



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
DEPARTMENT OF PSYCHIATRY

**THE PREVALENCE AND SEVERITY OF ANXIETY AND DEPRESSION IN PATIENTS UNDERGOING
HAEMODIALYSIS AT KENYATTA NATIONAL HOSPITAL AND M.P.SHAH HOSPITAL IN NAIROBI, KENYA**

DR TAHIR KADERNANI
H58/33699/2019

**RESEARCH DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE
AWARD OF A DEGREE OF MASTERS OF MEDICINE IN PSYCHIATRY**

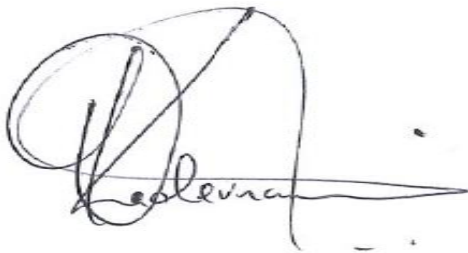
DECLARATION OF ORIGINALITY.

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.

I have not sought or used the services of any professional agencies to produce this work. I have not allowed, and shall not allow anyone to copy my work with the intention of passing it as his/her own work.

I understand that any false claim in respect of this work shall result in disciplinary action, in accordance with University plagiarism policy.

A handwritten signature in black ink, appearing to be 'K. O. Oluoch', written in a cursive style with a long horizontal stroke extending to the right.

Signature.....

Date: 31st May 2022

APPROVAL

This study proposal is submitted for evaluation with our approval as members of faculty:

1) Dr. Pius Kigamwa

M.B.Ch.B, MMED PSYCHIATRY

Senior Lecturer, Department of Psychiatry

University of Nairobi



Signature.....

Date: 31st May 2022

2) Roselyne Okoth

B.Sc PSYCHOL, M.Sc CLIN. PSYCHOL, PhD PSYCHOL(ONGOING)

Lecturer, Department of Psychiatry

University of Nairobi



Signature.....

Date: 31st May 2022

DEDICATION

IN THE NAME OF ALLAH (GOD), THE MOST BENEFICIAL AND THE MOST MERCIFUL.

I would like to dedicate this thesis to my parents and my family who have always supported me and stood steadfast in my corner.

ACKNOWLEDGEMENTS

Firstly, I would like to acknowledge all my supervisors who spent their time and had the patience to walk with me in this journey.

Dr. Manasi Kumar who was my first supervisor before leaving Kenya on a permanent basis but still took her time wherever she was to guide me with my work.

My mentor, Dr. Husein Bagha, who has been my guide ever since I qualified as a doctor and has always been there to show me the way.

Nazeesh Admani who gave her valuable knowledge and insight in this piece of work.

TABLE OF CONTENTS

Contents

DECLARATION OF ORIGINALITY	2
APPROVAL.....	3
DEDICATION.....	4
ACKNOWLEDGEMENTS.....	5
TABLE OF CONTENTS	6
LIST OF FIGURES.....	8
LIST OF TABLES.....	9
<i>LIST OF ABBREVIATIONS</i>	10
OPERATIONAL DEFINITIONS	11
ABSTRACT	12
INTRODUCTION.....	13
1.1 HAEMODIALYSIS, DEPRESSION AND ANXIETY.	13
1.2 PROBLEM STATEMENT	13
LITERATURE REVIEW.....	15
2.1 MENTAL HEALTH IN CHRONIC AND PALLIATIVE CONIDITIONS	15
2.2 GLOBAL FINDINGS.....	15
2.3 REGIONAL AND KENYAN FINDINGS	16
2.4 ANXIETY AND DEPRESSIVE DISORDERS: RISK FACTORS.....	17
2.5 CONCEPTUAL FRAMEWORK	18
3.0 RESEARCH QUESTION, OBJECTIVES AND JUSTIFICATION	19
3.1 RESEARCH QUESTION	19
3.2 STUDY OBJECTIVES	19
3.3 STUDY JUSTIFICATION.....	19
4.0 RESEARCH METHODOLOGY	20
4.1 STUDY DESIGN.....	20
4.2 STUDY SITE	20
4.3 STUDY POPULATION.....	20
4.4 INCLUSION AND EXCLUSION CRITERIA.....	20
4.5 DATA COLLECTION PROCEDURE.....	20
4.6 SAMPLING PROCEDURE	21
4.7 SAMPLE SIZE DETERMINATION	21
4.8 DATA MANAGEMENT AND STATISTICAL ANALYSIS	21

4.9 QUALITY ASSURANCE PROCEDURES	22
4.10 ETHICAL CONSIDERATIONS	22
4.11 STUDY DISSEMINATION PLAN	22
5.0 RESULTS	23
5.1 RECRUITMENT RESULTS.....	23
5.2 DESCRIPTIVE ANALYSIS	23
5.3 STATISTICAL ANALYSES OF PREVALENCE OF GAD AND MDD.....	26
6.0 DISCUSSION	31
6.1 PREVALENCE AND SEVERITY OF GAD	31
6.2 PREVALENCE AND SEVERITY OF MDD	32
6.3 STUDY STRENGTH AND LIMITATIONS.....	33
6.5 CONCLUSIONS AND RECOMMENDATIONS.....	34
6.0 REFERENCES.....	35
APPENDICES.....	41
APPENDIX 1: PARTICIPANT INFORMED CONSENT FORM	41
APPENDIX 2: SOCIODEMOGRAPHIC QUESTIONNAIRE	45
APPENDIX 3: PATIENT HEALTH QUESTIONNAIRE(PHQ-9).....	47
APPENDIX 4: GENERALISED ANXIETY DISORDER 7 (GAD-7)	48
APPENDIX 5: KISWAHILI VERSION OF THE PARTICIPANT INFORMED CONSENT FORM	49
APPENDIX 6 : KISWAHILI VERSION OF SOCIODEOGRAPHIC QUESTIONNAIRE	52
APPENDIX 7: KISWAHILI VERSION OF PHQ-9.....	54
APPENDIX 8: KISWAHILI VERSION OF GAD-7.....	55
APPENDIX 9: ERC APPROVAL	56
APPENDIX 10: NACOSTI APPROVAL	57
APPENDIX 11: SUPPLEMENTARY RESULTS ON ASSOCIATION OF ALCOHOL USE AND GENDER AND EFFECT ON DEPRESSION.....	58

LIST OF FIGURES

Figure 1: Conceptual framework18

Figure 2: Flow Chart.....23

LIST OF TABLES

Table 1: Demographic characteristics for patients undergoing hemodialysis in KNH and MP Shah.....	24
Table 2: Socioeconomic characteristics for patients undergoing hemodialysis in KNH and MP Shah.....	24
Table 3: Relevant past medical history and substance use for patients undergoing hemodialysis in KNH and MP Shah.....	25
Table 4: Anxiety diagnosis and its severity among haemodialysis patients.....	26
Table 5: MDD diagnosis and its severity among haemodialysis patients	26
Table 6: Anxiety and characteristics of patients undergoing haemodialysis.....	27,28
Table 7: Multivariable logistic regression analysis of factors associated with anxiety in haemodialysis Patients.....	28
Table 8: Depression and characteristics of patients undergoing haemodialysis.....	29,30
Table 9: Multivariable logistic regression analysis of factors associated with MDD in haemodialysis Patients.....	30

LIST OF ABBREVIATIONS

ACKD	<i>Advanced Chronic Kidney Disease</i>
AIDS	<i>Acquired Immunodeficiency Syndrome</i>
AKI	<i>Acute Kidney Injury</i>
CKD	<i>Chronic Kidney Disease</i>
DSM 5	<i>Diagnostic and Statistic Manual of Mental Disorders version 5</i>
ESRD	<i>End Stage Renal Disease</i>
GAD	<i>General Anxiety Disorder</i>
HD	<i>Haemodialysis</i>
HIV	<i>Human Immunodeficiency Virus</i>
HRQOL	<i>Health Related Quality of Life</i>
GFR	<i>Glomerular Filtration Rate</i>
KNH	<i>Kenyatta National Hospital.</i>
MDD	<i>Major Depression Disease</i>
MoH	<i>Ministry of Health</i>
PHQ9	<i>Patient Health Questionnaire</i>
QOL	<i>Quality of Life</i>
WHO	<i>World Health Organisation</i>

OPERATIONAL DEFINITIONS

Chronic Kidney Disease (CKD)- General term that encompasses all degrees of decreased kidney function from mild to severe depending on the glomerular filtration rate

End Stage Renal Disease (ESRD) – Last stage of chronic kidney disease where gfr is below 15mL/min and the patient is on to be on dialysis.

Anxiety - Anxiety is a feeling of tension, worried thoughts, and restlessness and includes physical changes such as increased blood pressure and increased heart rate.

Depression - Defined as a mood disorder in which one feels sad/ low mood and loses interest in things that previously one used to enjoy.

ABSTRACT

INTRODUCTION

Patients on haemodialysis suffering from Chronic Kidney disease (CKD)/End Stage Renal Disease (ESRD) has been on the rise and the percentage increase is only second to that of HIV and AIDs. Common psychological disorders that patients on haemodialysis present with are Anxiety and Depression. These mood disorders impact dialysis patients' quality of life negatively.

AIM

The primary goal of this research was to determine the prevalence and severity of anxiety and depression amongst patients undergoing maintenance haemodialysis (HD) at Kenyatta National Hospital and M.P. Shah Hospital in Nairobi, Kenya. The other aim was to assess the effect of various sociodemographic factors on the severity of anxiety and depression.

METHOD

This study is a cross-sectional descriptive study conducted at the dialysis departments of KNH and M.P. Shah hospital after appropriate approvals were sought and received. The study population was any adult undergoing maintenance HD who gave written consent and met the inclusion and exclusion criteria. The data collection tools used for this study were the sociodemographic questionnaire as well as the GAD 7 and PHQ 9 administered to assess anxiety and depression respectively.

DATA ANALYSIS

Data collected was analysed using Stata version 16. Bivariable analysis comparing sociodemographic categorical variables and depression as well as anxiety outcome was conducted using chi-square test. Student's T-test was used to compare means for continuous variables between participants with depression and those without depression as well as those with anxiety and those without anxiety. Statistical significance was assessed using a p value < 0.05. Data was then tabulated and presented in graphs where appropriate.

RESULTS

A total of 160 patients participated in this study with a mean age of 50.1 (SD ± 16.9) years. The overall prevalence of depression was 72.5% (116 out of 160), with a prevalence of 82% (96 out of 117) in KNH and 47%(20 out of 43) in MP Shah. The mean PHQ 9 score was 9.3 (SD±6.4). Patients' level of education (p= 0.003), history of alcohol use (p=0.022) and the hospital a patient attended (p<0.001) were significantly associated with depression. The prevalence of anxiety was 45% (72 out of 160), and 52% (61 out of 117) in KNH compared to MP Shah (p=0.003). There was a significant association between anxiety and gender (p=0.042). Anxiety was also significantly associated with level of formal education (p=0.025).

CONCLUSION

A high proportionate of patients on haemodialysis were diagnosed with anxiety and depression. Majority of the patients diagnosed with anxiety had mild anxiety, and those diagnosed with depression were mostly spread out between mild to moderately severe. This study further demonstrated that history of alcohol use and choice of hospital were crucial variables that were associated with the prevalence of depression in individuals. Routine screening of CKD/ESRD for depression and anxiety prior to starting haemodialysis is recommended.

INTRODUCTION

1.1 HAEMODIALYSIS, DEPRESSION AND ANXIETY.

An essential kidney function is to filter out and remove excess fluid from the blood. In the event of kidney failure, whether acute kidney injury (AKI), chronic kidney disease (CKD) or end stage renal disease (ESRD), haemodialysis is one of the methods of artificial filtration and removal of excess fluid.

Haemodialysis helps in the control of blood pressure and maintaining electrolyte levels such as potassium, calcium and sodium in blood. The process of haemodialysis involves the blood pumped out of the body and passing through a series of tiny tubes in a 'dialyser' also called an 'artificial kidney'. The tubes allow waste material and fluids across it, and allow dialysate (clear fluid) to pass outside the tubes in the opposite direction. The dialysate receives the waste products and the excess fluid and is then drained out leaving the blood clean of impurities after which the clean blood is pumped back into the body.

Dialysis sessions usually last between 3 to 4 hours and occur twice or thrice a week depending on the body requirement. Body requirement in this instance includes;

- how well your kidneys work
- how much fluid weight gain is present in between treatments
- waste accumulation in the body.
- Size of the patient- the bigger the patient the longer the sessions or increased number of sessions.

Patients undergoing haemodialysis are susceptible to multiple physiological and psychological effects directly related to CKD/ESRD, including but not limited to low blood pressure, muscle cramps, access site infection, hyperkalemia, insomnia, anxiety and depression.

