Association between depression, anxiety and adherence to treatment among patients attending the Kenyatta National Hospital (KNH) diabetes outpatient clinic.

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MBChB (UoN) 2009

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A dissertation submitted in partial fulfillment of the requirements of the Master of Medicine Psychiatry (MMEd Psychiatry) degree.

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This dissertation is submitted with our approval

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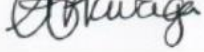
Signed  **Date** 5.3.2022

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Dedication.

To my parents Bornface Njiru Nyaga and my late mother Salome Kori Sabira, to keep your star shining. My wife Colleta, for the support during this period. My children, may this motivate you whenever you read it, to light your paths, to inspire and drive you to aim higher and make our world a better place. Finally, my entire family, my friends and my colleagues for all your invaluable support.

Declaration of originality

Declaration of Originality

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Abstract

Introduction: General medical clinical settings face a challenge in the identification, screening, diagnosis and linkage to treatment of patients with psychiatric comorbidities. The psychological and emotional distress in these patients, when not promptly addressed, affects their adherence to prescribed treatment plans. In diabetes patients, the setback in diagnosis and treatment of comorbid mental illnesses impairs their adherence to treatment thus disrupting the control of their blood sugar. This potentiates an increase in morbidity and mortality with ultimate negative effects on their quality of life. Despite this evident challenge, there is a paucity of data and information on the effects of depression and anxiety on levels of adherence to treatment in diabetes' outpatient healthcare settings. **Objectives:** The objectives of this study were two pronged; to assess the prevalence of depression and anxiety to evaluate the association between them and levels of adherence to treatment among diabetes patients on treatment at the Kenyatta National Hospital (KNH) diabetes outpatient clinic. **Method:** This was a cross-sectional study carried out at the KNH diabetes outpatient clinic. 213 patients with confirmed diagnoses of diabetes and who had been on treatment for at least 6 months were recruited. The patients were evaluated using a researcher designed social demographic questionnaire. The Hospital Anxiety and Depression scale (HADs) was used to assess the patients' levels of depression and anxiety. The Medication Adherence Report Scale 5 (MARS-5) was used to assess the patients' levels of treatment adherence. The Diabetes Distress Scale 17 (DDS-17) and Diabetes Quality of Life (DQOL) scale were integrated to assess the corresponding psychometric measures and treatment outcomes. **Results:** Statistical analysis was done using R Software (RStudio Version 4.1.2) to derive descriptive and inferential statistics. The study established a comorbid prevalence of anxiety at 100 (47.4%) and depression at 84 (39.6%) out of 213 patients. The comorbid prevalence of anxiety and depression in the same sample was at 76 (36.2%). Being diagnosed with anxiety decreased the odds of adherence to treatment by a factor of 0.05 ($p < 0.0001$) while being diagnosed with depression decreased the odds of adherence to treatment by a factor of 0.06 ($p < 0.0001$). **Conclusion and recommendations:** Given the significant correlation between anxiety, depression and adherence to treatment in diabetes patients, it imperative to optimize the identification, screening, diagnosis and linkage to care of these patients with psychiatric comorbidities. There is a fundamental role of hospitals and policy makers to integrate collaborative clinical care models in order to provide the patients with holistic care. To achieve that, it will be crucial to develop integrated and multidisciplinary clinical care guidelines in order to facilitate comprehensive care of patients with medical conditions while having comorbid mental illnesses.

Keywords: Diabetes, depression, anxiety, adherence, treatment

Abbreviations

T2DM	Type II diabetes
DSM V	Diagnostic and Statistical Manual of Mental Illnesses Version 5
HADS	Hospital Anxiety Depression Scale
MARS-5	Medication Adherence Report Scale 5
DQOL	Diabetes Quality of Life
WHO	World Health Organization
NCDs	Non-communicable Diseases
KNH	Kenyatta National Hospital
UON	University of Nairobi

Chapter One: Introduction

1.1 Background

Mental illnesses are common in general medical populations (Chaturvedi et al., 2019; Cirulli et al., 2009). However, in these populations, identifying, screening and diagnosis of comorbid mental illnesses in these patients in order to link them to mental healthcare is often suboptimal (Thom et al., 2019).

The spectrum of psychiatric illnesses frequently does not exist as distinct clinical entities but often coexist with other medical conditions (Katon et al., 2007; Ndetei et al., 2009). This coexistence between a physical illness and mental illness, in addition to the emotional response of having a chronic disease, make it difficult to distinguish whether the psychological distress is independent or caused by the medical illness (Thom et al., 2019). Assessing these different but coexisting disease phenomena by clinicians and researchers is important for purposes of understanding the relationships between the disease processes in order to formulate rational and collaborative treatment plans (Scott et al., 2016).

Diabetes is a chronic disease and is responsible for increasing global health burden. In 2013, 382 million people had diabetes and this number is projected to rise to 592 million by 2035 (Guariguata et al., 2014). In Kenya, the health landscape has been historically dominated by communicable infectious diseases but an increase in the contribution of NCDs to overall morbidity and mortality is changing the disease patterns (Achoki et al., 2019).

The comorbidity of mental disorders with diabetes poses major clinical and policy challenges (Balhara, 2011). The pathophysiology of diabetes, the disease etiology, screening, diagnosis and treatment are all psychologically demanding (Kruse et al., 2003). Nevertheless, diabetes patients with comorbid mental illness and psychological distress tend to be poorly identified. Their treatment tends to be suboptimal in sub-Saharan Africa (Akena et al., 2015). Research is ongoing to determine whether there are any shared biological mechanisms in the pathophysiology of diabetes and depression and other mental health conditions. There is likelihood that depression and diabetes share biological origins in the activation of innate immunity, cytokine-mediated inflammatory responses and dysregulation of the hypothalamic-pituitary-adrenal axis (Moulton et al., 2015). A discovery of shared markers of depression and diabetes will offer useful targets for primary prevention and treatment of both diseases.

In diabetes patients, biopsychosocial factors like marital status, negative life events, occupational status, diabetes complications, and poor socioeconomic ability tend to lead to increased risk of depression (Habtewold et al., 2016). While the prevalence of depression and anxiety symptoms is greater in diabetes patients than in the general population, the association between diabetes and mental health disorders gets worse in stressful environments. The psychological distress causes a continuous loop of depressive symptoms and adverse diabetes outcomes that worsens the disease processes, impairs adherence to treatment and negatively affects the outcome and impact of healthcare. In the clinical environment, this situation has been worsened by the emotional overload and psychological distress emerging from the COVID-19 pandemic (Alessi et al., 2020).

1.2 Problem Statement

Globally, there is progressive increase in the prevalence of non-communicable diseases (NCDs). NCDs account for significant global morbidity and mortality. The wide array of NCDs is prevalent in both highly developed and less developed countries. The major NCDs include cardiovascular disease (CVD), diabetes, cancer, chronic obstructive pulmonary diseases, rheumatic heart disease, sickle cell disease, and mental health conditions (Siddharthan et al., 2015). Globally, the NCDs cause death of more than 41 million people annually, accounting for 71% of all annual mortality (Roth et al., 2018). Reports of the Division for Sustainable Development Goals (DSDG) in the United Nations Department of Economic and Social Affairs (UNDESA) indicate that the probability of dying from any of the four main NCDs – cardiovascular diseases, cancers, chronic respiratory diseases and diabetes between the ages of 30 and 70 was 18% in 2016 (Sustainable & Goals, 2011).

Patients suffering NCDs are more likely to suffer mental illness than the general population (Chapman et al., 2005). Mental health disorders, by virtue of their lifelong disease process have been justifiably categorized among the NCDs. Integrating the care of mental disorders alongside other classical NCDs will significantly improve the quality of life of people affected by chronic illnesses worldwide (Stein et al., 2019). In addition past studies and research have postulated a bidirectional relationship between mental illnesses and NCDs (Lin & Scott, 2012). The incidence of mental illnesses tends to be increased in patients with NCDs while the severity of NCDs is increased in patients with mental illness.

The comorbidity of NCDs and mental illness faces a challenge in the timely identification, screening, diagnosis of the mental illness and linkage of the patients to psychiatric treatment and long term follow up. In diabetes, the patients' characteristics, their mental health and their adherence to treatment guidelines have a significant impact on their ultimate quality of life. Patients with higher medication adherence tend to have better quality of life while mental illness is associated with poor adherence and consequent lower quality of life (Khdour et al., 2020).

Depression and anxiety are common mental illnesses associated with key diabetes-related measures. Therefore, health providers need to be enlightened of the importance of detection and management of psychological symptoms while treating patients with diabetes (Naicker et al., 2017). Evidence based practice shows that patients having elevated anxiety and depression symptoms tend to report proportional poor adherence to treatment plans (Smith et al., 2015).

In Kenya, the factors associated with poor adherence in diabetes patients are diverse. They range from the cost of healthcare, patient’s poor knowledge on the disease process, inadequate family support, complexity of treatment regimens and lack of clarity in communication with health providers (Masaba & Mmusi-Phetoe, 2020). Major patients' characteristics associated with non-adherence include patients’ perception of effects of non-adherence, general knowledge, other comorbidities, family support and deeply held personal believes.

This study served the purpose of generating up to date data and information on the effects of depression and anxiety on adherence to treatment in patients attending the KNH Diabetes Outpatient Clinic. This knowledge is useful in formulation of collaborative and multidisciplinary care models for patients with comorbid medical and psychiatric illnesses.

1.3 Research Questions

1.3.1 General Question

What is the relationship between depression, anxiety and adherence to treatment among diabetes patients attending the Kenyatta National Hospital (KNH) diabetes outpatient clinic (DOPC)?

1.3.2 Specific Questions

i. What is the prevalence of depression and anxiety patients attending the KNH DOPC?
ii. What is the level of adherence to treatment among the patients at KNH DOPC?
iii. What is the association between depression, anxiety and adherence to diabetes treatment?

1.4 Study Objectives

1.4.1 General Objective

To evaluate the association between depression, anxiety and adherence to treatment among patients attending the Kenyatta National Hospital's diabetes outpatient clinic.

1.4.2 Specific Objectives

i. To establish the prevalence of depression and anxiety among diabetes patients attending the KNH DOPC.
ii. To determine the level of treatment adherence among the diabetes patients.
iii. To assess the correlation between depression, anxiety and treatment adherence among patients attending the KNH DOPC.

1.5 Hypotheses

1.5.1 Null hypothesis (Ho)

There is no difference in rate of adherence to hypoglycemic treatment among diabetes patients with depression and anxiety compared to patients without.

1.5.2 Alternative hypothesis (Ha)

The rate of adherence is significantly lower among depressed and anxious diabetes patients than among non-depressed and non-anxious patients.

1.6 Justification for the Study

The screening and diagnosis of depression and anxiety in general medical and outpatient care settings is important. Identifying such patients with psychological disturbances and linking them to care is important to address both their medical conditions and their mental health conditions.

In diabetes patients, the treatment of mental health illnesses improves overall adherence to treatment and enhances control of blood sugar levels. This ultimately minimizes short-term and long-term diabetes complications and augments the decrease in associated the morbidity and mortality rates.

It is crucial to understand the relationship between depression, anxiety and treatment adherence in diabetes patients. Adherence is the extent to which a patient follows and executes the lifestyle changes and takes the medications according to the guidelines and recommendations of his or her healthcare provider. In diabetes, adherence involves following the regimen of hypoglycemic medication, and recommendations for diet, physical activity and exercise. Comorbidity with a mental illness adds psychotropic treatment regimen thus adding an extra layer of psychiatric care and follow up.

Reports of the 2015 Kenya national STEPs survey of adults aged 18–69 years showed age standardized prevalence for prediabetes and diabetes were 3.1% (95% CI: 2.2, 4.0) and 2.4% (95% CI 1.8,3.0) respectively (Mohamed et al., 2018). These rates of diabetes prevalence in Kenya are consistent with the rest of Sub-Saharan African countries. In Kenya it has been found that patients have suboptimal treatment adherence which is associated with poor blood sugar control (Masaba & Mmusi-Phetoe, 2020). The glycemic control and diabetes care outcomes and impact of treatment are therefore suboptimal (Mwavua et al., 2016).

There is a paucity of data that illustrates the correlation between psychological factors and mental illness on diabetes self-care among diabetes patients in Kenya and in Africa (Shirey et al., 2015). However, the prevalence of depression in diabetes has been found to be as high as 20 -50 % in both rural and urban communities (Shirey et al., 2015; Waari et al., 2018). Further, studies have demonstrated that treatment adherence interventions have the potential of burden reduction and expediting clinical follow up of patients (Khabala et al., 2015).

