimemweleza shiriki mambo yote yanayohusu utafiti hu una ninaamini ya kwamba umeelewa na ametoa idhini ya kushiriki kwa hiari yake mwenyewe bila kushurutishwa.

Mtafiti: DR. ANGELINE MUTINDI, MMED PSYCHIATRY, UNIVERSITY OF NAIROBI.

Kwa habari Zaidi piga simu yangu: 0716165560 au barua pepe: angelinekioko@gmail.com

Waweza pia kuwasiliana na watafiti wasimamizi wafuatao:

- 1. DR. TERESIA MUTAVI, BA (CUEA), MA (NAIROBI), HND Counseling (KIPC), PhD, PSW (NAIROBI), LECTURER, DEPARTMENT OF PSYCHIATRY (UNIVERSITY OF NAIROBI) simu: 0722391236.
- 2. DR. PIUS KIGAMWA, MBChB, MMED (Psych) (Nairobi), SENIOR LECTURER, DEPARTMENT OF PSYCHIATRY (UNIVERSITY OF NAIROBI) simu: 0722521261.

APPENDIX B: SOCIO-DEMOGRAPHIC QUESTIONNAIRE WITH CLINICAL

CHARACTERISTICS Serial Number: Date: In-patient/Out-patient number: 1. Age in years: 2. Sex: Male Female 3. Marital Status i) Single ii) Married iii) Separated iv) Widowed v) Cohabiting 4. Highest Level of education i) No formal education ii) Primary iii) Secondary iv) Tertiary

5. Occupation

i) Student
ii) Formal employment
iii) Informal employment
iv) Business Person
v) Unemployed
vi) More than one category
6. Approximate amount of income per month (Ksh)
i) Less than 6,000
ii) 6,000-10,000
iii) 10,000-40,000
iv) 40,000-100,000
v) >100,000
7. Religion
i) Catholic
ii) Protestant
iii) Muslim
iv) Others Specify

8. Is there any history of mental illness in your family? If "YES", which
one?
9. Do you have any history of a mental illness? If "YES", which one?
10. Do you have any other illness? If "YES", which one?
11. Do you use any substances e.g. alcohol, cigarettes etc.? If "YES", which one?
12. What is the patient's diagnosis in the file?

SWAHILI VERSION

Tarehe:	Nambari:
Nambari ya Mgonjwa aliyelazwa/aliyeonekana hospitalini na kuruhusiwa kwenda nyumb	ani:
1. Umri kwa miaka:	
2. Jinsia: Kiume Kike	
3. Hali ya ndoa	
i) asiyeolewa	
ii) aliyeolewa	
iii) walioachana	
iv) Mjane	
v) Kuishi pamoja	
4. Kimo cha masomo	
i) Hamna masomo rasmi	
ii) Msingi	
iii) Sekondari	
iv) Chuo kikuu	
5. Kazi	
i) Mwanafunzi	
ii) Kazi rasmi	

iii) Kazi isiyo rasm
iv) Mtu wa biashara
v) Huna kazi
vi) Zaidi ya kiwango kimoja, taja
6. Mshahara wako huwa takriban pesa ngapi (Ksh) katika kila mwezi
i) Chini ya 6,000
ii) 6,000 – 10,000 L
iii) 10,000-40,000
iv) 40,000-100,000
v) >100,000
7. Dini
i) Katoliki
ii) Mprotestanti
iii) Muislamu
iv) Kama ni nyingine taja
8.Kuna historia yoyote ya ugonjwa wa akili katika familia yako? kama
ndio ni
upi?

9.Una historia yoyote wa ugonjwa wa akili? kama ndio ni upi?
10.Una ugonjwa mwingine wowote? kama ndio taja?
11. Una tumia kitu chochote kama vile sigara, pombe na vinginevyo? Kama ndio nu
kipi?
12.Utambuzi wa ugonjwa wa mgonjwa katika faili hii ni upi?