Ng et al., (2015), showed that the mean level of anxiety and depression symptoms ranged between 44.7-54.1%(Ng et al., 2015).The study measured the symptoms over a year and the values didn't change much. This is an indication of how common depression and anxiety is amongst patients undergoing haemodialysis and the difficulty in early diagnosis and potential management of the same.

Major depressive disorder, often referred to as clinical depression, is characterized by feelings of sadness and hopelessness. The patient suffering from depression tends to lose interest in what they previously used to enjoy. For a diagnosis of depression to be made the symptoms should be present for at least 2 weeks. Depression and depressive symptoms are most frequently diagnosed psychological disorders amongst individuals with ESRD on Haemodialysis.(Amira, 2011; Chilcot et al., 2008)

Generalized Anxiety Disorder (GAD) or symptoms of anxiety are much less researched among haemodialysis patients as compared to depression. However, despite that the findings as mentioned above do not vary much. GAD is characterized by the presence of anxiety and excessive worry, which the patient finds very hard to control, for a minimum duration of 6 months. This is often accompanied by restlessness or being constantly on the edge, tiring easily, impaired concentration, irritability, increased muscle aches/soreness, insomnia. For a diagnosis of GAD according to DSM 5 at least 3 of the above physical symptoms must accompany the excessive worry and anxiety.

1.2 PROBLEM STATEMENT

ESRD impacts lives of patients considerably. The sufferer undergoes multiple stressors including loss of kidney function, reduction of sexual function, change in family and work status, loss of time, immobility, side effects

of medications, dietary constraints, increase in hospital admissions, constant fear of death and dependency on regular medication and haemodialysis(Chilcot et al., 2008). All the above mentioned are considered risk factors for depression and anxiety. As noted in multiple studies across the globe, anxiety and/or depressive symptoms are negatively correlated to patient Quality of life(Ottaviani et al., 2016).

Diagnosis of MDD and GAD is uncommon as these patients are usually attended to by a single disciplinary team (usually the nephrologist) in most settings and also because of the stigma surrounding mental health, the patient themselves don't address their concerns on the same. In Kenya, people believe that the cause of mental illness is supernatural forces like evil spirits or bewitchment or due to sins committed, but people are also "scared" to seek help for mental illness because of embarrassment or damage to reputation(*Providing Sustainable Mental and Neurological Health Care in Ghana and Kenya: Workshop Summary, 2016*)

Affordability and availability of the mental health practitioner is also another area of concern as there are limited mental health professionals to cater to all the patients on haemodialysis. In a study done in 2007 only 1.33% of medical practitioners were psychiatrists, giving a psychiatrist to population ratio of 1:594,339(Kokonya et al., 2007). Recent statistics show that for a population of above 50 million in Kenya(Marangu et al., 2021), fewer than 500 mental health professionals are available.

LITERATURE REVIEW

2.1 MENTAL HEALTH IN CHRONIC AND PALLIATIVE CONDITIONS

'Chronic diseases' is an umbrella term used for long-term diseases in individuals. Chronic conditions that often come under the umbrella term Chronic disease are functional disabilities which may not be diseases in themselves, however can be developmental disorders and visual impairment. The World Health Organisation (WHO) defines chronic diseases(WHO (2021). *Noncommunicable Diseases*. [Online] *Who.Int*. Available at: <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>., n.d.) as:

"...not passed from person to person. They are of long duration and generally slow progression. The four main types ... are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes"

Observations of mental health decline in patients with chronic diseases have been noted for decades, with one of the earlier records by Lewis J A was in 1954. He observed that a key factor in the increase in prevalence of chronic illnesses is an increase in the ageing population, which brings a larger group of the general population into an age where chronic illnesses are predominant and, due to the advancement of science and medicine, are recognisable. The author also suggested that mental health was affected and likely to be poor amongst those chronically ill, because of the emotional, economic and social stresses that came along with prolonged illnesses(Lewis, 1954).

Over recent years, observations of mental health decline, or disruption of psycho-emotional states in individuals afflicted with such chronic illnesses and palliative conditions has led to numerous studies being conducted on the incidence of anxiety and depression in such patients(Gerontoukou et al., 2015) . An earlier study in 1996 observed well-being and comorbid anxiety in 876 patients with hypertension, diabetes, heart disease and depressive disorders. The investigators reported that patients who were hypertensive and diabetic with comorbid anxiety had poorer physical health related quality of life (HRQOL) than those without comorbid anxiety at both, baseline and the 2-year follow-up(Sherbourne et al., 1996).

A systematic review by Clarke & Currie in 2009, collated 159 reviews of studies on depression and anxiety amongst patients with long term illnesses: Heart diseases, stroke, diabetes, arthritis and osteoporosis, cancer, and asthma. The authors reported a strong association between long term physical illnesses and depression and/or anxiety, stating that having a physical illness can be a risk factor for mental health disorders(Clarke & Currie, 2009). Other risk factors that can lead to such mental health disorders can be worsening condition, functional impairment whether from disease or treatment, social isolation, and diagnostic and treatment regimens(Evans et al., 2005).

One such treatment regimen that could affect patient's mental health is Haemodialysis. Approximately 30% of sufferers on haemodialysis describe indicators of, or are clinically diagnosed with depression(Cohen et al., 2007). In such patients, an increasing risk of hospitalization and potential death is presented due to depression and declining mental health. It is also reported that haemodialysis patients with depression are unlikely to adhere to specific instructions in regards to diet, to quit haemodialysis, and potentially commit suicide(Fischer et al., 2013).

2.2 GLOBAL FINDINGS

In the past decade, numerous studies have been conducted into patient well-being and/or quality of life. A very recent study in Saudi Arabia, observed the effects of anxiety and depression on QOL for individuals

undergoing dialysis (Al-Nashri & Almutary, 2022). The authors discovered the QOL is negatively affected in patients who have been diagnosed with depression and anxiety. The study further reported that amongst the participants, 50% had anxiety and 44.7% were diagnosed with depression, making these mood disorders quite common. These findings parallel previous studies done in 2020 and 2016 (Mosleh et al., 2020; Vasilopoulou et al., 2016).

An earlier study (Bayat et al., 2011), supports the above findings at a lower scale for patients on haemodialysis. It compared anxiety and depression symptoms within patients with different chronic medical conditions; they enrolled 2234 participants of which 68 were being treated with only haemodialysis therapy. The authors reached the conclusion that all chronic illnesses they investigated need mental health consideration, where specifically, patients on chronic haemodialysis (and those with coronary artery disease) expressed higher depression levels compared to other chronic diseases.

García-Llana et al., (2014), reviewed and concluded there is a mounting increment of Advanced Chronic Kidney Disease (ACKD) globally; the amount of ACKD afflicted individuals who are undergoing haemodialysis and/or need replacement therapy is increasing as well. Murtagh et al., (2007), estimated the prevalence of both, depression and anxiety disorders in End Stage Renal Disease (ESRD), to be ranging from 12% to 52%. In a research article (Kimmel et al., 1998), the authors presented that from the dialysis patients, almost 9% were diagnosed with a mental health condition. Furthermore, this was 1.5 to 3.0 times higher for patients who were diagnosed with kidney failure compared to other chronically ill patients. Palmer et al., (2013), further stated that depression was the most frequently reported psychiatric condition especially in ESRD. Similarly, (Bates et al., 2017), estimated that 1 in every 5 patients with ESRD suffer from depression.

A number of researchers (Li et al., 2016; Moreira et al., 2015; Radic et al., 2010) have demonstrated that mental health disorders can be considered as prominent influences of poor QOL for those on dialysis. Patients on dialysis diagnosed with depression and/or anxiety have been shown to have higher suicide ideation rates compared to patients on dialysis who weren't diagnosed with depression and/or anxiety (Chen et al., 2010). Sadeghian et al., (2016), report that amongst haemodialysis patients, some key factors that cause stress and psychological disorders (mainly depression and anxiety) are: body changes, sexual dysfunction and a dramatic reduction of social activities.

2.3 REGIONAL AND KENYAN FINDINGS

Whilst depressive and anxiety disorders have been studied extensively in developed countries, there have been numerous studies conducted across middle- and low-income countries too. In West Africa, Ganu et al., (2018), conducted a cross sectional study of prevalence of depression and quality of life in 106 patients on long term haemodialysis. The investigators discovered that 45% of the individuals screened had positive depressive symptoms and 19% achieved poor ratings on the WHO QOL assessment. They also found a significant association between overall quality of life and depression. Some factors that were correlated to quality of life were, income, education and length of treatment, whereby no significant correlation was found in any of them. The authors suggested that due to 91.5% and 84.9% of the patients having supportive family and receiving at least 9 years of education, respectively, may be factors that would have enhanced the patients' coping mechanisms. Nonetheless, the positive association between depression and depleting QOL suggested the need for further studies for a larger population base, so patients with depressive disorders can be treated appropriately and improve their general well being.

A similar sized North Western cross-sectional study in Africa was conducted in Morocco (El Filali et al., 2017). They studied the prevalence of depression and anxiety and quality of life in 106 individuals undergoing chronic haemodialysis in Morocco. The investigators found that of the study population, 34% had Major depressive

episode (MDE), 25.2% were diagnosed with an anxiety disorder and 16.5% had suicide ideation thoughts. The authors also discovered an association between MDE and the following factors: living alone, the presence of pain, and anxiety disorder. Those who lived alone and had anxiety disorders were also more likely to fall into the suicidal ideation category.

Elkheir et al., (2020) also conducted a study observing prevalence and risk factors of depressive symptoms amongst 75 dialysis patients with ESRD in Sudan. Interestingly, the study presented that new patients, who have been on dialysis for 1 year or less had more depressive symptoms (66.7%) than patients who had been on dialysis for 2–3 years (21.6%) or over 3 years (11.8%). The authors reasoned that this be due to adaptation of lifestyle after long term dialysis. Regardless, these figures still mean that more than 66% of patients on dialysis have presented symptoms of depression, which can greatly impact the QOL, as seen by the previous study (Ganu et al., 2018). Other than duration on haemodialysis, another factor which were correlated significantly with depression was age, whereby younger patients had a higher prevalence compared to older patients.

In Sub-saharan Africa, Muiru et al., (2020) review that individuals may be at risk from CKD due to numerous risk factors such as gene risk variants, the prevalence of HIV infection and it's treatment, hypertension, and diabetes. In a multi-centre population based study, they estimated that CKD prevalence was 6.8% (95% CI 5.7–8.1%) overall between Uganda and Western Kenyan region, with the prevalence in Western Kenya being 2.7–5.1%(Muiru et al., 2020).

A key study within Nairobi, Kenya, that inspired this study was conducted by Nguringa, (2020). The study aimed to determine the prevalence of depression in ESRD patients undergoing maintenance haemodialysis at three centres within Nairobi. The study included 170 participants and results calculated incidence of depression at three stages: mild (32.4%), moderate (7.06%) and severe (1.17%). The results concluded that a significant number of participants undergoing haemodialysis had concomitant depression. The study also aimed to assess determinants of depression amongst the selected patients and concluded that lack of social support, lack of formal education, age (18-29 years) and retirement from formal employment were contributing risk factors to depression amongst haemodialysis patients(Nguringa, 2020).