In this study, these mental health problems that impact negatively on treatment adherence in diabetes patients were evaluated. It has been found that there is a strong case for integrating care for mental illness in diabetes outpatient care settings by formulating targeted, informed and rational collaborative clinical care models and developing multifaceted clinical care programs and teams.

Chapter Two: Literature review

2.1 The Metabolic syndrome, diabetes and mental illnesses.

Metabolic syndrome is a cluster of conditions (Samson & Garber, 2014) that significantly increase the risk of heart disease, cardiovascular complication (stroke) and Type II diabetes (T2DM) (McCracken et al., 2018). The syndrome includes elevated blood pressure, elevated plasma glucose, obesity, body fat deposits and deranged cholesterol and triglyceride levels. Obesity and insulin resistance contribute significantly to metabolic syndrome (Perrin et al., 2017). Diabetes is a metabolic disorder whereby the body's digestion of food for growth, development and energy levels is deranged (Skyler, 2004). In diabetes, there is inadequate insulin production or impaired utilization of insulin (Tesauro & Mazzotta, 2019). Mental illnesses aggravate the risk and severity of the metabolic syndrome (Penninx & Lange, 2018).

2.2 Psychological and emotional distress in diabetes (diabetes distress)

There is significant psychological and psychiatric comorbidity in patients with diabetes with than 20% of people with diabetes suffering depression (Snoek et al., 2015). This interferes with their treatment outcomes and impairs their quality of life. Diabetes distress is an expression of this intimate association between diabetes depression which imperatively affects adherence to treatment and glycemic control. It is important to expeditiously identify and appropriately treat vulnerable patients (Dennick et al., 2017). This should be done while paying attention to clinical predictors and mediators of general psychological distress. Therefore, the screening of patients with diabetes for distress and linking them to psychiatric care as need arises is a reasonable effort in order to improve their overall disease management (Parsa et al., 2019).

2.3 Clinical presentation, types and diagnosis of diabetes

Diabetes is a common metabolic disease that affects multiple systems in the human body (Diabetes, 2009). The metabolic derangement in diabetes is characterized by hyperglycemia due to defective insulin secretion, insulin utilization or both (Skyler, 2004). The major categories of the diabetes are gestational diabetes, prediabetes, Type I diabetes and Type II diabetes (Tesauro & Mazzotta, 2019). Prediabetes manifests with having blood sugar levels are higher than normal approaching the diabetic range (Khetan & Rajagopalan, 2018). The fasting plasma glucose and glucose tolerance gradually deteriorate. Prediabetes precedes T2DM.

Type I diabetes occurs most commonly in children and adolescents (Gan et al., 2012). It is characterized by the inability of the body to produce sufficient insulin. Treatment involves lifelong insulin injections to maintain blood glucose levels under control (Diabetes, 2009).

Type II diabetes is more common in adults and accounts for more than 90% of all cases of diabetes. In T2DM, the possibilities are Islet β-cells in the pancreas secreting deficient insulin, the tissues receptors having resistance to insulin and the endocrine system having a deranged insulin secretory response (Galicia-Garcia et al., 2020). The cornerstone of treating T2DM is a healthy lifestyle, optimal physical activity and eating a healthy diet (Pfeiffer & Klein, 2014). However, over time most people with T2DM require oral drugs and/or insulin therapy to keep the blood glucose levels under control.

Gestational diabetes (GD) involves patients having high blood glucose levels during pregnancy. It is associated with complications to both mother and child (Plows et al., 2018). GD usually resolves after pregnancy. However, the affected mothers and their children are at increased risk of developing T2DM in future (Hyochol Ahn 2017, 2017).

Patients with diabetes present in the clinics with history and symptoms of polyuria, polydipsia, polyphagia and weight loss. They have frequent urination, increased thirst and increased appetite (Astrid Petersmann et al., 2019).

Regular laboratory tests for the diagnosis and evaluation of diabetes include:

i. Random plasma glucose levels. A plasma glucose test done at any time.
ii. Fasting plasma glucose. A plasma glucose test is done after 8 hours of fasting. This is often done in the early in the morning.
iii. Oral glucose tolerance test (OGTT). A FPG is first done. The person takes an oral glucose bolus challenge of a sweet drink containing 75g glucose, then rests for 2 hours after which the plasma glucose test is repeated.
iv. Glycated hemoglobin (HbA1c). A measure of the percentage of blood sugar linked with hemoglobin. HbA1c indicates the trend of plasma glucose levels over the previous 2 to 3 months.

Table 1: Laboratory tests for blood sugar monitoring and diabetes diagnosis.

Laboratory test	**Normal values**	**Prediabetes**	**Diabetes**
Random plasma glucose	< 200 mg/dL < 11.1 mmol/L		> 200 mg/dL > 11.1 mmol/L
Fasting plasma glucose	72 - 99 mg/dL 4.0 - 5.5 mmol/L	100 – 125 mg/dL 5.5 – 6.9 mmol/L	> 126 mg/dL > 7.0 mmol/L
Oral glucose tolerance test (OGTT)	< 140 mg/dL < 7.8 mmol/L	140 – 199 mg/dL 7.8 – 11.0 mmol/L	> 200 mg/dL > 11.1 mmol/L
Glycated hemoglobin (HbA1c)	< 42 mmol/mol < 6.0 %	42 – 47 mmol/mol 6.0 - 6.4 %	> 48 mmol/mol > 6.5 %

2.4 Clinical presentation and diagnosis of depression and anxiety

Patients with depression present for care with signs and symptoms of mood disturbance. The Diagnostic and Statistical Manual (DSM V) ("Diagnostic and Statistical Manual of Mental Disorders," 2016) cluster of symptoms in a depressive episode include a persistently low mood, difficulty concentrating, poor decision making, low energy levels, decreased interest in previously enjoyable activities, increased or decreased appetite, too much or too little sleep (insomnia or hypersomnia), psychomotor changes (agitation or retardation) and a negative outlook to life. The patients may also have suicidal and homicidal ideation.

The patients with psychological disturbances also frequently present for care with anxiety. This may not be promptly identified and they end up not receiving immediate care. This is often because of diversity in clinical presentations of anxiety disorders while clinicians may lack a high index of suspicion to promptly diagnose and treat the condition, especially in non-psychiatric settings (Giacobbe & Flint, 2018).

While a certain level of anxiety is compatible with day-to-day life, patients with clinical anxiety exhibit a frequency and intensity of anxiety symptoms that are out of proportion to situations that trigger the anxiety (Nechita et al., 2018). Anxious patients express alarming psychological and sometimes physical signs and symptoms. The DSM V cluster of anxiety symptoms include having feelings of nervousness, fear and dread, lack of appetite, breathlessness, shaking, shivering, sweating, generalized weakness, palpitations, too much or too little sleep, and rapid heartbeat, a feeling of being out of control, difficulty in concentrating, irritability and excessive worry ("Diagnostic and Statistical Manual of Mental Disorders," 2016).

2.5 Comorbidity and impact of depression and anxiety on diabetes

The co-existence of diabetes, depression and anxiety presents a diagnostic and treatment challenge to clinicians (Rajput et al., 2016). This is more so because different clinical specialists, internists, endocrinologists and psychiatrists tend to treat each condition independently. Lack of collaborative care models and unified clinical care guidelines between the specialties make patient care difficult with possible lost opportunities to treat (Reddy et al., 2010). It is estimated that 415 million people live with diabetes worldwide while 193 million people have undiagnosed diabetes (Khetan & Rajagopalan, 2018). Type two diabetes accounts for more than 90% of global diabetes burden (Guariguata et al., 2014). Diabetes illness causes profound psychological and physical distress to patients and primary caregivers. It also strains the health-care system. The comorbidity with depression and anxiety worsens treatment efforts and impairs the outcomes of treatment in diabetes patients (Perrin et al., 2017).

2.6 Disease models of non-communicable diseases and mental health conditions.

Non-communicable diseases (NCDs) are medical conditions that are non-infectious and non-transmissible among people. They cause significant morbidity and mortality worldwide (Bennett et al., 2018). Risks that contribute to the causation of NCDs are broadly categorized into modifiable and non-modifiable risk factors and they span a spectrum of biological, physiological, behavioral and lifestyle categories (Uddin et al., 2020).

Age, gender and family history are non-modifiable risk factors. Modifiable risk factors closely correspond to behavior and lifestyle practices. The World Health Report (WHO) 2002 identified the important risk factors as elevated blood pressure, sedentary lifestyle and physical inactivity, obesity and overweight, deranged cholesterol levels, smoking and alcohol consumption. The effects are manifested across all age groups. An evaluation of these risks shows close correspondence with the biopsychosocial factors that are attributable in the disease processes of mental illnesses (Epstein et al., 2004).

T2DM is the most common of the four types of diabetes. It is caused predominantly by modifiable risk factors and accounts for greater than 90% of all adult diabetes cases worldwide (Wu et al., 2015). The International Diabetes Federation (IDF) considers diabetes to be among the worst global health emergencies in the 21st century" (World Health Organization, 2016).

Mental illnesses rank high alongside mainstream chronic diseases in the causation of global mortality and morbidity (Roth et al., 2018). More than 14% of the global burden of disease is attributable to psychiatric disorders which similar to NCDs have a chronic and disabling nature (Prince et al., 2007). These long-term mental health conditions have thus been justifiably categorized among the NCDs (Trachsel et al., 2016).

People living in resource-constrained environments tend to suffer worse effects of the chronic diseases and mental health conditions unlike the higher income countries (Saraceno & Barbui, 1997). Depression is a common and serious disease with a lifetime prevalence ranging from approximately 11% in low-income countries to 15% in high-income countries (Kessler & Bromet, 2013). The severity of mental disorders is influenced by the physical, social and economic situations that affect a person in their lifetime (Sederer, 2016). Risk factors for mental disorders are also associated with social inequalities whereby inequalities worsen the risks.

2.7 Prevalence of depression and anxiety in patients with diabetes

Research avers that co-morbid diabetes and mental illnesses are common but the implications for clinical practice remain unclear (Roy T & Lloyd, 2012). The global prevalence of depression and anxiety in diabetic patients is increasing. The prevalence rate of depression has been found to be thrice higher in people with T1DM (12%, range 5.8–43.3%) against general population (3.2%, range 2.7–11.4%) and twice as high in people with T2DM (19.1%, range 6.5–33% against general population (10.7%, range 3.8–19.4%) compared to those without (Egede & Ellis, 2010). General population studies have made prevalence estimates of anxiety and depression symptoms at 15.3% for anxiety and 10.4–11.2% for depression (Giacobbe & Flint, 2018). This prevalence of anxiety and depression symptoms in patients with diabetes is significantly higher than in general population samples (De Groot et al., 2001).

2.7.1 Local perspectives

There is a paucity of research and data about the burden of depression and anxiety in diabetes mellitus (DM) in resource-constrained environments. However, it has been demonstrated that more than 25% of patients attending general outpatient care settings in Kenya are likely to suffer comorbid psychiatric illnesses (Othieno et al., 2001). The evidence shows that there are treatment effects arising from comorbid mental illnesses in diabetes patients. A study done at Kenyatta National Hospital (KNH) found a resistance to Insulin at 82.6%, which was attributable to psychological factors (Gulam et al., 2017). A study of 220 diabetes patients at KNH using the Patient Health Questionnaire (PHQ-9) found the prevalence of comorbid depression at 32.3% (95% confidence interval, 26.4%–38.6%) (Otieno et al., 2017). A study at Moi Teaching an Referral Hospital (MTRH) in Western Kenya reported that patients who had difficulties with adherence to treatment had a high prevalence of depression at 37.5%, $p<0.0001$ (Nyaberi Z. et al., 2014). An evaluation of public hospitals in Nairobi has demonstrated that social stress, psychological distress, and physical illness among patients in Kenya, produces syndemic suffering whereby patients have complex clustering of symptoms and experiences of living with diabetes, depression and infection (Mendenhall, Ndetei et al., 2015).

Kenya in undergoing an epidemiological transition marked by decreasing rates of morbidity and mortality due to infectious conditions but with increasing burden of NCDs. The Kenya National Strategy for the Prevention and Control of NCDs 2015–2020 and the Kenya Mental Health Strategy 2015–2030 have emphasized that the management of risk factors is a pathway to reducing the rising burden of NCDs. In this regard, the Kenya Health Policy 2014-2030 focuses on the control of mental disorders, diabetes, cardiovascular diseases, chronic obstructive airway conditions, blood disorders (sickle cell conditions) and cancers. It is important to note that Kenyan's diabetes prevalence has been at 1.9% yet in those diagnosed and on treatment only 7% have glycemic control (Kenya National Bureau of Statistics and ICF International, 2015).