APPENDIX C: BDI – II TOOL

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully. And then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including nts in sure

today. Circle the number beside the statement you have picked. If several statemen
the group seem to apply equally well, circle the highest number for that group. Be
that you do not choose more than one statement for any group, including Item 16
(Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).
1. Sadness
0. I do not feel sad.
1. I feel sad much of the time.
2. I am sad all the time.
3. I am so sad or unhappy that I can't stand it.
2. Pessimism
0. I am not discouraged about my future.
1. I feel more discouraged about my future than I used to.
2. I do not expect things to work out for me.
3. I feel my future is hopeless and will only get worse.
3. Past Failure
0. I do not feel like a failure.

1. I have failed more than I should have.
2. As I look back, I see a lot of failures.
3. I feel I am a total failure as a person.
4. Loss of Pleasure
0. I get as much pleasure as I ever did from the things I enjoy.
1. I don't enjoy things as much as I used to.
2. I get very little pleasure from the things I used to enjoy.
3. I can't get any pleasure from the things I used to enjoy.
5. Guilty Feelings
0. I don't feel particularly guilty.
1. I feel guilty over many things I have done or should
have done.
2. I feel quite guilty most of the time.
3. I feel guilty all of the time.
6. Punishment Feelings
0. I don't feel I am being punished.
1. I feel I may be punished.
2. I expect to be punished.
3. I feel I am being punished.

7. Self-Dislike 0. I feel the same about myself as ever. 1. I have lost confidence in myself. 2. I am disappointed in myself. 3. I dislike myself. 8. Self-Criticalness 0. I don't criticize or blame myself more than usual. 1. I am more critical of myself than I used to be. 2. I criticize myself for all of my faults. 3. I blame myself for everything bad that happens. 9. Suicidal Thoughts or Wishes 0. I don't have any thoughts of killing myself. 1. I have thoughts of killing myself, but I would not carry them out. 2. I would like to kill myself.

3. I would kill myself if I had the chance

10. Crying
0. I don't cry any more than I used to.
1. I cry more than I used to.
2. I cry over every little thing.
3. I feel like crying, but I can't.
11. Agitation
0. I am no more restless or wound up than usual.
1. I feel more restless or wound up than usual.
2. I am so restless or agitated, it's hard to stay still.
3. I am so restless or agitated that I have to keep
moving or doing something.
12. Loss of Interest
0. I have not lost interest in other people or
activities.
1. I am less interested in other people or things
than before.
2. I have lost most of my interest in other people or
things.
3. It's hard to get interested in anything.

13. Indecisiveness

0. I make decisions about as well as ever.
1. I find it more difficult to make decisions than
usual.
2. I have much greater difficulty in making
decisions than I used to.
3. I have trouble making any decisions.
14. Worthlessness
0. I do not feel I am worthless.
1. I don't consider myself as worthwhile and useful
as I used to.
2. I feel more worthless as compared to others.
3. I feel utterly worthless.
15. Loss of Energy
0. I have as much energy as ever.
1. I have less energy than I used to have.
2. I don't have enough energy to do very much.
3. I don't have enough energy to do anything.
16. Changes in Sleeping Pattern
0. I have not experienced any change in my sleeping.
1a I sleep somewhat more than usual.

1b I sleep somewhat less than usual.
2a I sleep a lot more than usual.
2b I sleep a lot less than usual.
3a I sleep most of the day.
3b I wake up 1-2 hours early and can't get back to
sleep.
17. Irritability
0. I am not more irritable than usual.
1. I am more irritable than usual.
2. I am much more irritable than usual.
3. I am irritable all the time.
18. Changes in Appetite
0. I have not experienced any change in my
appetite.
1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.
2a My appetite is much less than before.
2b My appetite is much greater than usual.
3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty
0. I can concentrate as well as ever.
1. I can't concentrate as well as usual.
2. It's hard to keep my mind on anything for
very long.
3. I find I can't concentrate on anything.
20. Tiredness or Fatigue
0. I am no more tired or fatigued than usual.
1. I get more tired or fatigued more easily than usual.
2. I am too tired or fatigued to do a lot of the things I
used to do.
3. I am too tired or fatigued to do most of the
things I used to do.
21. Loss of Interest in Sex
0. I have not noticed any recent change in my
interest in sex.
1. I am less interested in sex than I used to be.
2. I am much less interested in sex now.
3. I have lost interest in sex completely.
Total Score:

THE PSYCHOLOGICAL CORPORATION

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SWAHILI VERSION

BDI-II

Maagizo , Dodoso hii inajimuika na viwango 21 ya taarifa. Tafadhali soma kwa makini kila kiwango cha taarifa kwa makini. Alafu cagua taarifa moja katika kila kiwango ambayo inakueleza vyema jinsi ulivyokuwa ukihisi katika wakati wa wiki 2 iliyopita, ikiwa pamoja na leo.Kama kuna taarifa kadhaa katika kiwango kimoja inayokueleza vyema, chora duara kwa nambari ya juu kabisa katika kiwango hicho. Kuwa na uhakika usichague zaidi ya taarifa moja katika kiwango chochote, ikiwamo nambari 16 (Kubalika kwa mifumo ya kulala) ama nambari 18 (Kubalika kwa hamu ya kula).

1. Huzuni

0. Sihisi huzuni
1. Wakati mwingi nahisi huzuni.
2. Nahisi huzuni wakati wote
3. Nina huzuni na kutofurahi sana hadi nashindwa kuendelea
2. Kukata tamaa
0. Sijakata tamaa kuhusu kesho yangu.
1. Nahisi nimekata tamaa kuhusu mwanzo yangu sasa kushinda mbeleni.
2. Sitaraji mambo kwenda vyema kwangu.
3.Nahisi kuwa kesho yangu haina matumaini na mambo yataendelea kwenda mrama.

0. Sihisi kama mshindwa.
1. Nimeshindwa zaidi kuliko nilivyofaa
2. Nikiangalia nyuma naona kushindwa kwingi
3. Nahisi kama mshindwa kabisa kama binadamu.s
4. Kupoteza raha
0. Napata raha zaidi kama mbeleni kwa vitu vinavyo ni burudisha.
1. Siburdiki sana kama mbeleni.
2. Napata raha kidogo kwa mambo yaliyo ni burudisha.
3. Sipati raha yoyote kwa vitu vilivyo ni burudisha.
5. Hisia za hatia
0. Sihisi kuwa ninahatia yoyote
1. Nahisi kuwa nina hatia kwa mambo niliyofanya ama nilivyofaa kufanya
2. Nahisi kuwa nina hatia wakati mwingi.
3. Nahisi kuwa nina hatia wakati wote.
6. Hisia za adhabu
0. Sihisi kuwa ninafaa kuadhibiwa
1. Nahisi kuwa naweza adhibiwa.
2. Nafaa kuadhibiwa
3. Nahisi kuwa nimeadhibiwa.

3. Kushindwa kwa zamani

7. Kutojipenda
0. Nahisi vilevile kujihusu
1. Nimeacha kujiamini
2. Nimekata tamaa kujihusu
3. Sijipendi
8. Kujikosoa
0. Sijikosoi au kujitia lawama kuliko kawaida.
1. Najikosoa sana kuliko mbeleni.
2. Najikosoa kwa kila kosa langu.
3. Najilaumu kwa kila kitu kibaya kitendekacho
9. Mawazo au tamani za kujiua
0. Sina fikira zozote za kujiua
1. Nina fikira za kujiua lakini siwezi kuyatekeleza
2. Ninaweza taka kujiua
3. Nikipata nafasi ninaweza kujiua
10. Kulia
0. Silii tena kama mbeleni.
1. Nalia zaidi kushinda mbeleni.
2. Huwa nalia kwa kila kitu kidogo.
3. Nahisi kulia lakini siwezi.

0. Huwa sihisi kutotulia au kujeruhiwa tena.
1. Nahisi kutotulia na kujeruhiwa kuliko kawaida.
2. Nina fadhaika na kutotulia, ni vigumu kukaa kimya.
3. Nina fadhaika na kutotulia sana hadi ni lazima nikue nikufanya kitu au kusonga.
12. Kupoteza hamu
0. Sijapoteza hamu kwa watu au shughuli
1. Nina nia kidogo kwa watu wengine na shughuli kuliko kitambo.
2. Nimepoteza hamu yangu mingi kwa watu na shughuli zingine.
3. Ni vigumu kupata hamu kwa kitu chochote.
13. Kufanya maamuzi
0. Nafanya maamuzi yangu vyema kushinda mbeleni.
1. Naipata ikiwa vigumu kufanya maamuzi kuliko kawaida.
2. Ninaipata ikiwa shida kubwa kufanya maamuzi kuliko nilivyokuwa mbeleni.
3. Nina taabu kufanya maamuzi.
14.Kutokuwa na thamani
0.Sihisi kuwa sina thamani.
1. Sijioni wa thamani kama mbeleni.
2. Najihisi kuwa sina thamani nikilinganishwa na wengine.
3. Najihisi kuwa sina thamani yoyote kanisa

