

**PREVALENCE AND ASSOCIATIONS OF DIABETES-
RELATED EMOTIONAL DISTRESS IN PEOPLE WITH
TYPE 2 DIABETES AT KENYATTA NATIONAL HOSPITAL**

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**A dissertation submitted to the Department of Clinical Medicine and
Therapeutics, School of Medicine in partial fulfillment of the requirements
for the degree of Master of Medicine, Internal Medicine
University of Nairobi**

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STUDENT'S DECLARATION

This dissertation is my original work and has not been presented for a degree at any other University.

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DEDICATION

I dedicate this thesis to my family, nuclear and extended that have offered unwavering support and encouragement during this postgraduate journey.

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LIST OF ABBREVIATIONS

BDI -	Beck Depression Inventory
CES-D -	Centre for Epidemiological Studies Depression scale
CI -	Confidence interval
DAWN 2-	Diabetes Attitudes, Wishes and Needs second study
DDS -	Diabetes Distress Scale
DM-	Diabetes Mellitus
DRD -	Diabetes related emotional distress.
HADS -	Hospital Anxiety and Depression scale
HbA1C -	Glycated hemoglobin
IQR -	Interquartile range
KNH -	Kenyatta National Hospital
LMP -	Last menstrual period
MDD -	Major depressive disorder
PAID -	Problem Areas in Diabetes
PHQ-9 -	Patient Health Questionnaire
PROM -	Patient reported outcomes measure.
SD -	Standard deviation
STATA -	Statistics and data software package
T2DM -	Type 2 Diabetes Mellitus
UKMPDS -	United Kingdom Prospective Diabetes Group
WHO -	World Health Organization

ABSTRACT

Background: Mental wellbeing is important among those living with diabetes as it has critical impact on healthcare outcomes. Diabetes Related Distress (DRD) is the negative emotions and emotional distress arising from the challenges of living with diabetes. Concerns about diet restrictions, potential complications and strict management regimens have great effect on the emotions and well-being of individuals with diabetes. Psychological evaluation of diabetes-related distress provides insight into the prevalence and factors associated with diabetes-related emotional distress.

The study's results give healthcare professionals a broader understanding of the level of diabetes-related emotional distress experienced by people living with type 2 diabetes in our population and identifies factors associated with DRD. Understanding the extent of the problem is of great clinical benefit as it helps to identify potential deficiencies in health care services and areas in which healthcare service delivery could be improved.

Objectives: This research aimed at (1) Determining the prevalence of emotional distress related to diabetes among those with diabetes type 2 in Kenyatta National Hospital. (2) Identifying factors associated to diabetes-related emotional distress.

Method: This was a descriptive, cross-sectional study that was conducted at the out-patient diabetes clinic at the Kenyatta National Hospital from August to October 2020. It involved administering the Diabetes Problem Areas tool along with a demographic questionnaire to participants with type two diabetes followed by assessment of HBA1C as a measure of glycemic control in DRD. Trained research staff reached out to eligible participants (adults over 18 years of age, with type two diabetes) awaiting their scheduled clinic appointment. The nature and intent of the study was explained to them, and their participation was requested. Those who were willing to participate in the research and who met the inclusion criteria were selected to take part in the research. The Problem Area in Diabetes (PAID) questionnaire is a 20-item questionnaire that the participants fill indicating the extent to which each item is a challenge to them. Each PAID item received a score that ranged from "not a problem" (score of 0) to "serious problem" (score of 4). Scores on the 20 items were aggregated; they were then multiplied by 1.25 to generate a score between 0-100 with the higher results indicating greater diabetes-related emotional distress. A score of 11 and above was categorized as DRD^{6,17}

Data analysis: Descriptive statistics comprising of percentages, means, and standard deviations (SD) were used to summarize patient characteristics and outcomes.

Demographic and clinical characteristics were summarized into percentages for categorical variables, while continuous data were presented as means with standard deviations or medians with interquartile ranges. PAID score of 11 and above indicated presence of DRD and the patients with this score were categorized to show prevalence presented as a percentage. Severity of DRD was also presented as percentages.

Results: The study included 298 participants. Of these 201 (67.4%) were female and 97(32.6%) were male. The mean age in years was 59.1. The prevalence of diabetes-related emotional distress was 44%. Diabetes-related emotional distress was found to be more common in people who were younger [$p < 0.001$]. Those categorized as married experienced less diabetes-related emotional distress [$p = 0.014$, CI 1.2-3.9].