2.7.2 Regional and Global Perspectives

A study carried out in Uganda's Mulago hospital found an overall prevalence of non-adherence among the respondents at 28.9% (Kalyango et al., 2008) with at least one in every four respondents not adhering to diabetes treatment. A Nigerian study found the rates of adherence at 19.8%, medium adherence at 30% and low adherence at 50.2% (Jackson et al., 2015). The factors that caused low adherence included literacy levels, forgetfulness, high cost of medication, limited access to care, complexity of treatment regimen, poor patient–provider communication, lack of trust in the provider, and depression. Still in Nigeria, it was established that there are overlaps in intentional and unintentional causes of non-adherence to treatment recommendations (Adisa & Fakeye, 2014). A Tanzanian study elicited factors consistently associated with poor adherence to diabetes treatment as regimen complexity, cost and side effects of medications, advanced age, female gender, long duration of diabetes, and comorbid conditions such as hypertension, hyperlipidemia, coronary artery disease and depression (Mutashambara, 2014). In Ghana it was found that diabetes distress significantly influences extent of treatment adherence (Kretchy et al., 2020)

In Asia, a population-based study in Chennai, India reported the prevalence of depression at 23.4% (Rajput et al., 2016). A study carried out among 889 patients in Pakistani established a prevalence rate of 57.9% for anxiety and 43.5% for depression (Khan P, Qayyum N, 2019). In Korea, it was found that individuals with a lifetime history of depression or with current depressive symptoms showed lower odds of using overall medical treatment than non-depressed people. This is noteworthy especially where depressed individuals with comorbidities (e.g. T2DM) exhibit less utilization of healthcare services than non-depressed individuals (Lee et al., 2020). A Mexican study reported that in a sample of 704 diabetes patients 48.27% were positive for depression and 55.10% for anxiety (Darla et al., 2014). A large prospective cohort study of diabetes patients in Madrid Spain established depression prevalence at 20.03% (Salinero-Fort et al., 2018).

In the high-income countries, high prevalence rates have been documented. Studies from UK and US have reported the prevalence of depression in patients with T2DM averaging 30% (Kouidrat et al., 2017). A cross sectional study in the United Kingdom found that almost one-third (33%) of diabetic persons suffers anxiety and one-fourth (25%) suffer depression (T. Roy & Lloyd, 2012).

The differences in prevalence rates between regions could be because of using different methodologies. Self-reported depression measures are different in patients clinically with depression and who are already on treatment. The lack of clear data and documents regarding relevant factors associated with the diseases, e.g. number of diabetes complications, psychiatric comorbidities, and medical comorbidity, has confounding effects on the prevalence rates.

Table 2: Summary of studies on relationship between depression/anxiety and adherence.

Researchers	Summary		Key findings
Fernanda S. Marinho et al, 2018 (Marinho et al., 2018)	Study population / Data sources (Brasil)	Rio de Janeiro Type 2 Diabetes Cohort Study	Emotional and physical performances are important determinants of good diabetic treatment adherence. Good adherence has beneficial impact on BMI, lipid, and glycemic control.
	Sample size / Study design	476 / Cross-sectional	
	Tools Used / Methodology	Summary of Diabetes Self-Care Activities (SDSCA) Questionnaire.	
Irene A. et al, 2020 (Kretchy et al., 2020)	Study population / Data sources (Ghana)	Pantang Hospital in Accra	Diabetes distress is a significant determinant of medication adherence behavior in patients with T2DM.
	Sample size / Study design	188 / Hospital-based cross-sectional study	
	Tools Used / Methodology	Problem Areas In Diabetes Questionnaire (PAID) Medication Adherence Report Scale (MARS)	
Idongesit L. Jackson et al, 2015 (Jackson et al., 2015)	Study population / Data sources (Nigeria)	University of Uyo Teaching Hospital, Akwa Ibom State, University of Calabar Teaching Hospital, Cross River State.	Adherence to medication was very low, probably because of factors such as cost of medications, forgetfulness, limited access to care, complexity of diabetes treatment regimen, poor patient–provider communication, and depression.
	Sample size / Study design	360 / Cross-sectional	
	Tools Used / Methodology	Modified Morisky Adherence Scale (MMAS 8)	
Jerry L. Grenard, PhD et al, 2011 (Grenard et al., 2011)	Study population / Data sources (United States)	PubMed and PsycINFO databases; search terms adherence (e.g., compliance, non-adherence, and refusal), depression (e.g., depressive disorder and mental health), barriers (e.g., predictors, determinants, and factors), and medication (e.g., drugs, drug therapy, pharmaceutical, and prescription).	Results of the meta-analysis showed a significant association between depression and medication adherence.
	Sample size / Study design	31 studies and (n =18,245). / Metaanalysis	
	Tools Used / Methodology	Systematic review	

Bala´zs Hanko et al, 2007(Hankó et al., 2007)	Study population / Data sources (Hungary)	Type 2 diabetes Hungarian patients attending community pharmacies between March and May 2004.	The adherence of Type 2 diabetic patients is lower than optimal. A significant association was found between adherence rates and quality of life. In 50% of cases non-adherence was due to active decisions by the patients themselves.
	Sample size / Study design	220 / Crossectional	
	Tools Used / Methodology	Social demographic and adherence questionnaire EQ-5D (EuroQol Group, 1993) quality-of-life questionnaire	
Lia Gentil et al, 2016(Gentil et al., 2017)	Study population / Data sources (Canada)	Type 2 diabetes Quebec patients.	Multiple-group analysis did not show any significant difference in oral hypoglycemic medication adherence ($p < 0.05$). Individuals with higher levels of education were less adherent to oral hypoglycemic treatment than those with lower levels of education ($p<0.05$) Medication adherence to oral hypoglycemic did not show any significant difference between participants with and without depression and anxiety disorders.
	Sample size / Study design	301 patients who received oral hypoglycemic pharmacotherapy. A longitudinal survey on senior's health	
	Tools Used / Methodology	Medication adherence was measured with the medication possession ratio. Andersen's behavioral model was used to explain adherence to oral hypoglycemic medication	

2.9 Conceptual Framework

The study assessed the effects of depression and anxiety on adherence in diabetes treatment using the biopsychosocial framework. This approach is intended to assess the congruence between the modifiable and non-modifiable risk factors attributable in NCDs and the biological, psychological and social factors imputed in psychological and psychiatric disorders.

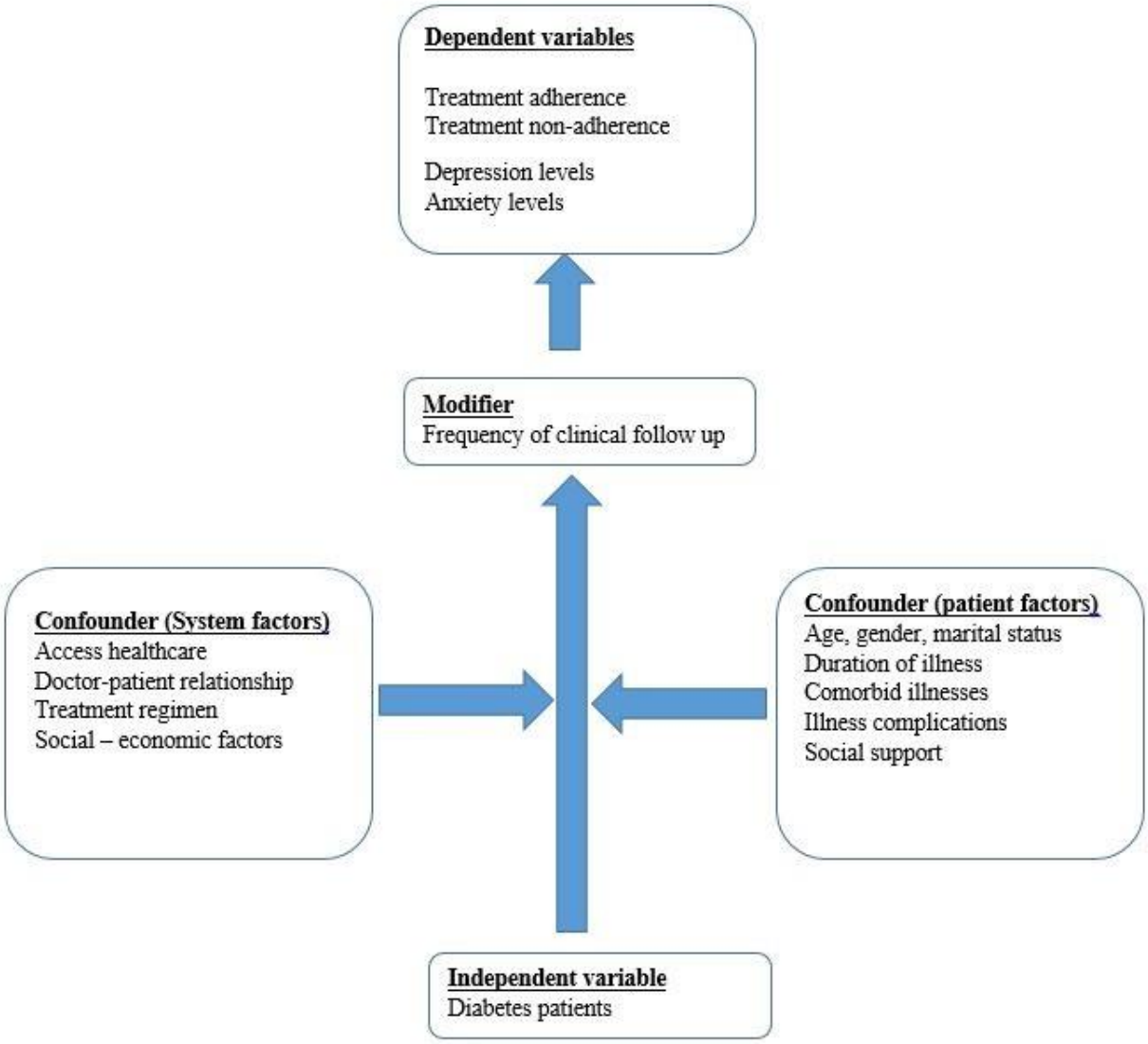

Figure 1: Conceptual Framework

2.11 Study Variables

The variables in the study were organized according to the above framework. This grouping of independent and dependent variables is broken down in Table 3 below. The study collated social demographic, economic factors and the patients' quality of life situation. The key measures reported were psychological measures of depression and anxiety and the patients' level of adherence to treatment.

Table 3: Study variables

Confounding variables (C	**Dependent Variable**
Social demographic factors; *age, sex, marital status, education level, religious affiliation, residence* Socio economic factors; *level of income, cost of living, occupation* Quality of life measures; *Satisfaction, impact, and worry* Diabetes related measures; *Duration of illness, blood sugar control, complication, medical or surgical comorbidities, laboratory investigations* Treatment factors; *Type of drug, frequency of medication, drug side effects* System / provider factors; *Satisfaction levels*	**Therapy outcome***;* *Treatment adherence,* *Treatment non-adherence* *Depression levels* *Anxiety levels*
Modifiers Frequency of clinical follow up	
Independent variable Diabetes patients' population	

Chapter Three: Methodology

3.1 Study design.

This was a cross-sectional study carried out at the Kenyatta National Hospital (KNH) diabetes outpatient clinic (DOPC). The levels of depression and anxiety were assessed among patients attending the clinic. The patients were evaluated for their adherence to treatment.

3.2 Study site

KNH is a tertiary national referral hospital located in Nairobi County, Kenya. It serves as the teaching hospital for the University of Nairobi College Of Health Sciences. The facility is among the oldest hospitals in the country having been founded in 1901 as the Native Civil hospital catering to the indigenous population. It was renamed King George VI hospital in 1952 and subsequently Kenyatta National Hospital after the country gained independence. KNH offers an array of preventive, protective, curative and rehabilitative healthcare services.

KNH has comprehensive inpatient and outpatient facilities offering general medical and surgical services. There is an accident and emergency (A/E) department that receives patients referred for specialist care. Depending on severity of illness, patients are admitted to the corresponding medical or surgical wards.

Diabetes patients are reviewed and directed to the appropriate clinic from the A/E. Depending on severity of illness, those who need admission to the wards are assigned corresponding ward, then discharged for follow up through the DOPC.

The diabetes clinic is carried out daily from Monday to Friday by a clinical team comprising of consultant endocrinologists, resident doctors, clinical officers, nurses and auxiliary healthcare and support staff. The patients' clinical appointments are scheduled over two major clinic days on Wednesday and Friday with minor clinic days on Monday, Tuesday and Thursday. On Wednesday major clinic day, patients with diabetes and patients with other endocrine conditions are treated while on Friday major clinic day, only diabetes patients are treated. During minor clinic days an average of 30 – 50 patients are attended each day while during major clinic days an average of 50 – 70 patients are attended.