2.4 ANXIETY AND DEPRESSIVE DISORDERS: RISK FACTORS

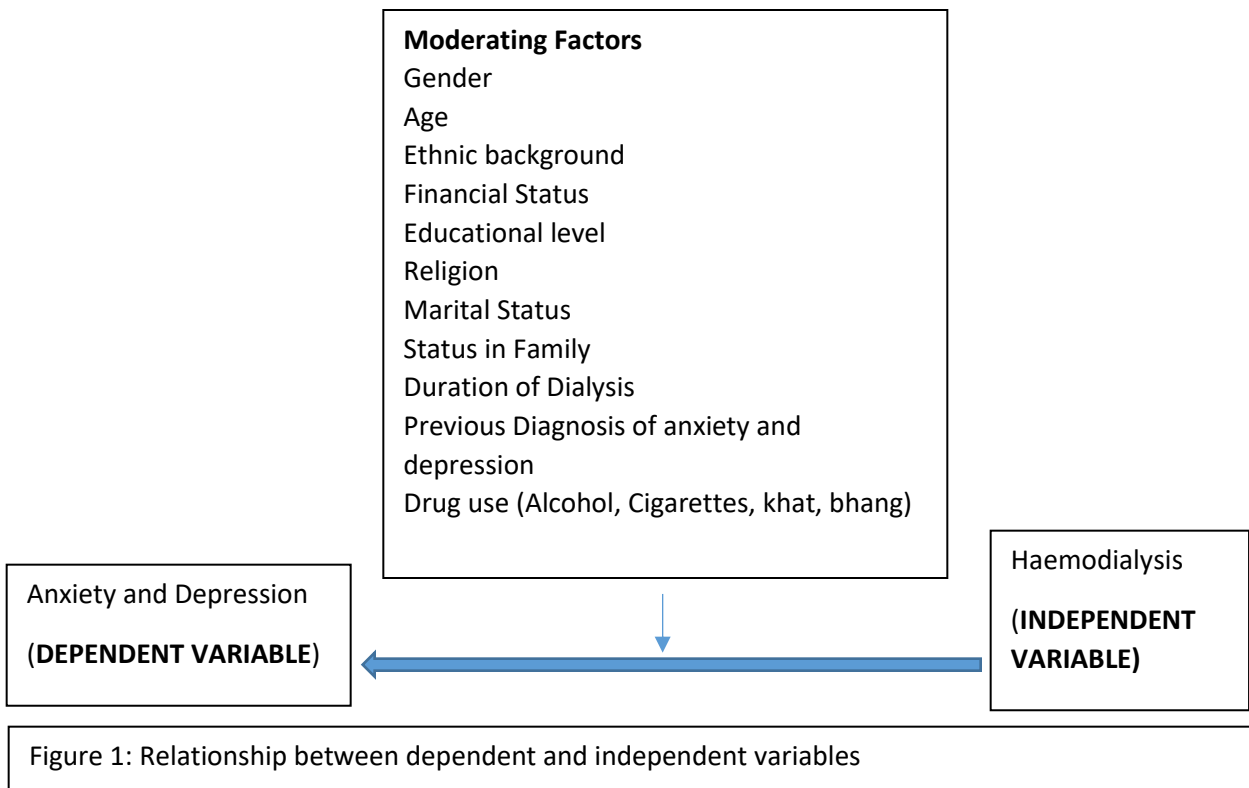
There have been several research studies which have investigated multiple key factors such as social, psychological and clinical factors, that are associated with depression in patients with CKD/ESRD. After reviewing a number of key articles, Goh & Griva (2018) concluded the association of numerous sociodemographic factors with anxiety and depression. Observations made were: women were more likely to develop anxiety whereas men were more prone to depression, patients from an ethnically white background were at higher risk of depression as opposed to those with African–American backgrounds, and patients who were not employed or lacked higher education qualifications were at an increased risk of being diagnosed with depression. In addition, Veater & East (2016), conducted a literature review where they reviewed depression in patients who were going through renal transplantation. The authors recognised key risk factors that were associated with the development of depression: sleep quality, gender, financial status, sleep quality and employment.

Mosleh et al.,(2020) investigated the occurrence and factors associated with anxiety and depression among patients in Saudi Arabia with CKD who were on treated by haemodialysis. Their results portrayed a higher prevalence of anxiety symptoms amongst females, when compared to males ($P = 0.04$). Older age was another factor that was seen to significantly ($P=0.003$) be positively correlated with depression. In contrast to above studies mentioned, there was an insignificant association ($P>0.005$) between employment status, haemodialysis and illness duration, education level, and patients' depression and anxiety symptoms. In

comparison, a study by Araujo et al.,(2012), also observed risk factors for patients with depressive disorders undergoing haemodialysis. Interestingly, the authors concluded that women on chronic haemodialysis had a higher risk of showing symptoms of depressive disorders. Furthermore, factors such as unemployment, other ailment e.g. diabetes, hypoalbuminemia, and low education had a statistically significant correlation with depressive symptoms. The varying results between both studies shows a need for further research into risk factors associated with anxiety and depression amongst patients undergoing haemodialysis.

2.5 CONCEPTUAL FRAMEWORK

Based on previous studies mentioned in the literature review (Section 2.4) several risk factors that may influence the prevalence of Anxiety and Depression were identified. For this study, we have identified multiple socio-economic factors which may influence the outcome investigated (GAD and MDD).



3.0 RESEARCH QUESTION, OBJECTIVES AND JUSTIFICATION

3.1 RESEARCH QUESTION

What is the prevalence and severity of Anxiety and Depression in patients aged 18 and above years undergoing maintenance haemodialysis at Kenyatta National Hospital and M.P Shah Hospital?

3.2 STUDY OBJECTIVES

Overall Objective

The overall objective is to determine the prevalence and severity of MDD and GAD in patients at Kenyatta National Hospital and MP Shah Hospital, who are on maintenance haemodialysis .

Specific Objectives

To determine:

- 1) the prevalence of MDD amongst haemodialysis patients at KNH and MP Shah Hospital
- 2) the prevalence of GAD amongst haemodialysis patients at KNH and MP Shah Hospital
- 3) the severity of MDD amongst haemodialysis patients at KNH and MP Shah Hospital
- 4) the severity of GAD amongst haemodialysis patients at KNH and MP Shah Hospital

The secondary objectives of this study include:

- 1) To find out the impact of sociodemographic factors – age, gender and income – on the severity of mental health outcomes in patients on haemodialysis.
- 2) To observe any significant variations in anxiety and/or depression prevalence in patients undergoing haemodialysis at a private setup when compared to a government facility.

3.3 STUDY JUSTIFICATION

The literature review (Section 2) has further demonstrated an increasing observation and consideration of mental health conditions amongst those with chronic conditions, and for the purpose of this study, specifically haemodialysis. While depressive symptoms have been well recognised amongst patients with ESRD, more evidence contributing to the prevalence of both, depression and anxiety, amongst patients undergoing haemodialysis would be beneficial for future treatment options.

In 2017, the Ministry of Health (MoH) in Kenya reported an approximation of 4 million Kenyans suffering from CKD with about 10,000 patients requiring dialysis. The growing figures of CKD in Kenya and global findings of mental health disorders associated with patients undergoing haemodialysis, more research into mental health disorders in such patients is imperative. This study has hence been specifically designed to further garner and contribute to evidence of prevalence and severity of GAD and MDD amongst patients undergoing haemodialysis, in East Africa, where there is limited research on mental health disorders amongst such patients.

The evidence in the study may provide scope for mental health consideration and possible early detection and diagnosis of GAD and MDD, which may raise the need for treatment in affected individuals, potentially providing an improved quality of life for patients on haemodialysis, and ultimately, a better prognostic outcome overall.

4.0 RESEARCH METHODOLOGY

4.1 STUDY DESIGN

The study design is descriptive cross-sectional study.

4.2 STUDY SITE

The study sites chosen for this study were the dialysis units of Kenyatta National Hospital and M.P Shah Hospital (Parklands branch).

Kenyatta National Hospital is the largest referral and teaching hospital in Kenya and has a bed capacity of 1800. The renal unit/dialysis unit has approximately 110 patients undergoing haemodialysis, where approximately 25-30 patients undergo dialysis each day.

M.P Shah hospital is one of the leading private hospitals in the country. The renal unit has about 50 patients undergoing haemodialysis.

Both sites presented the chance to achieve an adequate sample size. The difference in geographic location and target audience was a suitable comparison between two different socioeconomic groups of patients at the hospitals.

4.3 STUDY POPULATION

Participants undergoing haemodialysis were selected at random from both study sites and were consented to being part of the study. They were requested to fill out questionnaires/forms described in chapter 4.5 and attached in supplementary documents, which assessed socio-economic demographics of patients, and prevalence and severity of major depressive and anxiety disorders. The forms were collected and statistically analysed, as described in section 4.8, to achieve the study objectives.

4.4 INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria was:

- Patient is 18yrs and above
- Patient is undergoing maintenance haemodialysis for longer than 3 months.

Exclusion criteria was:

- Patient who declines consent
- Patient undergoing dialysis for less than 3 months.
- Patients below 18 years of age
- Recent admission within the last 1 month not involving diabetes mellitus, Hypertension or complications of haemodialysis.

4.5 DATA COLLECTION PROCEDURE

Participant recruitment occurred at Kenyatta National Hospital Renal Unit and M.P Shah Hospital. Written consent was obtained from those who meet the criterion and data was collected by the principal investigator and trained assistants. Three questionnaires were administered to the participants and in case of any queries, they were free to seek help from the principal investigator or assistants who were present as they answered the questionnaires. The questionnaires were:

- Socio-demographic questionnaire
- GAD-7 questionnaire
- PHQ-9 questionnaire

Socio-demographic questionnaire

Researcher designed questionnaire which included information on participants age, gender, marital status, education level, religion, employment status, income as well as clinical history and drug use.

GAD-7 Questionnaire

The GAD-7 questionnaire is a self-administered patient questionnaire used as a screening tool and severity measure for generalised anxiety disorder. It has a sensitivity of 89% and specificity of 82% (Spitzer et al., 2006). The fact that the tool has been translated and validated in the national language, Kiswahili (Nyongesa et al., 2020), as well as its specificity and sensitivity made it an appropriate tool to use.

The tool is scored by assigning scores of 0,1,2 and 3 to the responses and adding the total scores with cut-off points at 5,10 and 15 denoting mild, moderate and severe depression respectively.

PHQ-9 Questionnaire

This questionnaire is a self-administered patient questionnaire which has been validated for use in primary care (Cameron et al., 2008). This tool is used in monitoring the severity of depression and has a sensitivity and specificity of 88% for major depression (Kroenke et al., 2001). It has been translated and validated in Kiswahili (Omoro et al., 2006) which made it an appropriate tool to measure depression and its severity.

In this questionnaire, each question is scored from 0-3 and then the total is calculated and severity is assessed as follows:

0-4 none, 5-9 mild, 10-14 moderate, 15-19 moderately severe, 20-27 severe.

4.6 SAMPLING PROCEDURE

All patients undergoing haemodialysis at both centers were approached to participate in the study. This was done until the determined sample size was reached.

4.7 SAMPLE SIZE DETERMINATION

The sample size was determined using Cochran's formulae for calculating sample size in cross-sectional studies:

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

Where, n = Sample size

Z = Z statistics for 95% level of confidence

P = Expected prevalence for severe depression in patients on haemodialysis. A narrative review estimated the prevalence of anxiety and depression in haemodialysis patients to range between 0% - 45.7% (Goh and Griva., 2018). P will be considered at prevalence of 11.8% based on figures from the closest regional study (Elkheir et al., 2020).

d = Precision around estimated prevalence (set at 5% for this study), therefore,

$$n = \frac{1.96^2 0.118(1-0.118)}{0.05^2} = 159.9, \text{ therefore, sample size was 160 patients.}$$

4.8 DATA MANAGEMENT AND STATISTICAL ANALYSIS

All data collected was kept under lock and key and accessibility to it was restricted to the PI. After completion of data collection, all data was to be entered into a password protected Microsoft Access data base. It was then verified by the PI and analysed.

Descriptive Analysis

The sociodemographic characteristics of the sample were summarised using descriptive statistics. Measures of central tendency, including means and medians and corresponding measures of spread, namely standard deviation and interquartile range, were calculated and presented for continuous variables, such as age. Categorical variables were presented using frequency tables showing counts in each category and corresponding percentages. All descriptive analysis was done according to participating hospital and overall results.

Analysis Outcome

Descriptive analysis of the prevalence and severity of depression was conducted by calculating percentage of patients in each category of depression defined using established cut off presented in section 4.5. The overall prevalence of depression was determined using a binary variable derived from PHQ-9 scores with patients scoring 5 and above on the total PHQ-9 score. Bivariable analysis comparing sociodemographic categorical variables and depression outcome were conducted using chi-square test. Multivariable analysis was performed using logistic regression with depression as the dependent variable and including variables that show significant association with depression in the bivariable analysis as independent variables. Statistical significance was assessed using a p value < 0.05 . Odds ratios and 95% confidence intervals were also obtained from the logistic regression and presented with corresponding Wald P-values estimated from the regression models. Similar procedures for bivariable and multivariable analysis were applied for anxiety prevalence and severity that was determined using GAD-7 questionnaire.

4.9 QUALITY ASSURANCE PROCEDURES

A research assistant was adequately trained on data collection process as well as the research instruments. The questionnaires were be double checked by the PI to reduce chances of any errors. A qualified biostatistician was sought for proper data entry, verification, management and analysis. The Research assistant and biostatistician signed confidentiality agreement to protect the patients' identities before involvement in the study. The data collected was then kept under lock and key and was only available to the PI, the assistant and the biostatistician.

The PHQ9 and GAD7 questionnaires were the tools used to assess the prevalence and severity of depression and anxiety respectively. These tools have been used for the same purpose extensively globally and have also been culturally validated for use locally.

4.10 ETHICAL CONSIDERATIONS

Approval was sought from Kenyatta National Hospital and University of Nairobi Ethics and Research Committee, along with the ethical committee from MP Shah Hospital.

Confidentiality was observed by ensuring no names or out-patient numbers were used. Hard copies of questionnaires were kept in a lock and key cabinet and electronic copies were stored in a password protected device, accessible to the researcher only.