Conclusion: The prevalence of DRD in our population is significant enough to warrant change in how healthcare is delivered to our patients with type 2 diabetes.

1.0 CHAPTER ONE: INTRODUCTION

Diabetes is a metabolic disorder characterized by hyperglycemia. Worldwide, approximately 422 million adults live with diabetes¹, 90 per cent of these individuals have type two diabetes. Diabetes prevalence is on an upward trajectory, and this has been attributed to increasing rural-urban migration, urbanization and the adoption of unhealthy diets and sedentary lifestyles leading to obesity. In Kenya, the prevalence of diabetes is estimated at 3.3 per cent, with a forecast increase to 4.5 per cent by 2025.²

There has been significant emphasis placed on achieving glycemic targets in order to prevent microvascular and macrovascular complications of the disease.³ However, the psychological, social, and economic implications of diabetes are often overlooked and may go unaddressed. Research shows an association between diabetes and mental health issues. These range from diagnosable psychiatric disorders to diabetes associated emotional distress.⁴

Unlike the general population, the prevalence of psychiatric disorders is higher for individuals with diabetes. These include major depressive disorder, sleep disorders, anxiety disorders, bipolar disorders, and stress-related disorders.⁴ People living with diabetes and depression have greater incidence of all-cause mortality unlike those with diabetes but without depression⁴. Mental health concerns are important in people living with diabetes as they carry significant impact on health outcomes. There is rising proof relating mental health, self-care and quality of life.^{4,5} Emotional distress (DRD) due to diabetes has several signs that correlate with known disorders of mental health, for example depression. Despite their similarities, they are different constructs and need different methods of appraisal and management. Diabetes related emotional distress, unlike depression, does not presume psychopathology but focuses on the emotional reaction of patients specifically to living with diabetes and not to life in general.⁶

DRD refers to the negative emotions and emotional distress created by the burden of self-care and diabetes management.⁷ This includes, but is not limited to, the challenge of continuous monitoring and treatment, anxiety about potential diabetes complications and dietary restriction.⁴

The Problem Areas in Diabetes (PAID) is a universally used for grading DRD. It is a questionnaire that analyzes different psychometric properties related to diabetes with each item representing an area of emotional distress specific to diabetes.^{5,8,9}

Given the effect of mental health on health outcomes of individuals living with diabetes, regular screening of individuals with diabetes for symptoms of common psychiatric disorders and the existence of diabetes related distress with an aim of providing holistic care and management would be ideal practice. It is noteworthy, that the current Kenyan clinical guidelines on Diabetes Mellitus and actual clinical practice of Diabetes Mellitus management rarely discuss the psychological effect of living with diabetes.^{10,2}

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Background

Diabetes Mellitus is a disease that results in significant physical and psychological challenges. Diabetes Related Distress refers to the negative emotions experienced by individuals living with diabetes and is comprised of several related domains that include distress due the emotional burden of a diagnosis of diabetes, distress as a result of the self-management regimen, stress related to social relationships and distress due to patient-provider interactions.¹¹ It is a concept that emerged as a result of research into stress, coping and emotional response to stressors and has been shown to be correlated with low self-care and glycemic control.¹¹

The Diabetes, Attitudes, Wishes and Needs 2 (DAWN2) was a research project undertaken to identify potential obstacles to effective diabetes management. The study, a survey of 16,000 people from 17 countries across four continents, identified several gaps in the management of diabetes. The findings showed that self-management in individuals with diabetes were inadequate and was often a result of DRD. The data from the DAWN2 study support a paradigm shift in the management of diabetes, to incorporate a person-centered chronic care model that emphasises the need for psychosocial support.¹²

These findings raise key issues that suggest that diabetes related distress is an important concept that has been insufficiently addressed in clinical practice. There are gaps in mental health screening of individuals living with diabetes, as healthcare professionals will tend to prioritize physical health. Efforts to identify and mitigate emotional distress would be of benefit in the management of all individuals with diabetes.