3.3 Inclusion Criteria

i. Male and female patients above 18 years of age.
ii. Patients with a diagnosis of T2DM that have been confirmed by history and confirmatory laboratory tests.
iii. Patients who have been on treatment and follow up for at least six (6) months.

3.4 Exclusion Criteria

i. Patients with major complications requiring hospitalization.
ii. Patients who do not consent to participate in the study.

3.5 Sample Size Calculation

The Daniel's formula (1999) used for finite populations was used to determine the minimum significant sample size (Pourhoseingholi et al., 2013). Reference was made to a study done in Ghana that reported that poor adherence to medications was recorded in 66.5% of the patients (Kretchy et al., 2020). The patients who were highly distressed had 68% lower odds of adhering to their medications compared to those who were not (OR: 0.32, 95% CI: 0.15-0.65). Ghana is a developing country with comparable to Kenya.

$$n \geq \frac{NZ^2_{\alpha/2}P(1-P)}{d^2(N-1)+Z^2_{\alpha/2}P(1-P)}$$

n = minimum significant sample size.

N = Total accessible sample population

P = 66.5% estimated prevalence of poor adherence estimated from a similar study done in Ghana.

Z = Critical value for a standard normal distribution at α = 0.05 level of significance (1.96)

d = Precision at 5% (0.05)

According to KNH diabetes clinic records of the year 2020, 7280 patients were attended to in the clinic with a monthly turnover of 607 patients. A total of 10% of these patients were between ages 16 and18 years hence a total eligible sample population (N) of 547 patients every month.

Thus n = 211. With 5% allowance for sampling deficits, sample size = 222 patients

3.6 Sampling method

The patients were selected using a census sampling technique. A census sampling technique was selected based on the reduction patient numbers in view of the ongoing COVID 19 pandemic. This technique allowed access to of the entire eligible population. Every next patient in the queue in order of the appointment schedule and arrival to the clinic on the clinic day was eligible for recruitment to the study.

3.7 Participant recruitment and consenting procedure.

The researcher reviewed each selected patient's file to confirm the diagnosis, duration of treatment and current treatment status. A confirmation was made that potential participants had been on treatment and follow up for at least six months. The researcher availed, read and explained to the patient the study and consent information to seek patients' consent. A explanation of the research objectives was made to each recruited participant.

3.8 Study flow

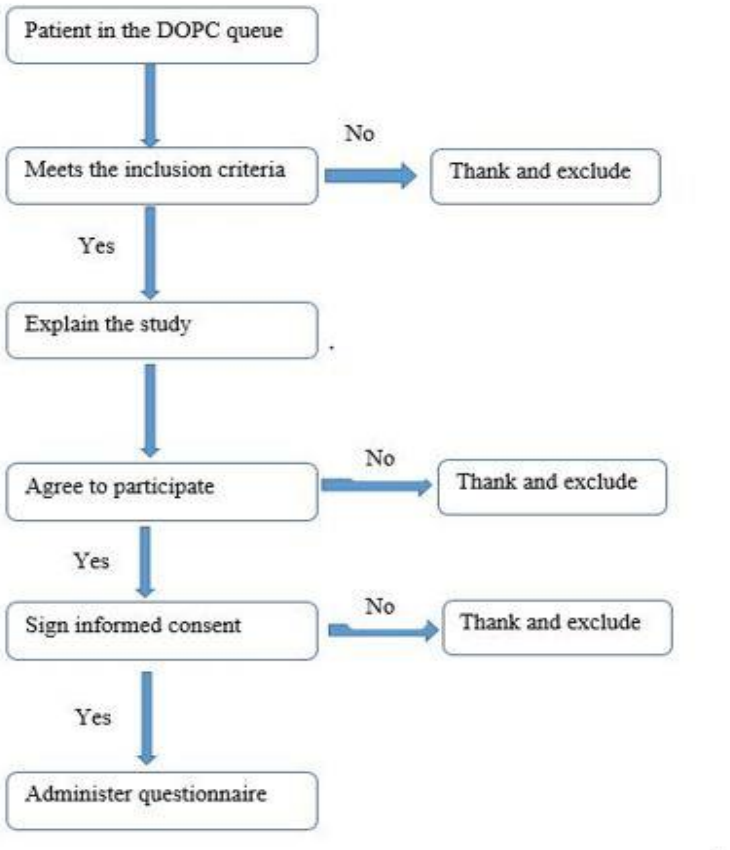

Figure 2: Study flow diagram

3.9 Ethical approval

Departmental approval of the study was received from the University of Nairobi, Department of Psychiatry. The study proposal was then submitted and approval received from Kenyatta National Hospital Ethics and Research. Finally, the Kenyatta National Hospital Department of Internal Medicine approved access to the Diabetes Outpatient Clinic (DOPC) and the patients.

3.10 Data collection procedure and tools

On the data collection day, the researcher approached patients in the DOPC during the clinic hours at 8:00 AM to 1:00 PM. An introduction and explanation of the details of the study was made. The researcher addressed any questions the patient raised then assured them of privacy and confidentiality. Written consent was sought from patients who were also assured that declining to participate in the study would not prejudice their medical care and that participation was voluntary.

The research questionnaire was then availed to the recruited participants and filled in with assistance by the researcher. The questionnaire gathered self-report measures of the different items under study.

A serial number was affixed on each questionnaire to facilitate confidentiality. No personally identifiable information was collected or keyed in on the questionnaire. The researcher shared official contact information with the participants who wanted to follow up of any concerns after the interview.

The patients who were identified to have clinically significant signs and symptoms of anxiety and depressive symptoms were guided through the clinic system for psychiatry consultation through the Mental Health Department of Kenyatta National Hospital.

Upon completion of interview, each questionnaire and was checked for completeness and accuracy. The filled in questionnaires were sealed in an envelope and taken off site for storage in a secured cabinet with controlled access.

3.10.1 Social Demographic Questionnaire

This tool was used to gather important participant background data including age, sex, marital status, occupation and income level, religious affiliation, education level, age of diagnosis, duration of time on treatment and day-to-day living conditions.

These data items did not include any personally identifiable information.

3.10.2 Hospital Anxiety and Depression Scale (HADs)

The HADs scale is a self-assessment scale that was developed by Zigmond and Snaith in 1983 (Zigmond & Snaith, 1983) to evaluate anxiety and depressive symptoms in general medical populations. It is also applicable in settings of general medical patients (Bdi-ii et al., 2011). The scale has 7 depression items measuring cognitive and emotional aspects of depression plus 7

anxiety items that focus on cognitive and emotional aspects of anxiety. HADs has been found to perform well in assessing the symptom severity in cases of anxiety disorders and depression in both somatic, psychiatric and primary care patients and in the general population (Bdi-ii et al., 2011).

The HADs assesses both anxiety and depression simultaneously (Bjelland et al., 2002). Anxiety involves emotions of fear with intense feelings of worry, apprehension, and dread. Depression is dominated by emotions of sadness with feelings of sorrow, hopelessness, and gloom. HADs has separate scores for each of these two domains while taking account of comorbidity between them.

The HADS items have a 4 point Likert scale (0 -3) with three denoting highest anxiety or depression level. The summary values for each subscale range from 0 to 21. A total score between 0 and 7 is "normal," between 8 and 10 "mild," between 11 and 14 "moderate," and between 15 and 21 "severe (Pais-ribeiro, 2018).

3.10.3 Medication Adherence Report Scale (MARS – 5)

The Medication Adherence Report Scale (MARS -5) was used to estimate the level of adherence to medications. The scale is designed to elicit both deliberate and inadvertent non-adherence to drugs (Horne & Weinman, 1999). The study participants provide self-scored measures to five questions on a five point Likert scale, with answers indicating the frequency ('always', 'often', 'sometimes', 'rarely' or 'never') for each question, with ascending scores from 'always' (1 point) to 'never' (5 points) (Stirratt et al., 2015). The MARS-5 total score is between 5 and 25. A higher score on the MARS-5 represents better medication adherence. The MARS-5 has acceptable reliability (internal and test-retest) and validity (criterion-related and construct validity) across patient groups with internal reliability (Cronbach's α) ranging from 0.67 to 0.89 (Chan et al., 2020).

The MARS-5 has previously been used for patients with diabetes in Ghana where the average MARS-5 score was 21.2±3.6 with one third of patients having optimal adherence levels (Kretchy et al., 2020). It was also used to study adherence in a Singaporean population where 57.1 % of the patients were found to have low adherence (Lee et al., 2017).

The MARS is a useful standardized tool for getting patient's self-reported feedback about treatment adherence. Standardized tools are useful monitoring medication adherence in clinical settings (Gonzalez, 2018). Self-report measures, though subjective, offer an accessible and quick way compared to objective measures like daily pill counts, directly observed therapy (DOTs) and electronic monitoring and reporting systems (Edelstein et al., 2010). An added advantage of MARS-5 is cognizance with underlying psychometric aspects in patient populations (Chan et al., 2020).

3.10.4 Diabetes Distress Scale (DDS-17)

Diabetes distress is a frequently encountered phenomenon in many diabetes patients. It entails the emotional and behavioral changes that result from the disease itself. However, in most clinical settings, diabetes distress is not explicitly evaluated. As a result, the measures of diabetes distress prevalence are not readily available.

The Diabetes Distress Scale-17 item (DDS-17) was used to evaluate diabetes distress in relation to the disease process, complications and modes of therapy. The tool was chosen to correlate the psychometric measures gathered with the HADs tool. The modes evaluated include treatment regimen, provider related factors, emotional burden factors and interpersonal distress factors (Polonsky, 2005).

The DDS has 17-items rated on a 6-point scale from 1 (not a problem) to 6 (a very serious problem). The patients indicate their degree of distress during the past month. The DDS yields a total score and four sub-scale scores: Interpersonal Distress, Regimen-related Distress, Physician-related Distress, and Emotional Burden. Higher scores indicate greater levels of distress. Internal reliability of the total DDS score and the four subscales is high (α = .87) (Amankwah-Poku et al., 2020).

The HADs, MARS-5 and DDS-17 tools were selected for their ability to evaluate psychometric scores.

3.10.5 Diabetes Quality of Life (DQOL) scale

The DQOL was used to evaluate the satisfaction, impact, and worries associated with the treatment of diabetes mellitus. In this regards, it is useful to evaluate diabetic populations on treatment (Nair & Kachan, 2017). It has important psychometric measures that are able to assess the effect of diabetes on patients' lives. The mere presence of diabetes deteriorates a person's quality of life (QoL).

The DQOL was introduced by the Diabetes Control and Complications Trial. Four dimensions of diabetes impact are evaluated: Satisfaction, treatment impact, anxiety for complications and social issues. High-risk patients at a prediabetic state tend to develop decreased QoL, anxiety and depression. Therefore, this dimension should not be ignored when evaluating patients.

The 15-item DQOL provides a total health–related quality of life score that predicts self-reported diabetes care behaviors and satisfaction with diabetes (Shen et al., 1999). It is a quick measure that offers a vehicle to quickly screen patients for readiness and specific treatment-related concerns.

The DQOL instrument provides an overall scale score, as well as four subscale scores for 1) satisfaction with treatment, 2) impact of treatment, 3) worry about the future effects of diabetes, and 4) worry about social/vocational issues (Shen et al., 1999).

3.11 Privacy and Confidentiality

To ensure patient privacy and confidentiality, no personally identifiable patient data was collected or entered in the study tools. All patient level data was de-identified. The study tool was coded with a serial number capturing only the day, date and time of interview.

For medical-legal purposes, the consent form capturing the patients name and signature was filled in. Contact information was shared with patients who needed feedback on the study results.

3.12 Study risks and limitations

This study solicited patient reported information. No immediate clinical risks and physical risks were involved and no physical samples were drawn.

While some questions overwhelmed participants emotionally, the researcher reassured the patients with the option to skip the questions. Where significant signs and symptoms of depression and anxiety were found, the patient and the DOPC clinic staff were engaged to facilitate referral for psychiatric consultation in the KNH Mental Health Unit.

3.12 Coronavirus evaluation.

During the study, the researcher followed the laid down infection prevention strategies set by the World Health Organization, the Kenya Ministry of Health and the guidelines of Kenyatta National Hospital Clinical department for infection control.

In addition, the researcher asked questions about patient's experience with the Coronavirus pandemic. Studies about Coronavirus in this study population have not yet been extensively done. However, the corona virus infection has affected many persons, with significant effects on those with chronic conditions (including diabetes). Since anxiety, mood disturbances and likely depression accompany COVID infection, these basic data were analyzed alongside other comorbid conditions to assess how prevailing coronavirus pandemic has affected on prevalence of anxiety, depression and treatment adherence in patients on treatment for diabetes at the KNH DOPC.