Prior to enlisting any participant in the study, informed consent was obtained.

4.11 STUDY DISSEMINATION PLAN

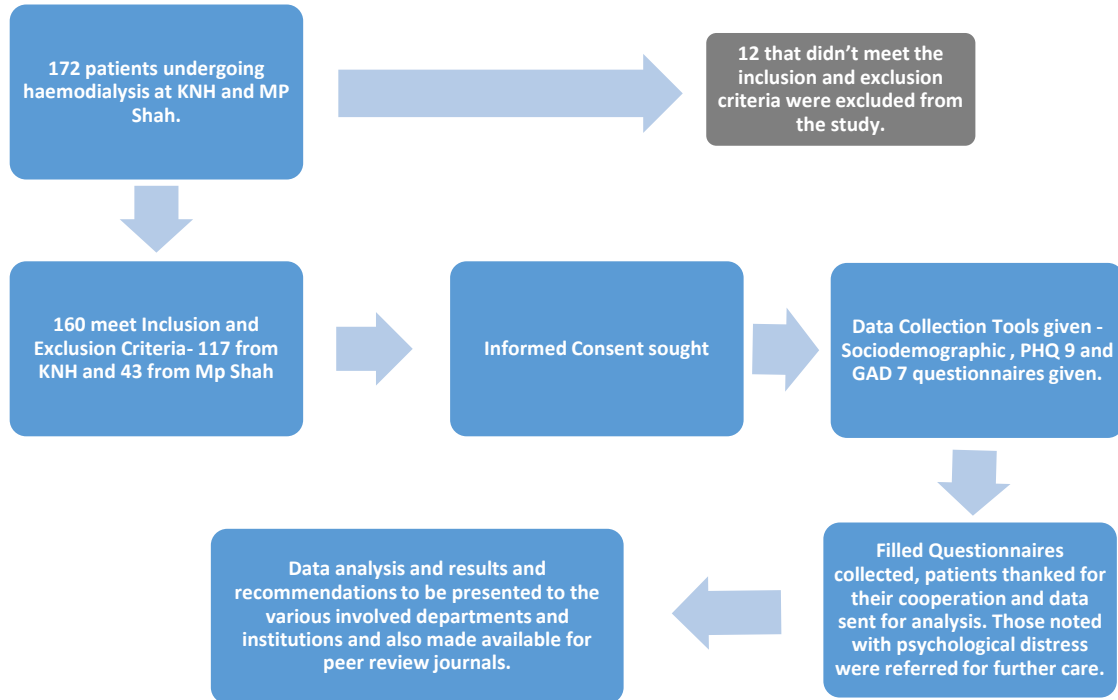
The results have been analysed and written up in this thesis for a degree in Masters of Medicine (Psychiatry) and once approved, will also be made available to the public via presentation of the thesis to the requisite departments at Kenyatta National Hospital as well as M.P. Shah Hospital. The results may also be disseminated through scientific publications in peer-reviewed journals.

5.0 RESULTS

5.1 RECRUITMENT RESULTS

The study recruited a total of 172 haemodialysis patients; 122 patients were recruited from KNH and 50 from MP Shah Hospital (Figure 1). A total of 12 patients were excluded from the study. 7 from MP Shah as they were on haemodialysis for less than 3 months and 5 from KNH as they were under the age of 18 years. Once 160 patients were selected, informed consent was sought, after which data collection began, and thereafter, data analysis.

Figure 2: Flow chart demonstrating the process of recruitment, data collection and results analysis



5.2 DESCRIPTIVE ANALYSIS

Demographic characteristics

The mean age of all patients included in the study was 50.1 (SD ± 16.9) years (Table 1). For patients in MP Shah, the mean age was 59.8 (SD ± 15.1) compared to 46.7 (SD ± 16.2) for patients in KNH. There were 94 (59%) males overall, and 28 (65%) males in MP Shah compared to 66 (56%) in KNH. One hundred and forty-six (91%) of patients in both hospitals were Christians (97% in KNH versus 74% in MP Shah). Five percent of participants were Asians and all of these patients attended MP Shah. There were 69 (43%) patients with secondary level education; 50% of patients in KNH had secondary level education while 67% of patients in MP Shah had tertiary level education. There were 98 (61%) married patients overall; 73 (62%) and 25 (58%) patients in KNH and MP Shah respectively were married.

Table 1: Demographic characteristics for patients undergoing hemodialysis in KNH and MP Shah

	KNH (n = 117)	MP Shah (n = 43)	Total (n = 160)
Mean age (±SD)	46.7 (±16.2)	59.8 (±15.1)	50.1 (±16.9)
Sex			
Male	66(56%)	28(65%)	94(59%)
Female	51(44%)	15(35%)	66(41%)
Religion			
Christian	114(97%)	32(74%)	146(91%)
Hindu	0(0)	8(19%)	8(5%)
Muslim	2(2%)	3(7%)	5(3%)
Non Believer	1(1%)	0(0)	1(1%)
Race			
African	117(100%)	35(81%)	152(95%)
Asian	0(0)	8(19%)	8(5%)
Level of education			
No formal education	6(5%)	1(2%)	7(4%)
Primary	31(26%)	3(7%)	34(21%)
Secondary	59(50%)	10(23%)	69(43%)
Tertiary/ university	21(18%)	29(67%)	50(31%)
Marital status			
Married	73(62%)	25(58%)	98(61%)
Unmarried	24(21%)	6(14%)	30(19%)
Widowed	12(10%)	10(23%)	22(14%)
Separated	8(7%)	2(5%)	10(6%)

Socioeconomic characteristics

Table 2 shows that there were important socioeconomic differences between the patients undergoing haemodialysis at the public and private hospitals in the study. Overall, 90 (57%) patients were household heads accounting for 34 (79%) patients in MP Shah and 56 (48%) patients in KNH. At least half of patients 82 (51%) were unemployed with 76 (65%) patients in KNH being unemployed compared to 6 (14%) in MP Shah. Similarly, half of participants 81 (51%) overall earned less than KShs 5000 per month with 80 (68%) patients in KNH and 1 (2%) patient in MP Shah reporting that they earned less than KShs 5000 per month.

Table 2: Socioeconomic characteristics for patients undergoing hemodialysis in KNH and MP Shah

	KNH (n = 117)	MP Shah (n = 43)	Total (n = 160)
Family status			
Head of the Family	56(48%)	34(79%)	90(57%)
Dependant	60(52%)	9(21%)	69(43%)
Employment status			
Unemployed	76(65%)	6(14%)	82(51%)
Employed	20(17%)	14(33%)	34(21%)
Retired	21(18%)	23(53%)	44(28%)
Monthly salary			
< 5000	80(68%)	1(2%)	81(51%)
5000-10000	7(6%)	3(7%)	10(6%)
10001-25000	17(15%)	7(16%)	24(15%)
250001-50000	7(6%)	8(19%)	15(9%)
>50000	6(5%)	24(56%)	30(19%)

Past medical history and substance use

Most 89 (56%) patients overall had been undergoing haemodialysis for less than 1 year (Table 3). There were 76 (65%) who had been on haemodialysis for less than a year in KNH while in MP Shah 23 (53%) patients had been on haemodialysis for a period of 1-5 years. Thirteen (8%) patients had ever been diagnosed with depression or anxiety disorder corresponding to 11 (9%) patients in KNH and 2 (5%) in MP Shah having a prior diagnosis of depression or anxiety disorder. Most of the previously diagnosed depression or anxiety disorder patients had been started on treatment for these conditions – 10 (6%) patients overall; 8 (7%) in KNH and 2 (5%) in MP Shah reported having been previously treated for anxiety or depression.

History of alcohol use was reported in 37% of patients overall and 37% of patients in each hospital. History of cigarette smoking was present in 33 (21%) patients overall, 27 (23%) in KNH and 6 (14%) in MP Shah. No patients in MP Shah had history of any other drug use and 6 (5%) of patients in KNH reported history of using other drugs.

Table 3: Relevant past medical history and substance use for patients undergoing hemodialysis in KNH and MP Shah

	KNH (n = 117)	MP Shah (n = 43)	Total (n = 160)
Duration since starting haemodialysis			
< 1 year	76(65%)	13(30%)	89(56%)
1-5 years	35(30%)	23(53%)	58(36%)
> 5 years	6(5%)	7(16%)	13(8%)
Ever diagnosed with depression or anxiety			
No	106(91%)	41(95%)	147(92%)
Yes	11(9%)	2(5%)	13(8%)
Started any treatment for depression or anxiety			
No	107(93%)	41(95%)	148(94%)
Yes	8(7%)	2(5%)	10(6%)
History of alcohol use			
No	74(63%)	27(63%)	101(63%)
Yes	43(37%)	16(37%)	59(37%)
History of cigarette smoking			
No	90(77%)	36(86%)	126(79%)
Yes	27(23%)	6(14%)	33(21%)
History of any other drug use			
No	111(95%)	42(100%)	153(96%)
Yes	6(5%)	0(0)	6(4%)

Prevalence and severity of GAD amongst haemodialysis patients at KNH and MP Shah Hospital

The mean GAD score overall was 4.9 (SD \pm 4.5) with a range from 0 to 19. The prevalence of anxiety was 45% (72 out of 160) overall, and 52% (61 out of 117) in KNH and 26% (11 out of 43) in MP Shah (Table 5). 52% (61 out of 117) of the patients in KNH had anxiety, whereas in MP Shah, only 26% (11 out of 43) had anxiety. Overall, 55% (88 out of 160) of the patients had none to minimal anxiety, and only 4% (6 out of 160) had severe anxiety.

Table 4: Anxiety diagnosis and its severity among haemodialysis patients

	KNH (n = 117)	MP Shah (n = 43)	Total (n = 160)
Mean GAD7 score (±SD)	5.6 (±4.2)	2.9 (±4.6)	4.9 (±4.5)
Anxiety			
No	56(48%)	32(74%)	88(55%)
Yes	61(52%)	11(26%)	72(45%)
Severity of anxiety			
None-Minimal	56(48%)	32(74%)	88(55%)
Mild	40(34%)	7(16%)	47(29%)
Moderate	17(15%)	2(5%)	19(12%)
Severe	4(3%)	2(5%)	6(4%)

Prevalence and severity of MDD in haemodialysis patients at KNH and MP Shah Hospital

The mean PHQ-9 score was 9.3 (SD±6.4) with a range from 0 to 26. The overall prevalence of depression was 73% (116 out of 160) with a prevalence of 82% (96 out of 117) in KNH and 47% (20 out of 43) in MP Shah (Table 4). Most patient overall (28%) and within KNH (32%) had moderate depression. In MP Shah 23 (53%) of patients did not have depression and 10 (23%) had mild depression.

Table 5: MDD diagnosis and its severity among haemodialysis patients

	KNH (n = 117)	MP Shah (n = 43)	Total (n = 160)
Mean PHQ-9 Score (±SD)	10.8 (±6.1)	5.4 (±5.5)	9.3 (±6.4)
Depression			
No	21(18%)	23(53%)	44(27.5%)
Yes	96(82%)	20(47%)	116(72.5%)
Severity of depression			
None- minimal	21(18%)	23(53%)	44(28%)
Mild	30(26%)	10(23%)	40(25%)
Moderate	37(32%)	7(16%)	44(28%)
Moderately severe	18(15%)	2(5%)	20(13%)
Severe	11(9%)	1(2%)	12(8%)

5.3 STATISTICAL ANALYSES OF PREVALENCE OF GAD AND MDD

Factors associated with anxiety in haemodialysis patients

The associations between anxiety and patient characteristics determined using chi squared and independent t-test are shown in Table 6. The prevalence of anxiety was significantly higher in KNH compared to MP Shah ($p = 0.003$) with 61 (52%) patients in KNH having anxiety compared to 11 (26%) in MP Shah (Table 6). There was a significant association between anxiety and gender ($p = 0.042$). The prevalence of anxiety among males was 38% compared to 55% among females. Anxiety was also significantly associated with level of formal education ($p = 0.025$) and family status ($p = 0.008$). The prevalence of anxiety was lowest among patients with tertiary or university education (28%) and increased in those with lower levels of education (49% to 59%). Patients who were dependants within families had higher prevalence of anxiety (57%) compared to those who were heads of the family (36%).