2.2 Diabetes and Mental Health

A growing body of literature shows an increasingly clear relationship between diabetes and mental health. Clinical practice guidelines established by Robinson et al identified a wide range of psychiatric conditions such as depression, anxiety disorders, sleep and eating disorders that have greater prevalence in individuals having diabetes in comparison to the general population.⁴

Anderson et al conducted a meta-analysis, reporting increased prevalence of co-morbid depression among diabetic adults¹³ and Ramkisson et al highlighted the increased incidence of anxiety and depression among a South African population with diabetes.¹⁴

It is critical to identify DRD as a distinct entity, to distinguish between emotional distress and diagnosable psychiatric disorders such as major depressive disorder (MDD). Diabetes distress is broadly defined in terms of the problems assessed by the PAID scale, which is considered the patient's primary measure of distress from diabetes. It focuses on the emotional distress associated with the daily aspects of living with diabetes, such as emotional experiences linked to care objectives, potential complications, dietary restrictions and social/interpersonal relationships.¹¹

Evaluation of these qualitative studies proposes that depression is too narrow a construct to adequately capture the divergent emotional experiences that represent persons who have diabetes.

2.3 Prevalence of Diabetes Related Emotional Distress

With increasing research, emotional distress associated with diabetes has gained growing awareness. An estimated 25% of adults living with diabetes in the United Kingdom experience elevated or severe emotional distress at one point in time.¹¹ Similar rates are documented across Europe, Australia and the United States.¹¹ An estimated 18-45 per cent of individuals living with diabetes have DRD.¹⁵

According to the Diabetes, Attitudes, Wishes and Needs (DAWN-2), the prevalence of emotional distress related to diabetes is 44.6 per cent and that of diabetes-related depression is at 13.8 per cent.¹² Though emotional distress and diabetes-related depression are related conditions, literature suggests that distress from diabetes occurs more extensively than depression. This research provides deeper insight into the needs of individuals with type 2 diabetes. The data collected represents views of a vastly diverse and international population and presents a global perspective on distress associated with diabetes.

Ramkisson et al performed a multi-center, cross-sectional analysis on 401 patients with type 2 diabetes in KwaZulu-Natal, SouthAfrica. The results revealed that 44 per cent of the study participants had moderate to high levels of distress. This added to the body of knowledge on DRD in the Africa.¹⁴

Perrin et al conducted a meta-analysis to assess the overall prevalence of DRD among those with type two diabetes.¹⁶ Relevant and eligible studies were obtained from seven databases, and the meta-analysis included 55 studies. Data were collected from USA, Canada, the Netherlands, Australia, China, Singapore, France, Germany, Italy, India, Iran, Japan, Malaysia, Norway, Serbia, Slovenia and South Africa and one multinational study.¹⁶

The studies showed a 36 per cent prevalence of DRD in people with type two diabetes. PAID or DDS were employed in the research to measure diabetes distress. The findings of the research using the PAID scale are summarized in Table 1.

Table 1: Problem Areas in Diabetes (PAID) Studies (17)

Study	Location	Design	N	Mean Age (years)	Gender (% male)	Mean HbA1c (%)	% DD
Karlsen et al, 2012	Norway	Cross-sectional	378	58.10	54.20	7.10	22.00
Nichols et al, 2000	USA	Cross-sectional	924	35.10	NR	7.95	35.17
Primožic et al, 2012	Slovenia	Cross-sectional	98	63.74	49.00	7.3%	13.2%
Stankoviv et al, 2011	Serbia	Cross-sectional	90	55.75	34.65	8.90	67.80
Stoop et al, 2014	Netherlands	Cross-sectional	1300	65.00	55.00	7.03	10.00
Venkataranam et al, 2016	Singapore	Cross-sectional	203	45.00	64.00	8.30	32.00
Zulman et al, 2012	USA	Cross-sectional	1834	70.00	48.00	NR	62.00

2.4 Instruments for Assessing Diabetes Related Distress

Various tools have been used to assess diabetes related distress among people with diabetes. The screening for DRD is carried out using clinical interviews and validated questionnaires. There are several screening instruments for DRD. These instruments are divided into three categories. These are Diabetes distress-specific measures, Quality of life measurements and Depressive/anxiety symptoms.⁴

Specific measures for distress in diabetes consist of the Diabetes Distress Scale (DDS) and the PAID scale.¹⁷ Quality of life measures include the WHO-5 screening instrument. Depression/anxiety symptoms are assessed using instruments such as the Hospital Anxiety and Depression scale (HADS), the Beck Depression Inventory (BDI), the

Patient-Health Questionnaire (PHQ-9) or the Centre for Epidemiological Studies Depression scale (CES-D).