3.13 Quality Assurance

i. The researcher has received training in clinical research methods and has received guidance from supervisors from the University of Nairobi, Department of psychiatry.
ii. The researcher has received training in Good Clinical Practice (GCP) and has requisite skills and knowledge to carry out clinical research to the required standards
iii. The proposal and final dissertation were reviewed by the University of Nairobi, Department of Psychiatry research panel to ensure they passes quality threshold.
iv. The proposal was submitted to the University of Nairobi / Kenyatta national Hospital Ethics Review Committee (UoN/KNH ERC) to ensure it met quality and ethics standards for human research.

v. The researcher got approval from the Kenyatta National Hospital Clinical Department to be allowed access to the DOPC and the patients.
vi. During the study, due diligence was followed to ensure respondents understood the questionnaire and provide accurate feedback.
vii. Data analysis was completed using appropriate biostatistics methods. Presentation of study results was done to the University Of Nairobi Department Of Psychiatry, the UoN/KNH ERC and the KNH research department.
viii. All reports, scientific presentations and publications emanating from the research will be subjected to appropriate peer review process.

3.13 Presentation of results and dissemination plan.

The results are delivered and disseminated through a final research dissertation presented for examination by the University of Nairobi, Department of Psychiatry. The researcher will also present the findings in academic research meetings. The final research report will be availed to the Diabetes Outpatient Clinic and the researcher will present in a Continuing Medical Education (CME) to the DOPC staff about the findings and recommendations. The researcher will also prepare to present in scientific conferences and write up manuscripts for publication in peer reviewed research journals.

4.1. Data collection, storage and analysis

The period of data collection was from September 30th 2021 to December 20th 2021. The process of data collection extended because of lower than expected numbers of patients in the clinic due to the effects of the COVID 19 pandemic. Nevertheless, total of 213 patients were successfully recruited to the study. The recruited participants were informed about the purpose, method and process of the study. The participants who agreed to participate gave their informed consent by appending their signature on the consent form. After this, they filled in the questionnaire with the guidance of the researcher.

The data was collected on the predefined data collection questionnaire. A corresponding digital form for handheld tablet devices was created to use ODK data Kit. Data transfer was done from the paper based forms using the ODK Collect Open source android application to a secure, password protected and encrypted database. The patients filled in all their responses on the paper based forms while data entry from the paper based forms to ODK collect and transmission to the online server was done by the researcher. Security of the database was ensured by Password protection and One Time Pin (OTP) authentication codes that were sent and accessible only through the researcher’s mobile phone number. All the data entered into ODK collect was checked for completeness and accuracy before being uploaded to the online database. The paper data collection forms were then moved off-site and stored under lock and key in a secure file storage cabinet. All the questionnaires were de-identified with no personally identifiable information collected. The consent forms were dated with the patients' signature affixed. Each questionnaire and consent form had a unique questionnaire code affixed for tracking purposes. Daily data entry was made to the aforementioned database. After the data from all questionnaires was keyed in, the researcher did a final review of all data entries in the database to confirm completeness and account for any missing data values.

Chapter Four: Results

4.1 Statistical analysis

Statistical analysis was performed using the R statistics (R foundation) version and R Studio Version. Summary calculations, data modeling, univariate, bivariate and multivariate statistical tests were done to determine means, mode and medians of the key variables and the association between the variables of interest. The results are presented below in form of narratives, bar charts, tables and pie charts. The effect of depression and anxiety on treatment adherence among patients attending the Kenyatta National Hospital's diabetes outpatient clinic was estimated through computation of odds ratios, their confidence interval and p-values. Fishers and Chi Square tests of association were used whenever a 2 by 2 contingency table were applicable. For the variables that demonstrated significant association with treatment adherence, a bivariate logistic regression model was fitted to check the strength and direction of association. The prevalence of depression and anxiety was determined by calculating the percentage of participants with the condition out of the total sample based on the HADs questionnaire scores. Medication adherence was determined by calculating the patient's adherence scores based on the MARS-5 questionnaire scores.

Multivariate analysis was done to determine the relationships between treatment adherence and the other categorical variables like gender, marital status, employment status, level of education, type and route of diabetic medication, presence of other comorbid diseases and any diabetes complications. Multivariate logistic regression model was used to control for social demographic factors and other possible confounders.

4.2 Socio-demographic characteristics

A total of 213 patients were sampled and included in the study with male patients being 63 (29.6%) and females 150 (70.4%). The mean age of the study patients was 53 years. Out of 213 patients, 153 (71.8%) were married, 29 (13.6%) had lost their spouses while 6 (2.8%) had either separated from or divorced their partners. A total of 68 (31.9%), 58 (27.2%), 32 (15.0%) and 52 (24.4%) patients had attained primary, secondary, tertiary or vocational training and university education levels respectively. Regarding their occupations 22(10.3%), 45(21.1%), 5(2.3%), 67(31.4%), 17(8.0%) and 27(12.7%) were either in part time employment, retired, students, self-employed, farmers or business persons respectively with a mean income of Kshs. 23,500 respectively. 23(10.8%) of the patients reported to have used an addictive substance. Alcohol was the most reported psychoactive substance.

4.3 Clinical characteristics of the study population

The summary of the patients' duration of illness showed 102 (48.1%) patients have been on treatment for more than 10 years, 48 (22.6%) between 5 to 10 years, 34 (16%) between 2 to 5 years and 24 (11.4%) less than 2 years of treatment. Blood sugar was poorly controlled in 61 (28.6%) of the patients who had glycated hemoglobin levels above 7.0. During the clinic day, 120 (56.6%) of the patients had elevated fasting blood sugar (hyperglycemia), while 4 (1.9%) were hypoglycemic. 88 (41.5%) had fasting blood sugar levels in normal reference ranges.

This Table 4 summarizes this demographic and clinical characteristics information.

Table 4 : Socio-Demographics Characteristics of DM Patients in KNH		
Characteristic	**Category**	**N = 213 (%)**
Gender	Male	63 (29.6)
	Female	
Marital Status	Married	153 (71.8)
	Widow/ Widower	29 (13.6)
	Separated/ Divorced	6 (2.8)
Religion	Muslim	27 (12.7)
	Christian	
Education	Primary school	68 (31.9)
	Secondary school	58 (27.2)
	Polytechnic/Vocational	32 (15.0)
	University	52 (24.4)
Occupation	Part Time Employment	22 (10.3)
	Retired	45 (21.1)
	Student	5 (2.3)
	Self employed	6
	Farmer	17 (8.0)
	Business person	27 (12.7)
Income (KSh)	Mean (Standard Dev)	22,669.00 (14,952.58)
Age (Years)	Mean (Std dev)	52.75 (14.84)
HbA1c	<5.0	7 (3.3)
	5.1 – 6..9	145 (68.1)
	>7.0	61 (28.6)
Fasting Blood Sugar	Hypoglycemia	4 (1.9)
	Normal	88 (41.5)
	Hyperglycemia	120 (56.6)
Addictive Substance	Yes	23 (10.8)
	No	189 (88.7)
Disease Duration (yrs)	< 1 Year	12 (5.7)
	1 – 2 Years	12 (5.7)
	2 – 5 Years	34 (16.0)
	5 – 10 Years	48 (22.6)
	>10 Years	102 (48.1)

4.2 Diabetes illness, comorbid diseases and complications.

A total of 132 (62.3%) patients reported comorbid illnesses, with hypertension being the most illness reported in 129(97.7%) of the patients. Asthma and HIV/ AIDS were reported by 8 (6.1%) and 2 (0.9%) patients respectively. A total of 132 (63.2%) were on treatment for these comorbid illnesses. Diabetes complications were identified in 77 (36.3%) of the patients with diabetic neuropathy in 43 (55.8%) and visual impairment in 42 (54.5%) being the most cited complications. Diabetic nephropathy was found in 4 (5.2%) patients. Diabetic foot was found in 9 (11.7%) patients while 6 (7.8%) had cardiovascular or small vessels' disease. This Table 5 summarizes this information.

Table 5: Comorbid Diseases and Diabetes Complications

Characteristics	Category	N (%)
Any other disease	Yes	132 (62.3)
Hypertension (n=132)	Yes	129 (97.7)
Asthma	Yes	8 (6.1)
HIV/ AIDS	Yes	2 (0.9)
Tuberculosis	Yes	1 (1.5)
On treatment	Yes	132 (63.20
DM complications	Yes	77 (36.3)
Diabetic Foot	Yes	9 (11.7)
Visual Impairment	Yes	42 (54.5)
Kidney Problem	Yes	4 (5.2)
Nerve Damage	Yes	43 (55.8)
Heart/ Blood Vessel Disease	Yes	6 (7.8)
Mental Illness (n=213)	Yes	9 (1.9)
Covid 19 Test	Yes	7
Covid 19 Vaccination (n=213)	Yes	92 (43.2)
Missed Clinical Appointment	Yes	161 (75.6)
Difficulty taking Treatment	Yes	34 (16.0)

It is worth noting that, only 9 (1.9%) of the patients reported to have ever been diagnosed with a mental illness and started on a treatment regimen.

4.3 Effects of the Coronavirus pandemic on the patients at the KNH DOPC.

In view of the ongoing Coronavirus pandemic, only 7 patients reported to having done any COVID-19 test while 92 (43.2%) had received COVID-19 vaccination. Noteworthy, 161 (75%) of the patients reported to have missed a clinical appointment because of either lockdown or curfew imposed during the pandemic while 34 (16.0%) reported to have faced actual difficulty in following their treatment regimen because of the pandemic.

4.4 Prevalence of anxiety and depression in patients at the KNH DOPC.

Results of the Hospital Anxiety and Depression Scale (HADs) found that a total of 100 (47.4%) study patients suffered from anxiety. Sixty-seven patients had borderline anxiety, which accounted for 31.8 % of the study participants. 20.9% of the patients had normal findings. In comparison, 84 (39.6%) of the patients had confirmed scores to make a diagnosis of depression, 73 (34.4%) had scores for borderline depression while 55 (25.9 %) had normal findings. This data is summarized in table 3 below.

Table 6: Prevalence of Anxiety and Depression among DM Patients attending the KNH Diabetes Outpatient Clinic

Diagnosis	Category	n (%)
Anxiety	Normal	44 (20.9)
	Borderline Anxiety	67 (31.8)
	Anxiety	100 (47.4)
Depression	Normal	55 (25.9)
	Borderline Depression	73 (34.4)
	Depression	84 (39.6)

A cross tabulation of anxiety and depression scores revealed that 31 (14.8%) of the study patients were absolutely free from both anxiety and depression. On the contrary, 76 (36.2%) had scores of both anxiety and depression. Another 38 (18.1%) suffered both borderline anxiety and borderline depression. Notably, no patient suffered depression alone and all patients who had depression either had borderline anxiety 7 (3.3%) or anxiety 76 (36.2%). This cross tabulation is summarized in Table 4 below.

Table 7: Cross Tabulation of anxiety and depression

Anxiety	Depression			Total
	Normal	Borderline	Depression	
Normal	31 (14.8)	13 (6.2)	0 (0.0)	44 (21.0)
Borderline Anxiety	21 (10.0)	38 (18.1)	7 (3.3)	66 (31.4)
Anxiety	2 (1.0)	22 (10.5)	76 (36.2)	100 (47.7)
Total	54 (25.8)	73 (34.8)	83 (39.5)	210 (100.1)

4.4 Treatment adherence scores among DM patients at the KNH diabetes outpatient clinic.

Treatment adherence was assessed using the Medication Adherence Report Scale - 5 (MARS-5). The MARS-5 total score is between 5 and 25 with high score (21- 25) on the MARS-5 representing better medication adherence. There was no big variation between treatment adherence score and non-adherence scores among diabetes patients attending the Kenyatta National Hospital's diabetes outpatient clinic. A total of 108 (50.9%) were classified as highly adherent while 104 (49.1) scored low on treatment adherence scores.

Table 8: Treatment adherence analysis among DM patients at KNH DOPC

	Category	**N = 212 (%)**
Adherence	High	108 (50.9)
	Low	104 (49.1)

4.4.1 Correlation between treatment adherence and anxiety

There was a significant association between treatment adherence and anxiety. It was noteworthy that high more numbers with high adherence were recorded among patients who had borderline anxiety or confirmed anxiety, fewer than those patients who did not have anxiety.

Table 9: Cross Tabulation of Treatment Adherence against Anxiety

Anxiety	**Adherence**		**Total**
	High	**Low**	
Normal	25 (18.1)	75 (35.7)	100 (53.8)
Borderline Anxiety	44 (21.0)	22 (10.5)	66 (31.5)
Anxiety	38 (11.9)	6 (2.8)	44 (14.7)
Total	107 (51.0)	103 (49.0)	210 (100.0)

X-squared = 55.55, df = 2, p-value = 0.02

4.4.2 Correlation between treatment adherence and depression

The association between treatment adherence and depression was also significant. Unlike anxiety, more patients with scores out of the depression range had remarkably high levels of adherence while fewer patients with scores in the depression range had high levels of adherence.