11. Uhamasishaji

0. Nina nguvu nyingi kuliko hapo awali. 1. Nina nguvu kidogo kuliko nilivyokuwa 2. Sina nguvu ya kutosha kufanya mengi. 3. Sina nguvu ya kufanya chochote. 16. Kubadilika kwa mifumo ya kulala 0. Sijahudhuria kubadilika kokote kwa kulala. 1a Nalala kwa kiasi fulani sana kushinda kawaid 1b Nalala kwa kiasi fulani kidogo kushinda kawaid 2a. Nalala zaidi kushinda kawaida 2b Nalala kidogo sana kushinda kawaida. 3a Nalala mchana sana. 3b Huwa naamka saa 1-2 mapema na nashindwaa kurudi kulala. 17. Kuwashwa 0.Huwa siwashwi kuzidi kawaida. 1. Huwa nawashwa kupita kawaida. 2. Huwa nawashwa zaidi kushinda kawaida. 3. Nawashwa kila wakati

15. Kupoteza nguvu

18. Kubadilika kwa hamu ya kukula 0. Sijahudhuria mabadiliko yoyote kwa hamu yangu ya kula. 1a Hamu yangu ya kula imebadilika kwa kiasi fulani na kuwa kidogo. 1b Hamu yangu ya kula imeongezeka kwa kiasi fulani. 2a Hamu yangu ya kula imepunguka sana kuliko kawaida. 2b Hamu yangu ya kula imeongezeka sana. 3a Sina hamu ya kula. 3b Nina hamu ya kula kila wakati. 19. Ugumu wa kumakinika 0. Niko makini kuliko mbeleni. 1. Siwezi makinika vyema kuliko mbeleni. 2. Ni vigumu kumakinika kwa muda mrefu. 3. Siwezi kumakinika kwa chochote. 20. Kuchoka 0. Sihisi uchovu tena kama mbeleni. 1. Nahisi uchovu kwa urahisi sana kuliko mbeleni. 2. Ninahisi uchovu kufanya kazi mingi kuliko mbeleni. 3. Nahisi uchovu lufanya mambo niliyokuwa nikifanya mbeleni. 21. Kukosa hamu ya ngono 0. Sijaona kubadilka kokote kwa kupoteza hamu ya ngono.

1. Nina hamu kidogo ya ngono kuliko mbeleni.
2. Nimepoteza hamu sana ya ngono saa hii.
3.Nimepoteza hamu ya ngono kabisa.
Jumla:

APPENDIX D: APPROVAL



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

Ref: KNH-ERC/A/55

Dr. Angeline Mutindi Reg. No.H58/11346/2018 Dept. of Psychiatry School of Medicine College of Health Sciences University of Nairobi

Dear Dr. Mutindi



KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202

Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi

15th February 2021



RESEARCH PROPOSAL – PREVALENCE OF DEPRESSION AMONG PATIENTS WITH CHRONIC KIDNEY DISEASE (CKD) AT THE KENYATTA NATIONAL HOSPITAL (P491/09/2020)

KNH-UON ERC

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Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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 15th February 2021 – 14th February 2022

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 notification.
- d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
- g. 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.

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN

The Senior Director, CS, KNH

The Chairperson, KNH- UoN ERC

The Assistant Director, Health Information Dept, KNH

The Dean, School of Medicine, UoN

The Chair, Dept. of Psychiatry, UoN

Supervisors: Dr. Teresia Ndilu Mutavi, Dept.of Psychiatry, UoN

Dr. Pius Kigamwa, Dept.fo Psychiatry, UoN

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