Table 6: Anxiety and characteristics of patients undergoing haemodialysis

	Anxiety	No anxiety	Chi square*	P
Mean age (\pm SD)*	49.5(\pm 16.8)	50.6(\pm 17.1)	-	0.687
Sex				
Male	36(38)	58(62)	4.1	0.042
Female	36(55)	30(45)		
Religion				
Christian	67(46)	79(54)	2.6	0.455
Hindu	2(25)	6(75)		
Muslim	3(60)	2(40)		
Non Believer	0(0)	1(100)		
Race				
African	70(46)	82(54)	1.4	0.243
Asian	2(25)	6(75)		
Level of education				
No formal education	4(57)	3(43)	9.4	0.025
Primary	20(59)	14(41)		
Secondary	34(49)	35(51)		
Tertiary/ university	14(28)	36(72)		
Employment status				
Unemployed	43(52)	39(48)	3.8	0.146
Employed	12(35)	22(65)		
Retired	17(39)	27(61)		
Marital status				
Married	42(43)	56(57)	7.6	0.055
Unmarried	10(33)	20(67)		
Widowed	12(55)	10(45)		
Separated	8(80)	2(20)		
Monthly salary				
< 5000	43(53)	38(47)	5.9	0.207
5000-10000	5(50)	5(50)		
10001-25000	10(42)	14(58)		
250001-50000	5(33)	10(67)		
>50000	9(30)	21(70)		
Family status				
Head of the Family	32(36)	58(64)	6.9	0.008
Dependant	39(57)	30(43)		
Duration since starting haemodialysis				
< 1 year	42(47)	47(53)	0.5	0.786
1-5 years	25(43)	33(57)		
> 5 years	5(38)	8(62)		
Ever diagnosed with depression or anxiety				
No	64(44)	83(56)	1.6	0.211
Yes	8(62)	5(38)		
Started any treatment				
No	65(44)	83(56)	1	0.322

Yes	6(60)	4(40)		
History of alcohol use				
No	48(48)	53(52)	0.7	0.401
Yes	24(41)	35(59)		
History of cigarette smoking				
No	59(47)	67(53)	0.6	0.445
Yes	13(39)	20(61)		
History of any other drug use				
No	69(45)	84(55)	0.1	0.813
Yes	3(50)	3(50)		
Hospital				
KNH	61(52)	56(48)	9	0.003
MP Shah	11(26)	32(74)		

A multi variable logistic regression was conducted on results that showed statistical significance in the bivariable chi-square tests (Table 7), adjusting for potential confounding factors in the associations. This presented no significant association between patient's sex ($p = 0.235$), education level ($p > 0.05$), family status ($p = 0.273$) or hospital attended ($p = 0.125$) and anxiety disorder.

Table 7: Multivariable logistic regression analysis of factors associated with anxiety in haemodialysis patients

	Odds Ratio	95% CI		P
Sex				
Male	1.0 (ref)			
Female	1.56	0.75	3.26	0.235
Level of education				
Primary	1.0 (ref)			
Secondary	1.33	0.24	7.23	0.743
Tertiary/ university	0.95	0.19	4.81	0.952
No formal education	0.55	0.10	3.05	0.498
Family status				
Head of the Family	1.0 (ref)			
Dependant	1.52	0.72	3.22	0.273
Hospital				
KNH	1.0 (ref)			
MP Shah	0.50	0.21	1.21	0.125

Factors associated with depression in haemodialysis patients

Patients' level of education ($p = 0.003$), history of alcohol use ($p = 0.022$) and the hospital a patient attended ($p < 0.001$) were significantly associated with depression in the bivariable analysis based on Chi squared tests (Table 8). The prevalence of depression increased with reducing level of education from 58% in patient with tertiary/ university education to 75% in those with secondary education and 85% and 86% for primary and no formal education, respectively ($p = 0.003$). The prevalence of depression in patients with history of alcohol use was 83% compared to 66% in those with no history of alcohol use ($p = 0.022$). 82% of patients in KNH had depression compared to 47% in MP Shah ($p < 0.001$).

Table 8: Depression and characteristics of patients undergoing haemodialysis

	Depression	No depression	Chi square	P
Mean age (\pm SD)*	49.4(\pm 16.5)	52(\pm 17.8)	-	0.392
Sex				
Male	66(70)	28(30)	0.6	0.439
Female	50(76)	16(24)		
Religion				
Christian	109(75)	37(25)	5.4	0.145
Hindu	4(50)	4(50)		
Muslim	3(60)	2(40)		
Non Believer	0(0)	1(100)		
Race				
African	112(74)	40(26)	2.1	0.144
Asian	4(50)	4(50)		
Level of education				
No formal education	6(86)	1(14)	9	0.03
Primary	29(85)	5(15)		
Secondary	52(75)	17(25)		
Tertiary/ university	29(58)	21(42)		
Employment status				
Unemployed	64(78)	18(22)	2.6	0.269
Employed	23(68)	11(32)		
Retired	29(66)	15(34)		
Marital status				
Married	76(78)	22(22)	7.1	0.068
Unmarried	18(60)	12(40)		
Widowed	13(59)	9(41)		
Separated	9(90)	1(10)		
Monthly salary				
< 5000	63(78)	18(22)	7.7	0.104
5000-10000	9(90)	1(10)		
10001-25000	18(75)	6(25)		
250001-50000	9(60)	6(40)		
>50000	17(57)	13(43)		
Family status				
Head of the Family	63(70)	27(30)	0.6	0.454
Dependant	52(75)	17(25)		
Duration since starting haemodialysis				
< 1 year	66(74)	23(26)	0.3	0.866
1-5 years	41(71)	17(29)		
> 5 years	9(69)	4(31)		
Ever diagnosed with depression or anxiety				
No	104(71)	43(29)	2.8	0.095
Yes	12(92)	1(8)		
Started any treatment				
No	105(71)	43(29)	1.7	0.193

Yes	9(90)	1(10)		
History of alcohol use				
No	67(66)	34(34)	5.2	0.022
Yes	49(83)	10(17)		
History of cigarette smoking				
No	90(71)	36(29)	0.7	0.397
Yes	26(79)	7(21)		
History of any other drug use				
No	110(72)	43(28)	0.4	0.539
Yes	5(83)	1(17)		
Hospital				
KNH	96(82)	21(18)	19.9	<0.001
MP Shah	20(47)	23(53)		

When conducting a multivariable logistic regression analysis for factors associated with MDD, there was a significant association between history of alcohol use and depression ($p = 0.011$) after adjusting for level of education and hospital attended. The odds of depression were three times higher in patients who had history of alcohol use (OR 3.13, 95% CI 1.29 to 7.53) compared to those without history of alcohol use. The hospital attended was also significantly associated with depression after adjusting for level of education ($p = 0.001$). The odds of being diagnosed with depression in MP Shah hospital was 78% lower (OR 0.22, 95% CI 0.09 to 0.52) than that of a similar diagnosis in KNH.

Table 9: Multivariable logistic regression analysis of factors associated with MDD in haemodialysis patients

	Odds Ratio	95% CI		P>z
Level of education				
Primary	1.0 (ref)			
Secondary	1.06	0.09	13.10	0.963
Tertiary/ university	0.54	0.05	5.87	0.616
No formal education	0.42	0.04	4.58	0.475
History of alcohol use				
No	1.0 (ref)			
Yes	3.12	1.29	7.53	0.011
Hospital				
KNH	1.0 (ref)			
MP Shah	0.22	0.09	0.52	0.001

6.0 DISCUSSION

ESRD, and consequently haemodialysis, can have a huge impact on a patients' lifestyle due to loss of kidney function, potential reduction of sexual function, loss of time because of increased hospital visits and change in family and work status. These factors may affect an individual's mental well-being, causing the development of depression and anxiety. We aimed to determine the prevalence and severity of MDD and GAD in patients undergoing haemodialysis for over 3 months, at a public hospital (KNH) and a private hospital (MP Shah).

6.1 PREVALENCE AND SEVERITY OF GAD

The overall prevalence of anxiety in patients undergoing haemodialysis was 45% and the mean overall score in the GAD7 assessment was 4.9, but individual patient scores for anxiety showed considerable variation around the mean as evidenced by the large standard deviation relative to the mean.

Although the prevalence of anxiety was high with approximately one in every two patients in the study being diagnosed with anxiety the majority of these patients had minimal to mild anxiety. Our study shows similar results (albeit slightly lower) to a study by Al-Nashri & Almutary, (2022) who used the HAD scale, to determine anxiety. The study of 114 participants concluded that 50% of the participants on haemodialysis were diagnosed with anxiety which also had a negative association with quality of life. Schouten et al., (2019) suggested that patients undergoing haemodialysis may feel anxiety because of the intensive kidney dialysis process itself and the feeling of the need to be put through such painful and time consuming process potentially multiple times a week. One reason for the slightly lower anxiety levels in our study may be because it excluded patients who had undergone haemodialysis for less than three months. Hence, the feeling of discomfort when undergoing such a painful and time intensive procedure may have been minimised over time, lowering the stress and anxiety levels felt prior to undergoing haemodialysis sessions.

In contrast, El Filali et al., (2017) determined the prevalence of anxiety disorder in 25.2% of their study population, using the 'Mini international neuropsychotic interview' (MINI). This group's findings further presented age as a significant socio demographic factor that was associated with the prevalence of anxiety disorders whereas in contrast, the bivariate analysis for our study showed that there was no significant association between age and prevalence of GAD. Some factors in our study that initially showed significant association with GAD in the bivariate analysis were, level of education, gender, family status and choice of hospital but these association were not present after adjusting for potential confounding effects in the multivariable analysis.

Multiple studies conducted in general populations have shown gender is associated with anxiety and this has been clearly evidenced in the study by McLean et al., (2011) where it was noted that lifetime and 12-month prevalence ratios anxiety disorders between men and women were 1:1.7 and 1:1.79, respectively. Hence, apart from social anxiety disorder (which presented no significant gender difference in prevalence), women overall showed higher rates of lifetime diagnosis of all anxiety disorders otherwise investigated. Comparatively, our study shows 55% of all females scored above 5, hence meeting the criteria for anxiety whereas only 38% of all males showed the same, suggesting that females have more prevalent GAD as compared to their male counterparts. However, when doing a multivariate regression analysis to account for confounding variables, there was not enough statistical power to determine a correlation between gender and prevalence on anxiety in patients on haemodialysis. Due to the higher prevalence of anxiety in haemodialysis patients compared to general populations it is plausible that the prevalence ratios for anxiety disorder may be lower in these patients compared to general populations.

Jessup et al., (2018) conducted a cross sectional survey in 3505 participants in health literacy (ability to read investigate and understand health information) between public and private healthcare services. They provided the Health Literacy Questionnaire (HLQ) to all participants and observed that patients with anxiety reported lower HLQ scores. They also concluded that even when adjusting for socio-demographic factors there was a reduction in health literacy in patients who received care in a public health set-up as opposed to patients who receive care at a private set-up. This may have the potential to cause more stress and anxiety in patients attending a public hospital. In our study, 52% of the patients at KNH scored higher than 5 on the GAD7 scale, suggesting presence of anxiety, whereas only 26% scored the same in MP Shah. Furthermore, in MP Shah, 74% of the patients had none to minimal anxiety whereas in KNH, only 48% of the patients presented the same. The Chi-square test showed significant association between the hospital that a patient attended and prevalence of GAD, however upon doing a multivariate regression, this association was not significant.

6.2 PREVALENCE AND SEVERITY OF MDD

The overall prevalence of MDD in patients undergoing haemodialysis was 72.5% and the mean score on the PHQ9 scale was 9.3. However, individual patient scores for MDD showed considerable variation around the mean as evidenced by the large standard deviation relative to the mean. Severity of depression was distributed somewhat evenly between mild to moderate with only 13% being moderately severe and only 8% being severe.

The study by Elkheir et al., (2020) reported depression prevalence at a slightly lower rate of 66%. In contrast, Ganu et al., (2018) who also used the PHQ9 scale to measure depression prevalence, noted that only 45% of the study population on haemodialysis had depressive symptoms. They further presented a negative correlation between income and prevalence of depression, suggesting that financial stability may be a factor that contributes to mental well-being. Upon conducting a bivariate analysis between prevalence of MDD and financial income in our study, level of income was not statistically significant. This however may be because this study was conducted in 2 different sites where the socioeconomic variables were quite varied with majority of the study participants from KNH being in the lowest cadre of income (68% of the patients had a monthly salary of <5000Kshs) and those from MP Shah being in the highest cadre (56% of the patients had monthly salary of >50,000Kshs).

When compared to the study conducted by Nguringa, (2020) at KNH and 2 private facilities in Nairobi, this study showed quite a significant rise in the prevalence of MDD. Nguringa, (2020) also used the PHQ9 scoring system and reported a prevalence of 32.4% of MDD. The advent of the COVID-19 pandemic and the impact this disease has had on mental and socioeconomic well-being, of the population, especially in patients with chronic illness requiring specialised care, could be one of the major factors in the severe increase of MDD prevalence. Janssens et al., (2021) noted that with the lockdown response to covid-19, income reduced in the households by a third and consequently, spending on transport and education reduced in the same households to allow for expenditure on food, presenting a major shift in socio-economic well-being. Posel et al., (2021) looked at the job loss and its impact on mental well-being during the Covid-19 pandemic in South Africa, and reported that adults who were laid off or lost their employment during the lockdown scored significantly higher on the PHQ9 scoring system suggesting higher rates of depression amongst that population, when compared to those who had retained their jobs during the same period. They concluded that the pandemic resulted unparalleled levels of job losses, which hence led to impaired mental well-being of those individuals significantly.