Table 10: Cross Tabulation of Treatment Adherence against Depression

Depression	**Adherence**	**Total**

	High	Low	
Normal	43 (20.4)	11 (5.2)	54 (25.6)
Borderline Depression	48 (22.7)	25 (11.8)	73 (34.5)
Depression	16 (7.6)	68 (32.2)	84 (39.8)
Total	107 (50.7)	104 (49.2)	211 (99.9)

X-squared = 58.369, df = 2, p-value = 0.02

4.5 Relationship modeling between depression / anxiety and treatment adherence.

To find out the relationships, bivariate analysis was done to fit the different findings in logistic regression models. There was a significant association between treatment adherence and anxiety on one side and depression on the other side. There was no significant association with comorbidity, age, gender and education. Adjusted odds ratios were obtained by fitting a multivariate logistic regression model. The significance of comorbidity, age, gender and education against treatment adherence remained unchanged. Anxiety and Depression remained significantly associated with treatment adherence. Table 11 below depicts this analysis.

Table 11: Association between adherence, anxiety, depression, comorbidity and socio demographic Factors

	Adherence		Crude OR	P-Value	Adj OR	P-Value
	High, n (%)	Low, n (%)				
Anxiety						
Normal	38 (35.5)	6 (5.8)		Ref		Ref
Borderline Anxiety	44 (41.1)	22 (21.4)	0.32	0.0241	0.38	0.0822
Anxiety	25 (23.4)	75 (72.8)	0.05	<0.0001	0.16	0.0047
Depression						
Normal	43 (40.2)	11 (10.6)		Ref		Ref
Borderline Depression	48 (44.9)	25 (24.0)	0.49	0.0892	0.93	0.8894
Depression	16 (15.0)	68 (65.4)	0.06	<0.0001	0.23	0.0172
Comorbidity						
No	42 (38.9)	38 (36.5)		Ref		Ref
Yes	66 (61.1)	66 (63.5)	0.90	0.7240	0.93	0.8566
Age (mean, sd)	54.3 (14.1)	50.9 (15.4)	1.01	0.0958	1.02	0.1690
Gender						
Male	30 (28.8)	32 (29.6)		Ref		Ref
Female	74 (71.2)	76 (70.4)	0.09	0.9000	1.47	0.3222
Education						
Primary	42 (40.4)	29 (26.9)		Ref		Ref
Secondary	28 (26.9)	30 (27.8)	1.55	0.2182	1.96	0.1527
Tertiary	34 (32.7)	49 (45.4)	2.09	0.0252	2.29	0.0616

4.6 Diabetes Quality of Life Measures

a) Satisfaction

A total of 92 patients scored above 50% in satisfaction. Most patients in the study scored between 50 % and 60 %. This was followed by a score of between 20% and 40%. Four patients scored between 70% and 80% while only one patient scored above 80%. The histogram below summarizes this information.

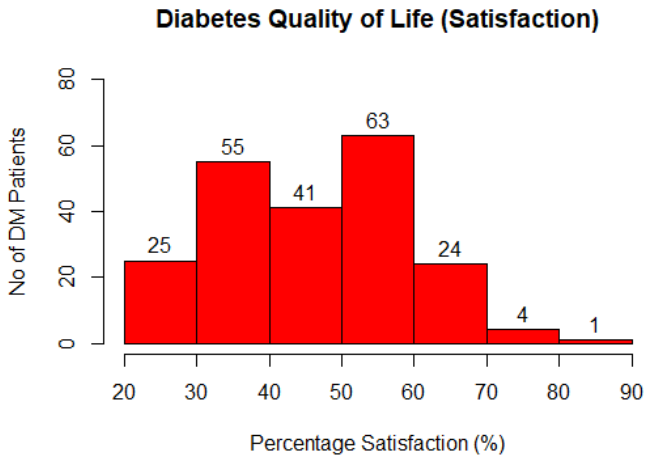

Figure 3: Patients satisfaction levels

b) Impact

In relation to impact on quality of life, a total of 65 patients scored above 50%. Most patients in the study scored between 20% and 30% (63 patients) while the lowest number scored between 70% and 80% (6 patients). Fifty-seven patients scored between 40% and 50%. 45 patients who scored followed this between 50% and 60%. The histogram below summarizes this information.

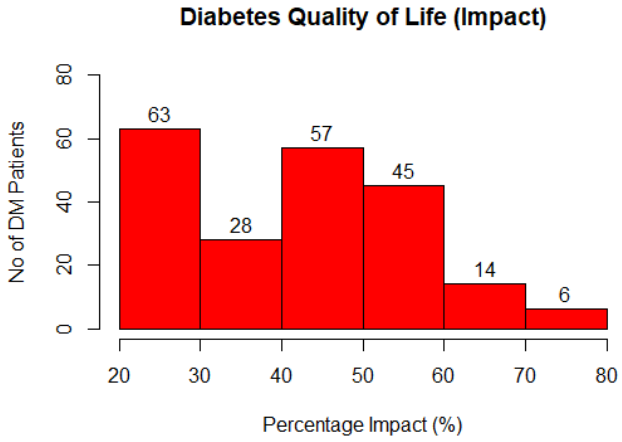

Figure 4: Impact of illness and treatment

c) Worry

A total of 108 patients score above 50% under worry as a quality of life. Most patients in the study scored between 50% and 60% (89 patients). 70 patients scored between 30% and 40% (70 patients). Six patients scored between 60% and 70% while only one patient scored above 90%. None of the patients scored between 80% and 90%. The histogram below summarizes this information.

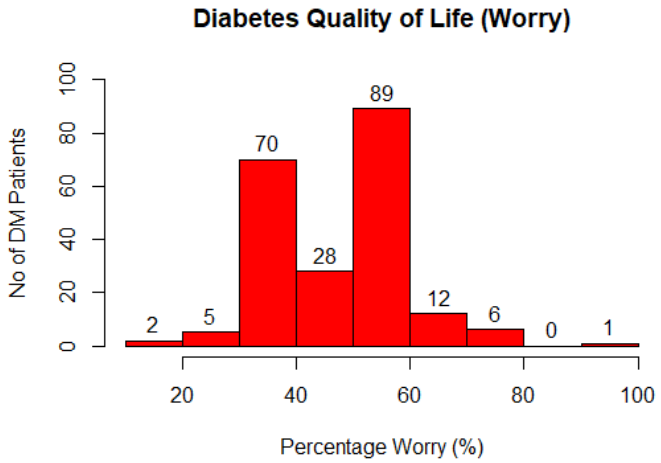

Figure 5: Emotional expression of worry

d) Overall Quality of Life

In relation to the overall quality of life measure, a total of 102 patients scored above 50%. Most patients in the study scored between 50% and 60% (78 patients) while 61 patients scored between 30% and 40%. 35 patients scored between 40% and 50%. On the extremes, 1 patient score below 20% and one patient scored above 90%. The histogram below summarizes this information.

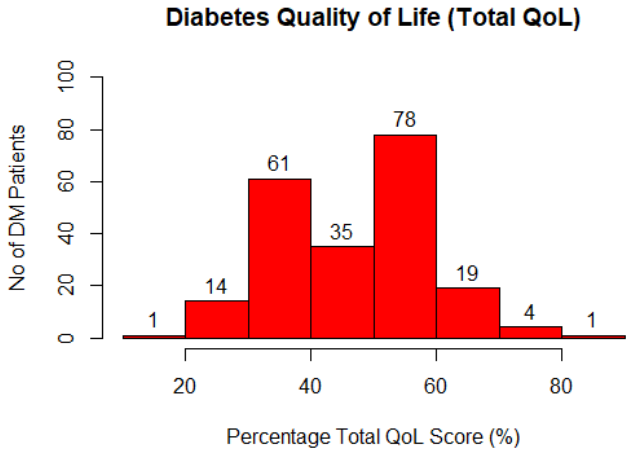

Figure 6: Summary of quality of life measures

4.7 Diabetes distress

The Diabetes Distress Scale 17 (DDS 17) was used to measure the level of distress among diabetic patients being attended in KNH Outpatient Diabetes Clinic. A total of 108 patients (50.9%) reported moderate level of distress. This group constituted the highest proportion of study participants. High and Low 5 and 99 patients recorded levels of distress respectively. These groups constituted proportions of 2.4% and 46.6% respectively. Table 9 below summarizes the information on the overall diabetes distress score while the pie chart gives a diagrammatic presentation of the same information.

Table 12: Diabetes Distress Scale of Diabetes Patients

Diabetes Distress Scale	Category	N = 212 (%)
High	>= 3.0	5(2.4)
Moderate	>= 2.0 to <3.0	108 (50.9)
Low	<2.0	99 (46.6)

Chapter Five: Discussion

Mental illnesses have shown an increase in prevalence both in the general population and in general medical settings. The prevalence of non-communicable diseases has been increasing globally. Quite often mental illnesses and NCDs are comorbid. Frequently, both need long term treatment. Adherence to treatment plans is important for the immediate remission of the signs and symptoms of the illness, the short term outcomes and long term impact on the disease process. However, given the comorbidity of mental illnesses and general medical conditions, there is a limitation in available research to explain the effects of mental illnesses on adherence to treatment.

This research aimed at establishing the effects of depression and anxiety on adherence to treatment among patients attending the Kenyatta National hospital diabetes outpatient clinic. To achieve this it was paramount to find out the prevalence of diabetes and anxiety in this population of diabetes patients, to find out their levels of adherence to treatment and then establish what relationship exists between anxiety, depression and adherence to treatment.

5.1 Prevalence of depression and anxiety in diabetes patients at KNH DOPC.

This study used the HADs tool and established a comorbid prevalence of anxiety at 100 (47.4%) and depression at 84 (39.6%) out of 213 patients sampled from the diabetes patients in the clinic. The comorbid prevalence of anxiety and depression in the same sample was at 76 (36.2%). This prevalence of comorbid depression is similar to rates reported in studies in patients in general medical settings in Kenyan hospitals (Ndetei et al., 2009; Nyaberi Z. et al., 2014). An earlier study in the same setting found the prevalence of depression in the same population at 32.3 % using the PHQ-9 questionnaire (Otieno et al., 2017) which is in the same range as the rate found in this study using the HADs scale. Various cohorts in similar Kenyan studies have documented the multiplicity of comorbid diagnoses in the hospitals that includes psychiatric illnesses alongside other chronic diseases (Mendenhall et al., 2015).

The numbers of diabetes patients with anxiety and depression represent a significant subset of the diabetes patients who would benefit from psychiatric evaluation and treatment with adjunct psychotherapy. The depression in these diabetes patients illustrates the interplay of bio-psycho-social, genetic, neurochemical and endocrine factors in diabetes and depression. The decrease in functional abilities and self-care has direct impact on health outcomes as evidenced by the decreased levels of quality of life in the patients.

The interaction of the predispositions for diabetes, depression and anxiety is an intricate web of genetic factors, intrinsic biological factors, environmental factors and other exacerbating conditions including metabolic syndrome. The medications used to treat diabetes also affect the endocrine system in the body. The endocrine system closely interacts with the neurochemical pathways and the central nervous system. This study found a significant prevalence of neuropathies which may have a role in the neurochemical imbalances that lead to depression and anxiety. This bidirectional relationship is important in prescribing medications used to treat anxiety and depression. These drugs have known side effects, such as weight gain, further increasing the possibility of developing diabetes or worsen already pre-existent diabetes.

5.2 Patterns of treatment adherence and glycemic control.

This study has demonstrated that comorbidity of anxiety and depression in the diabetes patients affects their levels of adherence to treatment. Treatment adherence and non-adherence showed no huge variability, with 109 (50.9%) patients being highly adherence and 104 (49.1%) having poor adherence.

However, a deeper analysis of the adherence patterns demonstrates a significant correlation between anxiety, depression and treatment adherence. Having been diagnosed with borderline anxiety decreased the odds of adherence to treatment by a factor of 0.32 ($p = 0.0241$). Likewise, having been diagnosed with anxiety decreased the odds of adherence to treatment by a factor of 0.05 ($p < 0.0001$). Both borderline anxiety and anxiety decreased the probability of treatment adherence in reference to normal patients.

Having been diagnosed with borderline depression decreased the odds of adherence to treatment by a factor of 0.49 ($p = 0.0892$). This reduction in odds however was not significantly different from that of normal patients. Likewise, having been diagnosed with depression decreased the odds of adherence to treatment by a factor of 0.06 ($p < 0.0001$).