The PAID scale is broadly regarded as an appropriate measure for emotional distress related to diabetes and is regarded as a reliable measure of patient-reported outcomes (PROM).^{11,17}

Jiyeon Lee et al conducted a systematic evaluation to identify instruments used in grading diabetes distress and to assess the evidence of their measuring properties.¹⁸ The measuring properties were assessed using the Terwee's quality criteria and an ancillary meta-analysis was performed.¹⁸ Six DRD instruments were evaluated and the instruments used were Problem Areas in Diabetes -5 items (PAID-5), Problem Areas in Diabetes -20 items(PAID -20), Problem areas in diabetes - 1 item (PAID -1), Problem areas in diabetes - short form (PAID - SF), Diabetes Distress Scale (DDS) and Diabetes Distress scale -2 items (DDS -2)

Every instrument was evaluated for content validity, reliability of internal consistency and responsiveness.¹⁸ It was established that the PAID had strong evidence for content validity, and it was the instrument most studied and authorised, and therefore recommended for use.^{18,16}

PAID scale demonstrated cross-cultural validity with high internal consistency and test-retest reliability in several studies. These studies include Snoek et al, 2000 Diabetes-related emotional distress in Dutch and U.S diabetic patients.¹⁹

Marit Graue et al,2011 Reliability and validity of the Norwegian versions of the Problem Areas in Diabetes (PAID) and Diabetes Distress Scale (DDS).⁹ The clinical utility and responsiveness of the PAID scale was determined in studies by Welch et al, 1997 and Polonsky et al.^{20,21} The surveys showed high internal reliability of the PAID scale.

2.4.1 Use of the Problem Areas in Diabetes (PAID) in Clinical Practice

When completing the questionnaire on Problem areas in diabetes (PAID), respondents fill the 20-item questionnaire indicating the extent to which each item is a challenge to them.^{6,17}

Each PAID item gets a score of 0-4 points, ranging from “not a problem” (score of 0) to “serious problem” (score of 4). Scores on the 20 items are aggregated; they are then multiplied by 1.25 to generate a score between 0-100 with the higher results indicting greater emotional distress.⁶

Total score:

Low: 0-10

Moderate: 11-39

Severe: >40

A score of 11 and above (moderate to severe) was categorized as DRD (1)(2)

The PAID-20 covers a wider range of diabetes-related emotional problems compared to shorter PAID variants and has demonstrated validity and reliability.²²

The Problem areas in diabetes (PAID) questionnaire is attached in appendix 3.

2.5 Factors Associated with Diabetes Related Emotional Distress

Research by Samantha Ramkisson et al conducted in South Africa looked at factors associated with the development of DRD.²⁶ In the study, the demographic characteristics attributed to the participants were compared to the level of emotional distress. The characteristics assessed were gender, education level, employment status, ethnic groups, marital status, and the medical facility of the study - private vs public. The results of the study revealed that 44% of the participants were shown to have levels of diabetes distress that ranged from moderate to high.

The greatest contributing elements were female gender, younger age, unemployment and attending public healthcare facilities. Diabetes distress levels were statistically higher in women (n=52, 21.4 percent) than in men (n=21, 13.29 percent). Unemployed participants (n=30, 26.32%) reported higher stress levels than employed participants (n=34, 18.58%). Participants who attended public medical facilities (n=49, 24.38%) were twice as stressed as those attending private facilities (n=24, 12%). These patients also had higher HbA1c levels.²⁶ In many ways these results are similar to those found in the DAWN 2 research.¹²

In this study, we set out to determine factors associated to diabetes distress. These include gender, age, education level, employment status, marital status, duration of type 2 DM, treatment regimen, HbA1c, and hypertension.