Of all socioeconomic variables measured in this study, level of education, history of alcohol use and choice of hospital presented a statistically significant association. Patients' level of education in the bivariate analysis also showed a negative correlation between the level of education and MDD, with increase in MDD from 58% in

those with tertiary level of education to 86% in those with no formal education. Similar results noted by Nguninga, (2020) where he discovered that the group of participants who'd had no formal education had an increased likelihood of suffering from depression as opposed to those with some or any kind of formal education. A multivariable regression analysis for this study factoring in confounding variables however, presented no statistical power of the association between level of education and prevalence of depression.

History of alcohol consumption was significantly associated with depression as portrayed by the bivariate analysis. When adjusting for effect of hospital choice and level of education, the multivariate logistic regression still presented a statistically significant association between history of alcohol use and MDD. Boden & Fergusson, (2011) conducted a study on alcohol and depression and suggested a casual link between alcohol use disorder and MDD, such that increased involvement with alcohol increases risk of depression. The same has also been seen in the study by Kuria et al., (2012) and also evidenced in the results from this research. A bivariate analysis (appendix) was conducted between history of alcohol use and gender. Interestingly, there was a strong association between both variables with females having a higher rate of history of alcohol consumption. Interestingly, after adjusting for the effect of gender in the multivariable regression there was a stronger association between depression and history of alcohol use.

When comparing private and public health services, choice of hospital is noted to have a significant effect on the prevalence of depression among patients undergoing maintenance haemodialysis. 82% of patients in KNH were diagnosed with depression according to the PHQ9 scoring, compared to 47% in MP Shah. In addition, in KNH, 15% and 9% of the population had moderately severe to severe depression, and in MP Shah it was 5% and 2% respectively. It is interesting to note that with severe depression, the percentages are quite close between both sites when compared to other levels of severity. This may be explained by the small study population overall and especially in MP Shah (43 patients).

The overall difference in prevalence and severity of depression between both hospitals may be explained by socio-economic differences. Most of the patients at MP Shah had received tertiary education (67%) in stark contrast to KNH where the majority were restricted to secondary education (50%). As mentioned previously, Jessup et al., (2018) noted a deficiency in health literacy among patients undergoing care at a public facility versus patients receiving care at a private facility, which decreased mental well being amongst those treated at public health facilities. Other socio-economic factors that may contribute to prevalence of depression may be financial stability. In MP Shah, 56% of the participants earned a monthly salary of over 50,000Kshs, whereas only 5% in KNH earned the same and as previously discussed, socio-economic well being can play a major role in diagnosis of MDD.

It is also imperative to note that patient care at public hospitals may not be as efficient and accommodating as that in private care in Kenya, due to higher number of patients in public care and potential lack of resources. These patients, when compared to private healthcare settings such as MP Shah, would hence be unsure when their next treatment sessions may be, either due to their financial status or unavailability of machines because of a breakdown or upsurge of patients, resulting in an increased waiting time for patients and ultimately potential deterioration of physical and thus mental health.

6.3 STUDY STRENGTH AND LIMITATIONS

To the best of our knowledge, a strength of this study is that it is the first of its kind to determine not only the prevalence but the severity too of both, anxiety and depression, in haemodialysis patients in Kenya. It is also the first study of its kind to attempt to compare mental well-being of haemodialysis patients in public and private healthcare service. The study uses GAD7 and PHQ-9 which have been validated as reliable tools for assessing anxiety and depression respectively.

This study also has some significant limitations that should be considered in interpreting its findings. To begin with, due to financial and time constraints the study population size is quite small which doesn't give the study enough statistical power to examine multiple associations and associations for factors rare exposures. Moreover, as seen in the results, there were more than twice the number of patients recruited in the public hospital than the private hospital which may limit the generalizability to private hospitals. Finally, it is imperative to note that this study was conducted during the Covid-19 pandemic, which may also have had mental health impacts including anxiety and depression in the patient population.

6.5 CONCLUSIONS AND RECOMMENDATIONS

A high proportionate of patients on haemodialysis were diagnosed with anxiety and depression. Majority of the patients diagnosed with anxiety had mild anxiety, and those diagnosed with depression were mostly spread out between mild to moderately severe. This study further demonstrated that history of alcohol use and choice of hospital were crucial variables that were associated with the prevalence of depression in individuals.

Some clinical implementations that could be made based on this research are:

- 1) Routine screening of CKD/ESRD for depression and anxiety prior to starting haemodialysis is recommended using validated tools e.g. PHQ-9 and GAD7 respectively. Patients should also be referred to a psychologist and/or a psychiatrist if needed.
- 2) When managing CKD/ESRD patients who are on haemodialysis, a collaborative team of qualified personnel is highly recommended. The team should involve a psychiatrist and/or a psychologist to monitor mental well being of patients.
- 3) Future studies should be conducted with a larger patient sample size to increase statistical power of the study and hence give a more defined conclusion. The hospital-specific or contextual factors that could explain differences in mental wellbeing require further investigation in studies conducted across multiple sites, and different facility types in the country, hence potentially prompting better quality of care, resource allocation and services for the public.

6.0 REFERENCES

- Al-Nashri, F., & Almutary, H. (2022). Impact of anxiety and depression on the quality of life of haemodialysis patients. *Journal of Clinical Nursing*, 31(1–2), 220–230.
- Amira, O. (2011). Prevalence of symptoms of depression among patients with chronic kidney disease. In *Nigerian Journal of Clinical Practice* (Vol. 14, Issue 4, pp. 460–463). Wolters Kluwer Medknow Publications.
- Araujo, S. M., de Bruin, V., Daher, E. de F., Almeida, G. H., Medeiros, C. A., & de Bruin, P. F. C. (2012). Risk factors for depressive symptoms in a large population on chronic hemodialysis. *International Urology and Nephrology*, 44(4), 1229–1235.
- Bates, N., Schell, J., & Jordan, A. (2017). Depression and anxiety in ESRD: a practical guide for nephrologists. *Kidney News Online*, 9(9).
- Bayat, N., Alishiri, G. H., Salimzadeh, A., Izadi, M., Saleh, D. K., Lankarani, M. M., & Assari, S. (2011). Symptoms of anxiety and depression: A comparison among patients with different chronic conditions. *Journal of Research in Medical Sciences: The Official Journal of Isfahan University of Medical Sciences*, 16(11), 1441.
- Boden, J. M., & Fergusson, D. M. (2011). Alcohol and depression. *Addiction*, 106(5), 906–914.
<https://doi.org/10.1111/j.1360-0443.2010.03351.x>
- Cameron, I. M., Crawford, J. R., Lawton, K., & Reid, I. C. (2008). Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. *British Journal of General Practice*, 58(546), 32–36.
- Chen, C.-K., Tsai, Y.-C., Hsu, H.-J., Wu, I.-W., Sun, C.-Y., Chou, C.-C., Lee, C.-C., Tsai, C.-R., Wu, M.-S., & Wang, L.-J. (2010). Depression and suicide risk in hemodialysis patients with chronic renal failure. *Psychosomatics*, 51(6), 528-528. e6.
- Chilcot, J., Wellsted, D., Da Silva-Gane, M., & Farrington, K. (2008). Depression on dialysis. *Nephron Clinical Practice*, 108(4), c256–c264.

- Clarke, D. M., & Currie, K. C. (2009). Depression, anxiety and their relationship with chronic diseases: A review of the epidemiology, risk and treatment evidence. *The Medical Journal of Australia*, *190*(S7), S54-60. <https://doi.org/10.5694/j.1326-5377.2009.tb02471.x>
- Cohen, S. D., Norris, L., Acquaviva, K., Peterson, R. A., & Kimmel, P. L. (2007). Screening, diagnosis, and treatment of depression in patients with end-stage renal disease. *Clinical Journal of the American Society of Nephrology : CJASN*, *2*(6), 1332–1342. <https://doi.org/10.2215/CJN.03951106>
- El Filali, A., Bentata, Y., Ada, N., & Oneib, B. (2017). Depression and anxiety disorders in chronic hemodialysis patients and their quality of life: A cross-sectional study about 106 cases in the northeast of morocco. *Saudi Journal of Kidney Diseases and Transplantation*, *28*(2), 341.
- Elkheir, H. K., Wagaella, A. S., Badi, S., Khalil, A., Elzubair, T. H., Khalil, A., & Ahmed, M. H. (2020). Prevalence and risk factors of depressive symptoms among dialysis patients with end-stage renal disease (ESRD) in Khartoum, Sudan: A cross-sectional study. *Journal of Family Medicine and Primary Care*, *9*(7), 3639.
- Evans, D. L., Charney, D. S., Lewis, L., Golden, R. N., Gorman, J. M., Krishnan, K. R. R., Nemeroff, C. B., Bremner, J. D., Carney, R. M., & Coyne, J. C. (2005). Mood disorders in the medically ill: Scientific review and recommendations. *Biological Psychiatry*, *58*(3), 175–189.
- Fischer, M. J., Porter, A. C., & Lash, J. P. (2013). Treatment of depression and poor mental health among patients receiving maintenance dialysis: Are there options other than a pill or a couch? *American Journal of Kidney Diseases*, *61*(5), 694–697.
- Ganu, V. J., Boima, V., Adjei, D. N., Yendork, J. S., Dey, I. D., Yorke, E., Mate-Kole, C. C., & Mate-Kole, M. O. (2018). Depression and quality of life in patients on long term hemodialysis at a national hospital in Ghana: A cross-sectional study. *Ghana Medical Journal*, *52*(1), 22–28.
- García-Llana, H., Remor, E., Del Peso, G., & Selgas, R. (2014). The role of depression, anxiety, stress and adherence to treatment in dialysis patients' health-related quality of life: A systematic review of the literature. *Nefrología (English Edition)*, *34*(5), 637–657.

- Gerontoukou, E.-I., Michaelidou, S., Rekleiti, M., Saridi, M., & Souliotis, K. (2015). Investigation of anxiety and depression in patients with chronic diseases. *Health Psychology Research, 3*(2).
- Goh, Z. S., & Griva, K. (2018). Anxiety and depression in patients with end-stage renal disease: Impact and management challenges—a narrative review. *International Journal of Nephrology and Renovascular Disease, 11*, 93.
- Janssens, W., Pradhan, M., Groot, R. de, Sidze, E., Donfouet, H. P. P., & Abajobir, A. (2021). The short-term economic effects of COVID-19 on low-income households in rural Kenya: An analysis using weekly financial household data. *World Development, 138*, 105280.
<https://doi.org/10.1016/j.worlddev.2020.105280>
- Jessup, R. L., Osborne, R. H., Beauchamp, A., Bourne, A., & Buchbinder, R. (2018). Differences in health literacy profiles of patients admitted to a public and a private hospital in Melbourne, Australia. *BMC Health Services Research, 18*(1), 134. <https://doi.org/10.1186/s12913-018-2921-4>
- Kimmel, P. L., Thamer, M., Richard, C. M., & Ray, N. F. (1998). Psychiatric illness in patients with end-stage renal disease. *The American Journal of Medicine, 105*(3), 214–221.
- Kokonya, D. A., Khasakhala, L. I., Kuria, M., Mutiso, V., Ongecha, F. A., & Ndeti, D. M. (2007). The challenges of human resources in mental health in Kenya: Original article. In *South African Psychiatry Review* (Vol. 10, Issue 1, pp. 33–36).
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine, 16*(9), 606–613. <https://doi.org/10.1046/j.1525-1497.2001.016009606.x>
- Kuria, M. W., Ndeti, D. M., Obot, I. S., Khasakhala, L. I., Bagaka, B. M., Mbugua, M. N., & Kamau, J. (2012). The Association between Alcohol Dependence and Depression before and after Treatment for Alcohol Dependence. *ISRN Psychiatry, 2012*, 482802. <https://doi.org/10.5402/2012/482802>
- Lewis, J. A. (1954). Mental health as it relates to chronic illness. *The West Virginia Medical Journal, 50*(12), 355–360.