5.4 Multi-systemic healthcare factors influencing treatment adherence and quality of life

Adherence to treatment remains a challenge for patients and clinicians. The World Health Organization (WHO) defines adherence as 'the extent to which a person's behavior of taking medication, following a diet regimen, and executing lifestyle changes corresponds with agreed recommendations from a health care provider' (WHO, 2018).

In this study there were significant findings regarding treatment adherence during the research. The cost of treatment, the years since diagnosis and the emergence of complications were significant determinants of how adherent patients were.

Multiple factors influence adherence to treatment. Patient dependent modulators are important, but adherence is not solely a patient driven effort, but a multifaceted scenario with multiple variables coming into play. There are patient factors, therapy specific factors and system dependent factors. To maximize adherence, conditions have to be maintained at optimum levels. Psychological and behavioral circumstances in the patient are crucial and health care providers can help to keep these in check through careful patient evaluation (Farris & Walgreen, 2019.).

The complexity of the regimen of drugs, the duration of treatment, previous treatment failures, frequent changes in treatment, the immediacy of beneficial effects, side effects, and the availability of medical support to deal with the side effects influence patient's use of drugs (Parra et al., 2019).

Social economic factors include social demographic variables, life situations and issues of poverty. Significant demographic factors include age, gender, physical disabilities, illiteracy, level of education, occupational status, family support, social support networks, stability of living conditions, distance to access treatment centers, costs of transport, cost of medication, weather conditions, environmental situations, culture and beliefs about illness and health seeking behavior (Walters-Salas, 2012).

The health care system can improve adherence by fostering harmonious patient-provider relationship. Where mutual plans of treatment are formulated, the patients are more likely comply with instructions of the provider and play an active role to follow the treatment plan (Nam et al., 2011).

The patient's attitude, knowledge, beliefs, perceptions and expectations are significant influences on adherence. Important personal influences include levels of forgetfulness, stress, anxiety, motivation, knowledge and skill, frequency of clinic follow-up, hopelessness and negative feelings, frustration and feeling stigmatized by the disease (Gonzalez, 2018). The severity of symptoms, level of disability (physical, psychological, social and vocational), rate of progression and severity of the disease temper the patient's perception of risk, the importance of following treatment, and the priority placed on adherence.

While poor medication adherence is a problem to persons with mental illness, the issue is compounded in patients with a comorbid chronic disease. Since mental illnesses have a long-term course, comorbidity with a chronic disease presents a multi-faceted risk of poor adherence to treatment of the medical conditions and the comorbid mental disease.

5.6 Study limitations

This study was carried out during a time period marked by significant strife owing to the Coronavirus 19 pandemic. The patient numbers in the clinic were relatively decreased while data collection was slowed by the requirements for COVID 19 containment such as physical distancing. The patients had also been experiencing significant constraints in terms of accessibility due to lockdowns and curfews. The financial constraints due to lost earnings were also significant.

Chapter Six: Conclusion and Recommendations

Conclusion

Diabetes patients face dual challenges on their psychological and emotional wellbeing. There is the natural progression of the diabetes illness coupled with the psychological distress experienced during treatment. All these have potential for negative impact on the psychological well being of patients.

It has been documented that being diagnosed with borderline anxiety decreased the odds of adherence to treatment by a factor of 0.32 ($p = 0.0241$). Likewise, having been diagnosed with depression decreased the odds of adherence to treatment by a factor of 0.06 ($p < 0.0001$).

It is important to evaluate and diagnose the psychiatric illnesses in these patients by following the guidelines of structured manuals like the Diagnostic and Statistical Manual for Mental Disorders (DSM V) in order to correlate the prospective effect of negative emotions their clinical implications. This will be useful to improve diabetes treatment, self-care and treatment adherence.

Recommendations.

It is important to integrate evaluation and screening for mental illness in the routine follow up of patients in general medical settings. Standardized tools like the HADs will be useful in this effort.

Multidisciplinary clinical care guidelines should be developed to encourage collaborative care models between the different specialties. This will ensure patients receive care promptly with minimal loss of opportunities to treat.

Given the increasing prevalence of mental illnesses in the population, policy formulation to focus efforts and integrate care for mental illness in mainstream clinical practice.

Healthcare practitioners need to be empowered with a minimum toolkit at their respective levels to strengthen their abilities in the screening, diagnosis and treatment of mental illnesses.

The findings in this study can be enhanced by designing and executing a longitudinal cohort study to evaluate relationships between the biological, psychological and social factors involved in mental illnesses versus the modifiable and non modifiable risk factors implicated in the disease progression of diabetes and other chronic non communicable diseases.

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Appendices

Appendix I: Research Budget

Research Budget		Research Protocol Title		*Correlates of depression, anxiety and adherence to treatment among patients attending the Kenyatta National Hospital (KNH) Diabetes Outpatient Clinic*	
		Principal Investigator		*Dr. Leonard Njeru Njiru*	
		Supervisors		*Prof. D M Ndetei, Prof A O Obondo, Dr. P A Kigamwa*	
		Institution		*University of Nairobi, College of Health Sciences, Department of psychiatry*	
		Research Site		*Kenyatta National Hospital, Diabetes Outpatient Clinic*	
Item Code	**Item Description**	Units	Unit Cost (Kshs)	Total Quantity	Total Cost
1.1	Intenet Access costs / Literature review	Monthly	2,500	8	20,000
1.2	Stationery (Papers / Pens / writing pads)	Dozens	500	10	5,000
1.3	Printing and photo copy questionnaires	Per copy	100	400	40,000
1.4	Proposal printing / photocopy	Per copy	100	10	1,000
1.5	Proposal Fee	One off	2,000	1	2,000
1.6	Data Entry / Data validation	One off	10,000	1	10,000
1.7	Statistical analysis	One off	30,000	1	30,000
1.8	Thesis development / Printing / Binding /	Per Copy	4,000	5	20,000
1.9	Transport / Daily subsistence costs	Daily	1,000	30	30,000
	Total Costs				**158,000**

Appendix II: Research Timeline

Research Timeline

Research Protocol Title	*Correlates of depression, anxiety and adherence to treatment among patients attending the Kenyatta National Hospital (KNH) Diabetes Outpatient Clinic*
Principal Investigator	*Dr. Leonard Njeru Njiru*
Supervisors	*Prof. D M Ndetei, Prof A O Obondo, Dr. P A Kigamwa*
Institution	*University of Nairobi, College of Health Sciences, Department of psychiatry*
Research Site	*Kenyatta National Hospital, Diabetes Outpatient Clinic*

		Month	January				February				March				April				May				June				July				August			
		Week	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	2	4	1	2	3	4	1	2	3	4
Task Code	**Task Item**																																	
1	**Proposal development**																																	
1.1	Desktop and literature review																																	
1.2	Meeting and discussing with supervisors																																	
1.3	Detailed writing of research protocol																																	
1.4	Work in Progress (WiP) presentation																																	
1.5	Departmental Research Presentation																																	
1.6	Proposal Corrections																																	
2	**Ethical Review and Approval**																																	
2.1	Submission to KNH/UoN ERC																																	
2.2	Proposal corrections																																	
2.3	Approval from KNH Research office																																	
3	**Execution of research protocol and data collection**																																	
3.1	Recruitment / enrollment of research participants																																	
3.2	Data collection and data cleaning																																	
3.3	Research progress updates																																	
4	**Statistical analysis**																																	
5	**Final research report writing**																																	
5.1	Results / Summary / Discussion / Conclusion																																	
5.2	Results Presentation																																	
5.3	Final Thesis writing																																	
5.4	Presentation of thesis for examination																																	

Appendix III: Consent information

Informed Consent information for patients attending diabetes outpatient clinic, KNH.	
Researcher	Dr. Leonard Njeru Njiru
Supervisors	Prof. D. M Ndetei, Prof. A. O Obondo Dr. P. A Kigamwa
Research title	*Correlates of depression, anxiety and adherence to treatment among patients attending the Kenyatta National Hospital (KNH) diabetes outpatient clinic.*

Introduction

Am undertaking a study on the relationship between depression, anxiety and adherence to treatment among patients attending the DOPC, KNH. This form is to give you the information you need before deciding if you want to participate in this study. As you read this form you may ask any questions of what you do not understand.

Purpose of Research

Psychological situations frequently influence how you follow the treatment plan agreed upon with your doctor. This could be because of stressful situations. Sometimes you may be unware of the strain or distress that might be affecting adherence to treatment. This research will help to understand these patient circumstances and provide guidance on how to evaluate and improve levels of adherence to treatment.

Procedures involved

You will sign a consent form, then a questionnaire with data with socio-demographic information scores of depression and anxiety and levels of adherence to treatment. I will guide you through this process to complete an interview lasting at most 30 minutes.

Your rights

Your participation in this research is voluntary. You will not be victimized in any way if you refuse to participate in this study. If you choose to participate and not answer certain questions, you are free to do so. You can terminate the interview and withdraw from the study at any time. Kindly ask questions before signing the consent form. All the results will remain confidential. Your individual responses will be stored securely accessible to only the researcher, supervisors and the statistician.

Risks and Benefits.

There are no physical risks involved in this research. No physical samples will be drawn. During the interview, some questions may overwhelm you emotionally. You have the right to inform the researcher and to skip them.

The information given will help in understanding the psychological situation of diabetes patients and recommend the best approach to improve their mental health and healthcare.

If you need clarification contact **Dr. Leonard Njeru Njiru** Phone number +254720813130

The Chairman, KNH/UON – Ethics and Research Committee Hospital Road along Ngong Road P.O BOX 20723, Nairobi (CODE 00202) Telephone number (+254-020)2726300 ext 44355

Appendix IV: Habari ya Idhini

Habari ya idhini ya wanaohudhuria kliniki ya wagonjwa wa kisukari, KNH.	
Mtafiti	Dk. Leonard Njeru Njiru
Wasimamizi	Prof. D. M Ndetei, Prof. A. O Obondo Dr. P. A Kigamwa
Kichwa cha utafiti	*Uhusiano wa unyogovu, wasiwasi na uzingatiaji wa matibabu kati ya wagonjwa wanaohudhuria Kliniki ya Kitaifa ya wagonjwa wa kisukari ya Kenyatta (KNH)*

Utangulizi.

Ninafanya utafiti juu ya uhusiano kati ya unyogovu, wasiwasi na kufuata matibabu kati ya wagonjwa wanaohudhuria DOPC, KNH. Fomu hii ni kukupa habari unayohitaji kabla ya kuamua ikiwa unataka kushiriki katika utafiti huu. Unaposoma fomu hii unaweza kuuliza maswali yoyote ya kile usichoelewa.

Kusudi la utafiti.

Hali za kisaikolojia huathiri mara nyingi jinsi unavyofuata mpango wa matibabu uliokubaliwa na daktari wako. Hii inaweza kuwa kwa sababu ya hali zenye mkazo. Wakati mwingine unaweza kuwa haujui shida au shida ambayo inaweza kuathiri kufuata matibabu. Utafiti huu utasaidia kuelewa hali hizi za wagonjwa na kutoa mwongozo wa jinsi ya kutathmini na kuboresha viwango vya uzingatiaji wa matibabu.

Taratibu zinazohusika

Utasaini fomu ya idhini, kisha dodoso lenye data na alama za habari za jamii na idadi ya watu ya unyogovu na wasiwasi na viwango vya kufuata matibabu. Nitakuongoza kupitia mchakato huu kumaliza mahojiano ya kudumu kwa dakika 30.

Haki zako

Ushiriki wako katika utafiti huu ni wa hiari. Hautadhulumiwa kwa njia yoyote ikiwa utakataa kushiriki katika utafiti huu. Ikiwa unachagua kushiriki na usijibu maswali fulani, uko huru kufanya hivyo. Unaweza kusitisha mahojiano na ujiondoe kwenye utafiti wakati wowote. Kuuliza maswali kabla ya kusaini fomu ya idhini. Matokeo yote yatabaki kuwa ya siri. Majibu yako ya kibinafsi yatahifadhiwa salama kwa mtafiti tu, wasimamizi na mtaalam wa takwimu.

Hatari na Faida.

Hakuna hatari yoyote ya mwili inayohusika katika utafiti huu. Hakuna sampuli za mwili zitakazotolewa. Wakati wa mahojiano, maswali kadhaa yanaweza kukushinda kihemko. Una haki ya kumjulisha mtafiti na kuziruka.

Habari iliyotolewa itasaidia kuelewa hali ya kisaikolojia ya wagonjwa wa kisukari na kupendekeza njia bora ya kuboresha afya yao ya akili na huduma ya afya.