2.5.1 Diabetes Related Distress and Glycated Hemoglobin

Diabetes related distress has significant effect on healthcare outcomes including achieving glycated hemoglobin targets and self-care practices that postpone or prevent the onset of complications.^{24,25}

Glycemic control is associated with Diabetes related distress. HbA1c fluctuates in relation to DRD. Reduction in DRD reflects clinically significant improvements in

HbA1c.²⁴ DRD predicts glycemic control according to Aikens et al in a study on prospective relationships between Diabetes distress and poor diabetes outcomes.⁵ Observational studies have suggested that diabetes distress has bigger impact on diabetes outcomes than depression. Research by Zagarins et al aimed to evaluate the impact of diabetes distress and depressive symptoms on glycemic control. Changes in depressive symptoms in multiple linear regressions did not result in change in glycemic control. However, change in diabetes distress was significantly associated with change in HbA1c.²⁹

These findings contribute to increasing literature on the health outcomes associated with diabetes related distress.

2.5.2 Diabetes Related Distress and Cardiovascular Disease

Cardiovascular disease has been linked to emotional distress in diabetes. Dalsgaard et al undertook a study to look at the link between diabetes distress and the risk of cardiovascular disease. The results showed higher rates of distress were associated with 1.8-fold greater mortality and 1.7-fold greater risk of cardiovascular disease.²⁸ The evaluation of psychological distress used the Mental Health Inventory 5 (MHI-5) questionnaire and not the PAID questionnaire.

2.6 Diagnosis of Diabetes Related Emotional Distress

Diagnosis of DRD is based on clinical interviews and the use of assessment tools for psychological evaluation. Regular assessment for DRD in people with diabetes would be beneficial as psychological problems are significantly underdiagnosed. Effective diabetes distress awareness will encourage early intervention and prevent further adverse healthcare effects. Assessment in different countries and cultures requires enhanced tool translation and research collaboration to enhance prospects for early diagnosis and better treatment and care.