- Li, Y.-N., Shapiro, B., Kim, J. C., Zhang, M., Porszasz, J., Bross, R., Feroze, U., Upreti, R., Martin, D., & Kalantar-Zadeh, K. (2016). Association between quality of life and anxiety, depression, physical activity and physical performance in maintenance hemodialysis patients. *Chronic Diseases and Translational Medicine*, *2*(02), 110–119.
- Marangu, E., Mansouri, F., Sands, N., Ndetei, D., Muriithi, P., Wynter, K., & Rawson, H. (2021). Assessing mental health literacy of primary health care workers in Kenya: A cross-sectional survey. *International Journal of Mental Health Systems*, *15*(1), 1–10.
- McLean, C. P., Asnaani, A., Litz, B. T., & Hofmann, S. G. (2011). Gender differences in anxiety disorders: Prevalence, course of illness, comorbidity and burden of illness. *Journal of Psychiatric Research*, *45*(8), 1027–1035. <https://doi.org/10.1016/j.jpsychires.2011.03.006>
- Moreira, J. M., Bouissou Morais Soares, C. M., Teixeira, A. L., Simões e Silva, A. C., & Kummer, A. M. (2015). Anxiety, depression, resilience and quality of life in children and adolescents with pre-dialysis chronic kidney disease. *Pediatric Nephrology*, *30*(12), 2153–2162.
- Mosleh, H., Alenezi, M., Alsani, A., Fairaq, G., & Bedaiwi, R. (2020). Prevalence and factors of anxiety and depression in chronic kidney disease patients undergoing hemodialysis: A cross-sectional single-center study in Saudi Arabia. *Cureus*, *12*(1).
- Muiru, A. N., Charlebois, E. D., Balzer, L. B., Kwarisiima, D., Elly, A., Black, D., Okiror, S., Kabami, J., Atukunda, M., & Snyman, K. (2020). The epidemiology of chronic kidney disease (CKD) in rural East Africa: A population-based study. *PloS One*, *15*(3), e0229649.
- Murtagh, F. E., Addington-Hall, J., & Higginson, I. J. (2007). The prevalence of symptoms in end-stage renal disease: A systematic review. *Advances in Chronic Kidney Disease*, *14*(1), 82–99.
- Ng, H. J., Tan, W. J., Mooppil, N., Newman, S., & Griva, K. (2015). Prevalence and patterns of depression and anxiety in hemodialysis patients: A 12-month prospective study on incident and prevalent populations. *British Journal of Health Psychology*, *20*(2), 374–395.

- Nguringa, K. (2020). *The Burden of depression among patients with end stage renal disease undergoing haemodialysis at Kenyatta National Hospital, Nairobi Hospital and Parklands Kidney Centre*. [MMed Dissertation, University of Nairobi, Dept of Clinical Medicine and Therapeutics,].
<http://erepository.uonbi.ac.ke/handle/11295/153834>
- Nyongesa, M. K., Mwangi, P., Koot, H. M., Cuijpers, P., Newton, C. R., & Abubakar, A. (2020). The reliability, validity and factorial structure of the Swahili version of the 7-item generalized anxiety disorder scale (GAD-7) among adults living with HIV from Kilifi, Kenya. *Annals of General Psychiatry, 19*(1), 1–10.
- Omor, S. A. O., Fann, J. R., Weymuller, E. A., Macharia, I. M., & Yueh, B. (2006). Swahili translation and validation of the Patient Health Questionnaire-9 depression scale in the Kenyan head and neck cancer patient population. *The International Journal of Psychiatry in Medicine, 36*(3), 367–381.
- Ottaviani, A. C., Betoni, L. C., Pavarini, S. C. I., Gramani Say, K., Zazzetta, M. S., & Orlandi, F. de S. (2016). Association between anxiety and depression and quality of life of chronic renal patients on hemodialysis. *Texto & Contexto-Enfermagem, 25*.
- Palmer, S., Vecchio, M., Craig, J. C., Tonelli, M., Johnson, D. W., Nicolucci, A., Pellegrini, F., Saglimbene, V., Logroscino, G., & Fishbane, S. (2013). Prevalence of depression in chronic kidney disease: Systematic review and meta-analysis of observational studies. *Kidney International, 84*(1), 179–191.
- Posel, D., Oyenubi, A., & Kollamparambil, U. (2021). Job loss and mental health during the COVID-19 lockdown: Evidence from South Africa. *PLOS ONE, 16*(3), 1–15. <https://doi.org/10.1371/journal.pone.0249352>
- Providing Sustainable Mental and Neurological Health Care in Ghana and Kenya: Workshop Summary*. (2016). National Academies Press (US). <https://doi.org/10.17226/21793>
- Radic, J., Ljutić, D., Radic, M., Kovacic, V., Sain, M., & Curkovic, K. D. (2010). The possible impact of dialysis modality on cognitive function in chronic dialysis patients. *Neth J Med, 68*(4), 153–157.
- Sadeghian, J., Roudsari, D. M., Seyedfatemi, N., & Rafiei, H. (2016). Body-image disturbance: A comparative study among haemodialysis and kidney transplant patients. *Journal of Clinical and Diagnostic Research: JCDR, 10*(5), OC14.

- Schouten, R. W., Haverkamp, G. L., Loosman, W. L., Shaw, P. K. C., Ittersum, F. J. van, Smets, Y. F. C., Vleming, L.-J., Dekker, F. W., Honig, A., & Siegert, C. E. H. (2019). Anxiety Symptoms, Mortality, and Hospitalization in Patients Receiving Maintenance Dialysis: A Cohort Study. *American Journal of Kidney Diseases*, 74(2), 158–166. <https://doi.org/10.1053/j.ajkd.2019.02.017>
- Sherbourne, C. D., Wells, K. B., Meredith, L. S., Jackson, C. A., & Camp, P. (1996). Comorbid anxiety disorder and the functioning and well-being of chronically ill patients of general medical providers. *Archives of General Psychiatry*, 53(10), 889–895.
- Spitzer, R. L., Kroenke, K., Williams, J. B. W., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine*, 166(10), 1092–1097. <https://doi.org/10.1001/archinte.166.10.1092>
- Vasilopoulou, C., Bourtsi, E., Giaple, S., Koutelekos, I., Theofilou, P., & Polikandrioti, M. (2016). The impact of anxiety and depression on the quality of life of hemodialysis patients. *Global Journal of Health Science*, 8(1), 45.
- Veater, N. L., & East, L. (2016). Exploring depression amongst kidney transplant recipients: A literature review. *Journal of Renal Care*, 42(3), 172–184.
- WHO (2021). *Noncommunicable diseases*. [Online] Who.int. Available at: <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>. (n.d.).

APPENDICES

APPENDIX 1: PARTICIPANT INFORMED CONSENT FORM



UNIVERSITY OF NAIROBI (UoN)
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(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) https://twitter.com/UONKNH_ERC



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

PARTICIPANT INFORMATION AND CONSENT FORM

SAMPLE ADULT CONSENT

FOR ENROLLMENT IN THE STUDY

(To be administered in English or any other appropriate language e.g Kiswahili translation)

Title of Study: The prevalence and severity of Major Depressive and Anxiety disorders in patients undergoing haemodialysis and the effect on their psychological well-being.

Principal Investigator and institutional affiliation: Dr Tahir Kadernani, University of Nairobi

Co-Investigators and institutional affiliation: None

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in medical research:

- i) Your decision to participate is entirely voluntary
- ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
- iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Protocol No.

What is the study about?

The researchers listed above are interviewing individuals who are on haemodialysis. The purpose of the interview is to find out the prevalence and severity of anxiety and depression in patients undergoing haemodialysis. Participants in this research study will be asked questions from questionnaires which address their:

- 1) overall wellbeing (WHO-5 well-being assessment),
- 2) prevalence of anxiety (GAD-7 questionnaire),
- 3) prevalence of depression (PHQ9 questionnaire), and
- 4) socio-demographic status to investigate possible factors that may affect mental well-being.

There will be approximately 140 participants chosen to randomly partake in this study. We are asking for your consent to consider participating in this study.

What will happen if you decide to be in this research study?

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

You will be requested to answer a questionnaire in an area where you feel comfortable answering it. Should you require help, a trained interviewer will be available. The questionnaire/interview will last approximately 20 to 40 minutes and will cover topics such as, your overall well-being, your mental well-being before and after being diagnosed and being on haemodialysis and your socio demographic status.

After you have finished the questionnaire, you will not be required to undergo any tests or give out any further personal information. You will be free to go.

Are there any risks, harms or 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.

It may be embarrassing or stressful for you to answer certain questions (e.g. event recalls or socio-demographic status). We will do everything we can to ensure that this is done in private and full confidentiality. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews.

Are there any benefits of being in this study?

You may benefit from this study by receiving a referral to a psychologist should the study doctor (also the study co-ordinator) have any concern, thus start early therapy to avert further complication that may come with a concerning mental health diagnosis. Also, the information you provide will help us better understand mental well-being in patients undergoing haemodialysis, which will help better scientific and clinical decision making in the future.

Will being in this study cost you anything?

Being in this study will not cost you anything.

What if you have questions in the 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

E-mail: 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.

I agree to participate in this study Yes No

Participant printed name _____

Participant signature/thumb stamp _____ Date _____

Researcher's Statement

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

Researcher's name _____

Researcher's signature _____ Date _____

Role in the study _____ *(ie study staff who explained informed consent form)*

For more information please contact:

Dr Tahir Kadernani at the University of Nairobi from 9:00am to 4:00pm.

APPENDIX 2: SOCIODEMOGRAPHIC QUESTIONNAIRE

SECTION 1: SOCIO-DEMOGRAPHIC QUESTIONNAIRE			
NO	Question	Response(tick at appropriate response)	
1	Gender	Male Female	
2	AGE	Number	
3	Religion	1. Christian 2. Hindu 3. Muslim 4. Other (specify)	
4	Race	African Asian White Mixed race	
4	Education level	1. None 2. Primary 3. Secondary 4. Tertiary 5. Other (specify)	
5	Employment	1. Employed 2. NOT Employed 3. Retired	

6	Marital status	1. Never married 2. Married 3. Separated 4. Divorced 5. Widowed	
8	Average income per month	Less than Ksh. 5,000.00 Between Ksh 5,000.00 – 10,000 Between Ksh 10,001 – 25,000 Between Ksh 25,001- 50000 Above Ksh 50,000	
9	Status in the family	Head of the Family Dependent	
10	How long have you been undergoing dialysis	1. Less than 3 months 2. 3months – 1 year 3. 1 year – 5 years 4. Greater than 5 years	
11a	Have you ever been diagnosed with depression/anxiety	1. No 2. Yes	
11b	If the answer to the above is yes, were you put on any form of treatment	1. No 2. Yes	
11c	If the answer to the above is yes please state what treatment you were/are on		
12	History of alcohol use	1. No 2. Yes	
13	History of smoking cigarettes	1. No 2. Yes	
14	History of other substance use e.g weed,khat,tobacco	1. No 2. Yes	

APPENDIX 3: PATIENT HEALTH QUESTIONNAIRE(PHQ-9)

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

ID #: _____ **DATE:** _____

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(use "✓" to indicate your answer)

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

add columns + +

(Healthcare professional: For interpretation of TOTAL, TOTAL:
please refer to accompanying scoring card).

GAD-7 Anxiety

Over the <u>last two weeks</u> , how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid, as if something awful might happen	0	1	2	3

Column totals _____ + _____ + _____ + _____ =

Total score _____

APPENDIX 5: KISWAHILI VERSION OF THE PARTICIPANT INFORMED CONSENT FORM

FOMU YA MSHIRIKI KWA HIARI

MADA YA UTAFITI

Athari na uzito wa madhara ya kiakili wanayoyapitia wagonjwa wa kutakaswa damu Kenyatta National Hospital na M.P. Shah Hospital mjini Nairobi, Kenya

UTANGULIZI

Kwa mujibu wa fomu hii ya kutaka kushirikishwa kwa hiari kwa utafiti huu, tungetaka ushiriki wako. Kususudi kuu la fomu hii ni kusaidia kwa yale yatakyokusaidia kufanya uamuzi wa kushiriki katika utafiti huu. Mchakacho huu unajulikana kama ushirika wa hiari. Fomu hii itakueleza kufahamu kiini cha utafiti na kile tunakusudia kukipata. Baada ya kuelewa kusudi kuu na kutoa kibali chako cha kushiriki tungekuuliza uweze kutia sahihi kwa majina yako chini ya fomu hii.

KUSUDI LA UTAFITI

Madhumuni ya utafititi hii ni kutathmini kiwango cha wagonjwa wanaotakaswa damu na kuathirika kiakili au kisaikolojia. Majaribio mengine tunayoyafanya ili kuitathmini hali hii ni kama yafuatayo

- Kutalii madhara ya kijamii kulingana na umri, jinsia na kiwango cha mapato kulingana na wagonjwa walioathirika kiakili baada ya kupitia mfumo wa kutakaswa damu
- Kutathmini tofauti za kisaikolojia kwa wagonjwa wanaopitia mfumo huu wa kutakaswa damu katika viwango vya hospitali za kibinafsi ukilinganisha na hospitali za umma.