Ikiwa unahitaji ufafanuzi wasiliana na **Dk. Leonard Njeru Njiru** Nambari ya simu +254720813130

Mwenyekiti, KNH / UON - Kamati ya Maadili na Utafiti ya Barabara ya Hospitali kando ya Barabara ya Ngong P.O BOX 20723, Nairobi (CODE 00202) Nambari ya simu (+ 254-020) 2726300 ext 44355

Appendix V: Ethical Approval

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

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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

Ref: KNH-ERC/A/342

28th September, 2021

Dr. Leonard Njeru Njiru
Reg. No.H58/7394/2017
Dept. of Psychiatry
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 28 SEP 2021 KNH/UoN-ERC P.O. Box 20723-00202 NAIROBI

Dear Dr. Njiru

RESEARCH PROPOSAL: EFFECTS OF DEPRESSION AND ANXIETY ON ADHERENCE TO TREATMENT AMONG PATIENTS ATTENDING THE KENYATTA NATIONAL HOSPITAL DIABETES OUTPATIENT CLINIC (P297/04/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above research proposal. The approval period is 28th September 2021 – 27th September 2022.

This approval is subject to compliance with the following requirements:

i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from KNH- UoNERC for each batch of shipment.
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.

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Psychiatry, UoN
Supervisors: Prof. David Musyimi Ndetei, Dept.of Psychiatry, UoN
Prof. Anne Atieno Obondo,Dept.of Psychiatry, UoN
Dr. Pius Akivaga Kigamwa,Dept.of Psychiatry, UoN

KENYATTA NATIONAL HOSPITAL
P.O. BOX 20723, 00202 Nairobi

Tel.: 2726300/2726450/2726550
Fax: 2725272
Email: knhadmin@knh.or.ke

Ref: KNH/HOD-MED/37/VOL.II/46 **Date: 12th October, 2021**

Dr. Leonard Njeru Njiru
Department of Psychiatry
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Njiru,

RE: APPROVAL TO CONDUCT A STUDY AT THE KNH MEDICINE DEPARTMENT

Following approval by the KNH/UON-Ethics & Research Committee for your research proposal and subsequent filing of the study registration certificate, this is to inform you that authority has been granted to collect data in Medicine Department, Diabetes Clinic on your study titled ***"Effects of depression and anxiety on adherence to treatment among patients attending"*** Kenyatta National Hospital.

Kindly liaise with the Assistant Chief Nurse Incharge, Diabetes Clinic for facilitation. By a copy of this letter, the Assistant Chief Nurse Incharge are informed and requested to facilitate.

You will also be required to submit a report of your study findings to the office of the undersigned after completion of your study.

Dr. B.Wambugu
Ag. HOD, MEDICINE

Cc. A.C.N. - Diabetes Clinic

KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
DR. LEONARD NJERU NGIRU
2. Email address: leonjeru@gmail.com Tel No. 0720-813130
3. Contact person (if different from PI).....
4. Email address: ..... Tel No. .....
5. Study Title
"Effects of depression and anxiety on drug adherence among patients attending Kenyatta National Hospital Diabetes' outpatient clinic." UoN-KNH ERC# P 297/04/2021
6. Department where the study will be conducted Diabetes clinic - KNH
(Please attach copy of Abstract)
7. Endorsed by KNH Head of Department where study will be conducted.
Name: DR. MWANIKI, B.M. Signature ..... Date 11/10/2021
8. KNH UoN Ethics Research Committee approved study number P 297/04/2021
(Please attach copy of ERC approval)
9. I Dr. Leonard Njeru Ngiru commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.
Signature ..... Date 8/October/2021
10. Study Registration number (Dept/Number/Year) Medicine/3003/2021
(To be completed by Medical Research Department)
11. Research and Program Stamp

KENYATTA NATIONAL HOSPITAL * Research Resource Centre * P.O. Box 20723-00202 Nairobi
12 OCT 2021

All studies conducted at Kenyatta National Hospital must be registered with the Department of Medical Research and investigators must commit to share results with the hospital.

Version 2: August, 2014

Appendix VI: Consent Form

Consent Certificate / Cheti cha idhini	
I have read the foregoing information and/or it has been explained to me. My questions regarding the research have been answered to my satisfaction. I consent of my own free will without coercion to participate in the research. Nimesoma habari iliyotangulia na / au nimeelezewa. Maswali yangu kuhusu utafiti yamejibiwa kwa kuridhika kwangu. Ninakubali kwa hiari yangu mwenyewe bila kulazimishwa kushiriki katika utafiti.	
Participant (Mshiriki)	Signature/Thumbprint …….. Date/Tarehe…….. (Saini / Kidole)
Researcher (Mtafiti)	Signature/Thumbprint …….. Date/tarehe…….. Saini / Kidole

Appendix VII: Research Questionnaire

Section A: Socio-demographic data		
Questionnaire code:…… Date of interview:……		
Data variables	**code**	**Response**
Gender	A1	Male
	A2	Female
Age	A3	
Religion	A4	Christian
	A5	Muslim
	A6	Hindu
	A7	Traditional
	A8	Other
Occupation	A9	Full time employment
	A10	Part time employment
	A11	Retired
	A12	Student
	A13	Self employed
	A14	Farmer
	A15	Business person
Income level (Kshs)	A16	<10,000
	A17	10,000 - 20,000
	A19	20,000 - 50,000
	A20	50,000 – 100,000
	A21	>100,000
Education level	A22	No schooling
	A23	Primary School
	A24	Secondary School
	A25	Polytechnic / Vocational training
	A26	University
Marital status	A27	Single
	A28	Married
	A29	Widow / Widower
	A30	Separated / Divorced

Section B: Patient health and diabetes status		
Data variables	**Code**	
Height	B1	
Weight	B2	
BMI (Calculated)	B3	
Laboratory investigations in file	B4	Hba1c
	B5	Glucose levels
	B6	Kidney function tests
	B7	Other
When were you diagnosed with diabetes? (month/year)	B8	
When did you start treatment for the disease? (month/year)	B9	
What type of treatment do you follow?	B10	Nutrition and lifestyle
	B11	Injectable drugs
	B12	Oral tablets
	B13	Oral and injectable
	B14	Alternative / herbal
How many drugs medicine do you take? (List the drugs)	B15	Number
	B16	
Have you ever been admitted in the hospital for diabetes treatment?	B17	No
	B18	Yes
	B19	Number of times
	B20	Last admission
Do you use any addictive substances?	B21	No
	B22	Yes
	B23	Alcohol
	B24	Cigarettes
	B25	Khat / Miraa
	B26	Other

Section C: Comorbid conditions and diabetes complications		
Question	**Code**	**Answer**
Do you have any other disease? (specify disease)	C1	No
	C2	Yes
	C3	Hypertension
	C4	Asthma
	C5	HiV / Aids
	C6	Tuberculosis
	C7	Other
Are you on treatment for the disease? (List drugs)	C8	No
	C9	Yes
	C10	
Do you have any complications from diabetes?	C11	No
	C12	Yes
	C13	Diabetic foot
	C14	Visual problems
	C15	Kidney problems
	C16	Nerve damage
	C17	Heart / blood vessel disease
	C18	Other
Have you ever been diagnosed with mental illness?	C19	No
	C20	Yes
Treatment if yes above (List drugs)	C21	Psychotherapy
	C22	Counseling
Have you been tested for Covid 19?	C23	
Have you received vaccination for Covid 19?	C24	
Did you miss any clinic appointment because of lockdown or curfew?	C25	
Have you faced any difficulties in taking your treatment because of Covid 19?	C26	

Section D	Medication Adherence Report Scale (MARS-5)		
	Question	**code**	**Score**
Scores key: 1. Always 2. Often 3. Sometimes 4. Rarely 5. Never	Do you frequently forget to take your medicine?	D1	
	Do you change the dose of your diabetes medicine without directions by your doctor?	D2	
	Have you failed to take your medication for a while without telling your doctor?	D3	
	When you feel like your sugar is under control, do you sometimes stop taking your medicine?	D4	
	Do you take less medicine than what you have been instructed by your doctor?	D5	
Total Score		D6	

Key: D7. Low adherence (19 and below).
D8. Medium adherence (20 to 23).
D9. High adherence (24 and above).

Conclusion: _____

Section E: Hospital Anxiety and Depression Scale (HADS)					
D	**A**		**D**	**A**	
		I feel tense or 'wound up'			**I feel as if I am slowed down**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen			**I have lost interest in my appearance**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I take basic care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Total Score Depression (E1) _____ Anxiety (E2) _____

Key:

E3. Normal (0 – 7) E4.Borderline depression score (8 – 10) E5. Depression case (11-21)

E6. Normal (0 – 7) E7.Borderline anxiety (8 – 10) E8. Anxiety case (11-21)

Section F: Diabetes Quality of life measures			
Domain	**Question**	**Code**	**Score**
Satisfaction Key: 1. Very satisfied 2. Moderately satisfied 3. Neutral 4. Moderately dissatisfied 5. Very dissatisfied	How satisfied are you with the amount of time it takes to manage your diabetes?	F1	
	How satisfied are you with the amount of time you spend getting checkups?	F2	
	How satisfied are you with the time it takes to determine your sugar level?	F3	
	How satisfied are you with your current treatment?	F4	
	How satisfied are you with your knowledge about your diabetes?	F5	
	How satisfied are you with life in general?	F6	
	Total Score/30	F6	
Impact Key 1. Never 2. Very rarely 3. Sometimes 4. Often 5. All the time	How often do you feel pain associated with the treatment for your diabetes?	F7	
	How often do you feel physically ill?	F8	
	How often does diabetes interfere with your family life?	F9	
	How often do you find diabetes limiting your social relationships and friendships?	F10	
	Total Score/20	F11	
Worry Key 0. Does not apply 1. Never 2. Very seldom 3. Sometimes 4. Often; 5. All the time	How often do you worry about whether you will pass out?	F12	
	How often do you worry that your body looks different because you have diabetes?	F13	
	How often do your worry that you will get complications from your diabetes?	F14	
	Total Score/15	F15	
Total Score/100		F16	

Scoring and summary

F17. Satisfaction (S): (6 items) 6 – 30 Percentage S/30 x 100 = _____

F18. Impact (I): (4 items) 4 – 20 Percentage I/20 x 100 = _____

F19. Worry (W): (3 items) 3 – 15 Percentage W/15 x 100 = _____

F20. Total Score (TS) (13 items) 13 – 65 Percentage TS/65 x 100 = _____

Higher score indicates poorer quality of life.

Section G: Diabetes Distress Scale -17			
Scores 1. Not a Problem **2.** A slight problem **3.** A moderate problem **4.** Maybe serious problem **5.** A serious problem **6.** A very serious problem			
Domain	**Question**	**Code**	**Score**
Emotional Burden	Do you feel that diabetes is taking up too much of your mental and physical energy every day?	**G1**	
	Do you feel angry, scared and/or depressed when you think about living with diabetes?	**G2**	
	Do you feeling that you will end up with serious long-term complications, no matter what you do?	**G3**	
	Do you feel that diabetes controls your life?	**G4**	
	Do you feel overwhelmed by the demands of living with diabetes?	**G5**	
	Total score	**G6**	
Physician distress	Do you feel that you doctor does not know enough about diabetes and diabetes care?	**G7**	
	Do you feel that your doctor does not give you clear enough directions on how to manage your diabetes?	**G8**	
	Do you feel that your doctor does not take your concerns seriously enough?	**G9**	
	Do you feel that you do not have a doctor who you can see regularly enough about your diabetes?	**G10**	
	Total score	**G11**	
Regimen distress	Do you feel that you are not testing your blood sugars frequently enough?	**G12**	
	Do you feeling that you are often failing with your diabetes routine?	**G13**	
	Do you feeling lacking in confidence in your day-to-day ability to manage diabetes?	**G14**	
	Do you feel that you are not sticking closely enough to a good meal plan?	**G15**	
	Do you feel not motivated to keep up your diabetes self-management?	**G16**	
	Total score	**G17**	
Interpersonal distress	Do you feel that friends or family are not supportive enough of your self-care efforts (e.g. planning activities that conflict with your schedule, encouraging you to eat the "wrong" foods)?	**G18**	
	Do you feel that friends or family do not appreciate how difficult living with diabetes can be?	**G19**	
	Do you feel that friends or family do not give you the emotional support that you would like?	**G20**	
	Total score	**G21**	
G22. Emotional burden Total score / 5 = Mean score =		**G23. Regimen distress:** Total score / 5 = Mean score =	
G24. Physician distress Total score / 4 = Mean score =		**G25. Interpersonal distress:** Total score / 3 = Mean score =	
G26. Total DDS Score: Sum of 17 scores / 17			

Interpretation: G27. Moderate distress. 2.0 – 2.9 G28. High distress. > 3.0