UTARATIBU UNAOFUATWA KATIKA UTAFITI

Uamuzi wa kushiriki katika utafiti huu ni kwa hiari kabisa na iwapo utakubali kushirikishwa basi itabidi kupewa idadi ya majaribio matatu ya maswali.

1. Kwa jumla tathmini ya athari za kiakili 7 (GAD 7)
2. Tathmini ya magonjwa kiafya 9 (PHQ 9)
3. Tathmini ya kijamii kulingana na kiwango husika.

Jaribo la maswali huweza kuchukua muda wa dakika 20-40 kumaliza aidha kufanyika kwa kuzingatia haki ya siri ukipenda . Iwapo una swali lolote , basi tafadhali umtaradhie mshirikishi mkuu wa utafiti, Dr. Tahir Kadernani, huku ukiendelea kujibu maswali au kumtaradhia baadaye.

Nambari ya simu:

Nani mweye uwezo wa kushiriki katika utafiti huu

Mgonjwa yeyote ambaye amekuwa akifanyiwa matibabu ya kutakaswa damu kwa kipindi kilichozidi miezi mitatu na ametimiza umri wa miaka kumi na minane na Zaidi amehitimu kushiriki katika utafiti huu.

Haki ya Siri

Majibu yeyote yaliyopatikana na pia matokeo yatahifadhiwa kwa siri. Baada ya kuwasilisha fomu hii ya kushirikishwa katika utafiti ni heri utie sahihi na unakili numba yako ya ushirika hapo chini. Mtandao asilia utakaowasilisha nambari ya ushirika na jina kuhifadhiwa kwa nambari yako ya siri kwenye kompyuta. Baada ya utafiti kukamilika habari za kimatandao zitaondevlewa kabisa kutoka kwa kompyuta.

Nambari yako ya kushiriki itahusishwa kwa majibu wa maswali na majibu husika. Majibu yoyote yalyochapishwa yatawasilishwa pamoja na nambari yako yakushiriki bila ya wazo la kukutambulisha. Habari hizi zinaweza kusahihishwa upya kwa nadra sana na tume ya maadili ya chuo cha Nairobi ama tume ya maadili ya M.P Shah Hospital, pale ambapo kitambulisho chako kitawasilishwa.

Faida za kushiriki

Unaweza kufaidika kwa majibu wa utafiti huu kwa kupokea mwaliko wa rufaa ya kumwona mwansaikolojia ili kuepuka madhara Zaidi yanayohusika na kiakili baada ya ukaguzi

Habari zinazopatikana kwa mujibu wa utafiti huu zitasaidia kufanya uamuzi wa busara wa kisayansi na kimatibabu katika kusimamia wagonjwa wanaopitia matibabu ya utakasaji wa damu kwa siku za usoni

Hatari za kushiriki

Hakuna hatari za moja kwa moja lakini kila ushirika wa utafiti wa aina hii huandamana na atahri za kisaikolojia, kijamii, kihisia na kimwili

Haki ya Kushiriki au Kujiondoa

Kushiriki katika utafiti huu ni kwa hiari kabisa na wakati unapoendelea una uwezo wa kujiondoa kwa hiari yako. Iwapo utajiondoa, majibu yako hayatajumuishwa katika matokeo ya utafiti wa mwisho. Hata hivyo haya hayatapelekea kukosa manufaa au kunyimwa haki ya kutibiwa katika hospitali husika.

Kufidiwa

Ni vyema ieleweke kuwa hakuna kufidiwa kifedha au kwa namna isiyo ya kifedha katika utafiti huu kwa vyovyote vile.

Maswali kuhusu utafiti

Iwapo una maswali au pendekezo lolote lile kuhusu kushirikishwa katika utafiti huu, tafadhali wasiliana na Daktari Tahir Kadernani kupitia nambari ya simu ifwatayo :

Kwa maelezo Zaidi kuhusu haki za mshiriki na utafiti huu unaweza kuwasiliana na katibu au mwenyekiti, Kenyatta National Hospital, Chuo Kikuu cha Nairobi cha maadili na tume ya utafiti.

Nambari ya simu : 2726300 Ext : 44102

Barua pepe : uonknh_erc@uonbi.ac.ke

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 utafiti wakati wowote bila udhalimu au kupoteza faida yoyote.

FOMU YA MAJALIZO (TAARIFA YA MAJIBU)

Taarifa ya mshiriki

Nimesoma fomu hii ya idhini au habari hiyo imesomwa kwangu. Nimekuwa na nafasi ya kujadili utafiti huu wa utafiti na mshauri wa utafiti. Nimejibiwa maswali yangu kwa lugha ambayo ninaelewa. Hatari na faida zimeelezwa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kujiondoa wakati wowote. Ninakubali kwa hiari kushiriki katika utafiti huu wa utafiti. Ninaelewa kuwa juhudi zote zitafanywa kutunza habari kuhusu kitambulisho changu kuwa siri.

(Saini / Uchapaji gumba wa mshiriki) (Tarehe)

(Jina la mshiriki - limechapishwa)

Taarifa ya Mtu Aliyepata Idhini

Habari katika hati hii imejadiliwa na mshiriki au, inapofaa, na mwakilishi aliyeidhinishwa kisheria wa mshiriki. Mshiriki ameonyesha kuwa anaelewa hatari, faida, na taratibu zinazohusika na kushiriki katika utafiti huu.

(Saini ya Mtu Aliyepata Idhini) (Tarehe)

(Jina la Mtu aliyepata Idhini – imechapishwa)

APPENDIX 6 : KISWAHILI VERSION OF SOCIODEOGRAPHIC QUESTIONNAIRE

Tathmini ya kijamii kulingana na kiwango husika			
NO	Swali	Jibu (Weka alama ya pata inapohitajika)	
1	Je, wewe ni wa jinsia gani?	Kiume Kike	
2	Miaka/Umri	Nambari	
3	Dini	1. Ukristo 2. Uhindu 3. Uislamu 4.Nyingine (Bainisha)	
4	Kabila	Mwafrika Muhindi Mzungu Chotara	
4	Kiwango cha Elimu/Miaka ya masomo	1. Hamna kabisa 2. Shule ya msingi 3. Shule ya Sekondari 4. Chuo Kikuu/ shule ya sahanati 5. Nyingine (Bainisha)	
5	Kauli ya Ajiira	1. Umejiriwa 2. Haujaajiriwa 3. Mstaafu	

6	Habari kuhusu ndoa	1. Hujaolewa/ hujaoa 2. Umeolewa/ Umeoa 3. mmetengana 4. talaka 5. Mjane	
8	Malipo kwa mwezi	Chini ya Ksh. 5,000.00 Katikati ya Ksh 5,000.00 – 10,000 Katikati ya Ksh 10,001 – 25,000 Katikati ya Ksh 25,001- 50000 Zaidi ya Ksh 50,000	
9	Hali katika familia	Mkuu wa familia Tegemezi	
10	Je! Una muda gani tangu kuanza kutakaswa damu kwa machine(haemodialysis)	5. Chini ya miezi mitatu 6. Miezi 3 – mwaka 1 7. Mwaka 1 – miaka 5 8. Zaidi ya miaka 5	
11a	Umewahi kukutwa na ugojwa wa kisaikolojia?	3. La 4. Ndio	
11b	Kama jibu la swali iliyo juu ni ndio, uliwahi anzishwa kwa matibabu yeyote?	3. La 4. Ndio	
11c	Kama jibu la swali iliyo juu ni ndio, tafadhali eleza ni matibabu aina gani		
12	Historia ya matumizi ya pombe ?	3. La 4. Ndio	
13	Historia ya kuvuta sigara ?	3. La 4. Ndio	
14	Historia ya matumizi ya damu nyingine ya kulevya kama kuvuta bhangi, uchongaji wa miraa ama kutafuna tumbaku	3. La 4. Ndio	

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Kwa kila swali, tafadhali nielezee ni <u>kwa</u> kiasi gani umetatizika au kusumbuliwa na hali hizo za afya katika wiki mbili zilizopita . (Katika/kwa wiki mbili zilizopita)	haijatoke zea kabisa	siku kadha	Zaidi ya nusu ya siku hizo	takriban kila siku
1. Kutokuwa na hamu au raha ya kufanya mambo	0	1	2	3
2. Kuvunjika moyo, kuhuzunika au kukosa matumaini	0	1	2	3
3. Shida ya kupata usingizi au kuendelea kulala mfululizo Au kulala sana	0	1	2	3
4. Kujisikia kuchoka au kutokuwa na nguvu	0	1	2	3
5. Kutokuwa na hamu ya kula au kula sana	0	1	2	3
6. Kujihisi vibaya, kujiona umeshindwa kutimiza malengo yako ya maisha au kuhisi umejidunisha au umedunisha familia yako	0	1	2	3
7. Shida ya kumakinika katika mambo fulani kwa mfano unaposoma gazeti au kuangalia runinga au kufanya kazi zingine	0	1	2	3
8. Kutembea au kuongea polepole sana mpaka watu Hawaoni tafauti (au kinyume chake) kwamba hutulii na Unashangaika sana kuliko ilivyo kawaida	0	1	2	3
9. Kuwaza kuwa ni afadhali zaidi ungekuwa umekufa au ujidhuru kwa namna fulani	0	1	2	3

GAD-7 hofu ya kiujumla

<u>Kwa kila swali, tafadhali nielezee ni kwa kiasi gani umetatizika au kusumbuliwa na hali hizo za afya katika wiki mbili zilizopita</u>	<u>Hajatokezea kabisa</u>	<u>Siku kadhaa</u>	<u>Zaidi ya nusu ya siku hizo</u>	<u>Takriban Kila siku</u>
<u>1. Katika wiki mbili zilizopita, Je, Umejihisi kuwa na hofu, wasiwasi?</u>	0	1	2	3
<u>2. Katika wiki mbili zilizopita, Je, Umeshindwa kujizuia au kudhibiti wasiwasi?</u>	0	1	2	3
<u>3. Katika wiki mbili zilizopita, Je, Umekuwa na wasiwasi mwingi kuhusu mambo tofauti?</u>	0	1	2	3
<u>4. Katika wiki mbili zilizopita, Je, Umekuwa na wakati mgumu kupumzika?</u>	0	1	2	3
<u>5. Katika wiki mbili zilizopita, Je, Umekuwa na hali ya kutotulia kiasi kwamba ikawa ni vigumu kukaa kwa utulivu.?</u>	0	1	2	3
<u>6. Katika wiki mbili zilizopita, Je, Umekasirika au kuudhika kwa haraka?</u>	0	1	2	3

APPENDIX 9: ERC APPROVAL



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



KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726330-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

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

Ref: KNH-ERC/A/102

15th March, 2022

Dr. Tahir Kadernani
Reg. No. H58/33699/2019
Dept. of Psychiatry
Faculty of Health Sciences
University of Nairobi



Dear Dr. Kadernani,

RESEARCH PROPOSAL: THE PREVALENCE AND SEVERITY OF ANXIETY AND DEPRESSION IN PATIENTS UNDERGOING HAEMODIALYSIS AT KENYATTA NATIONAL HOSPITAL AND M.P. SHAH HOSPITAL IN NAIROBI, KENYA (P976/12/2021)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P976/12/2021**. The approval period is 15th March 2022 – 14th March 2023.

This approval is subject to compliance with the following requirements;

- i. Only approved documents including (informed consents, study instruments, MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected 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.
- v. Clearance for export of biological specimens must be obtained from relevant institutions.
- vi. 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.
- vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Protect to discover

APPENDIX 11: SUPPLEMENTARY RESULTS ON ASSOCIATION OF ALCOHOL USE AND GENDER AND EFFECT ON DEPRESSION

There was a significant association between sex and history of alcohol use with 55 (83%) women reporting history of alcohol consumption compared to 46 (49%) men ($p < 0.001$).

	History of alcohol use		P value
	Yes	No	
Sex			
Female	55 (83%)	11 (17%)	<0.001
Male	46 (49%)	48 (51%)	

After adjusting for the effect of sex in the multivariable regression there was a stronger association between depression and history of alcohol use.

	Odds Ratio	95% CI		P>z
Level of education				
Primary	1.0 (ref)			
Secondary	1.30	0.10	16.27	0.837
Tertiary/ university	0.69	0.06	7.60	0.764
No formal education	0.52	0.05	5.81	0.599
History of alcohol use				
No	1.0 (ref)			
Yes	3.73	1.47	9.47	0.006
Sex				
Female	1.0 (ref)			
Male	1.69	0.73	3.92	0.221
Hospital				
KNH	1.0 (ref)			
MP Shah	0.22	0.09	0.54	0.001