2.7 Conceptual Framework

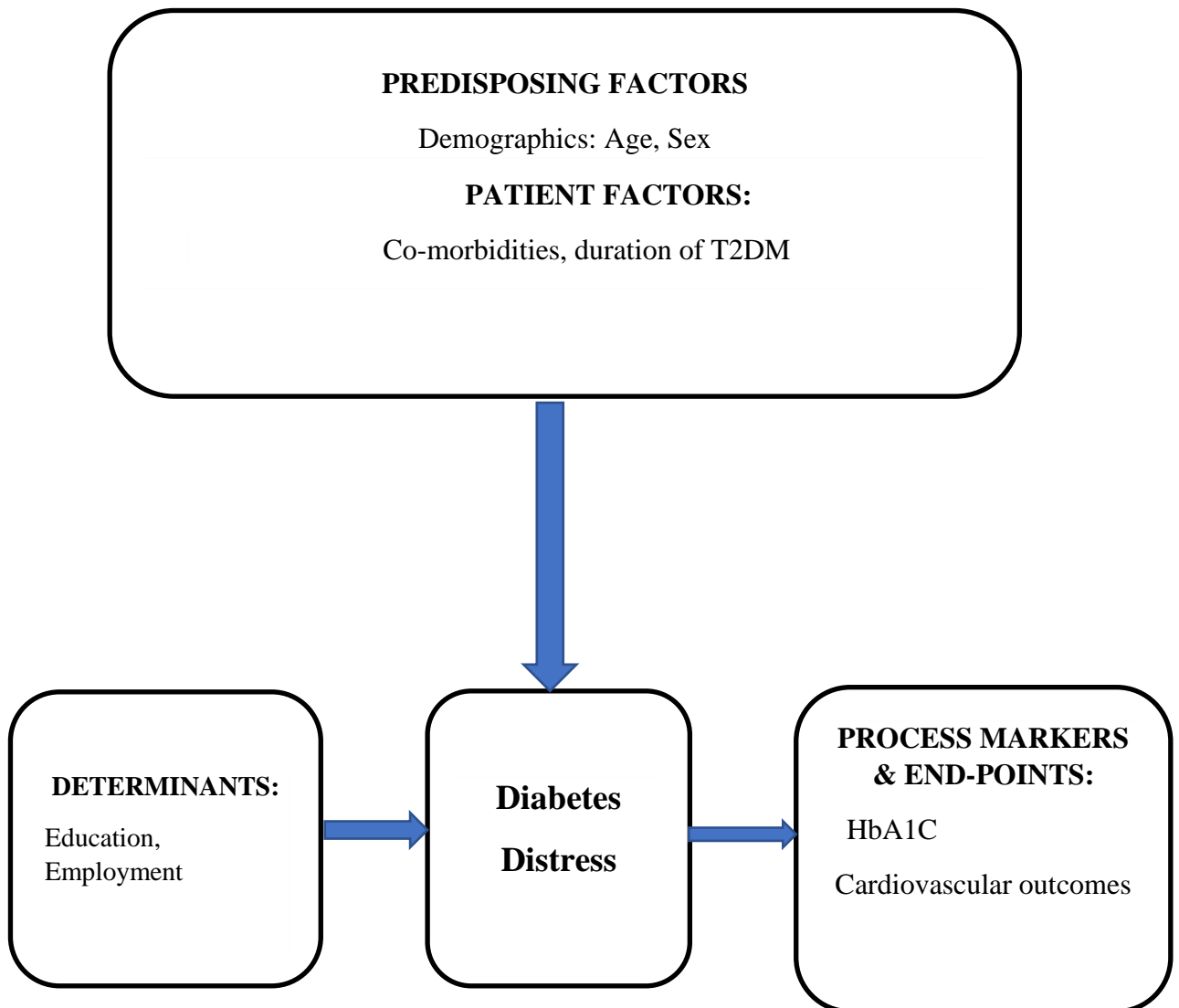


Figure 1: Framework of the relationships and interactions between variables (exposures & outcomes)

2.8 Problem Statement

Diabetes related emotional distress is a prevalent psychiatric comorbidity in people living with diabetes.¹⁹ However; screening for DRD is often neglected in healthcare practice despite its significant impact on healthcare outcomes.

2.9 Study Justification

The focus by healthcare service providers in diabetes management is often on achieving glycemic control and preventing macrovascular and microvascular complications in individuals living with diabetes.^{2, 3,10} The psychological, emotional, and social impact often remains unaddressed. There is no local data on the burden and effects of DRD.

Understanding the level of diabetes distress in our population and identifying factors associated with DRD, is of great clinical benefit. This would give healthcare professionals a broader understanding of the level of distress experienced by people living with diabetes in relation to diabetes mellitus diagnosis, treatment regimen, diet, possible complications, social support, and patient-provider interactions. Understanding the extent of the problem would guide on including it as a standard of care.

2.10 Research Question

What is the burden and associations of diabetes-related distress in individuals with type 2 diabetes at KNH?

2.11 Research Objectives

2.11.1 Broad Objective

To establish prevalence and severity of diabetes related emotional distress in patients with type 2 diabetes attending the diabetes clinic at KNH.

2.11.2 Specific Objectives

- a) To identify the proportion of type 2 DM patients with diabetes-related emotional distress at the KNH.
- b) To determine the severity of DRD in people living with T2DM.

2.11.3 Secondary Objective

To determine associations of DRD of the participants and the level of education, duration of type 2 diabetes, treatment regimen, hypertension, and glycemic control.

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Design

It was a Cross-sectional, descriptive study design.

3.2 Study Site

The Outpatient Diabetic clinic at Kenyatta National Hospital. This is a specialized clinic located at the Diabetes and Endocrinology centre. It is run by Specialist endocrinologists, Physicians, graduate resident doctors, clinical officers, nurses, and diabetes educators. The clinic runs from Monday through Friday.

3.3 Study Population

Ambulatory patients with type 2 diabetes on follow up at the diabetic clinic at Kenyatta National Hospital.

Individuals above 18 years of age with a clinical diagnosis of diabetes mellitus type 2 on follow up in the diabetic clinic. They must be ambulatory with no recent hospital admission in the preceding 6 months.

3.4 Case Definition

Diabetes-related emotional distress (DRD): A score of 11 and above (moderate to severe) on the Problem Areas in Diabetes (PSID) score was categorized as DRD ^{1,2}

Hypertension: Patients with a previous diagnosis of hypertension on treatment or with at least two blood pressure readings above 130/80 were classified as having hypertension.²⁵

3.5 Study Instrument

Problem Area in Diabetes (PAID) questionnaire. This is a 20-item questionnaire that the participants fill indicating the extent to which each item is a challenge to them^{1,2}

Each PAID item gets a score of 0-4 points, ranging from “not a problem” (score of 0) to “serious problem” (score of 4). Scores on the 20 items are aggregated; they are then multiplied by 1.25 to generate a score between 0-100 with the higher results indicating greater emotional distress

Total score:

Low: 0-10

Moderate: 11-39

Severe: >40

Diabetes-related emotional distress (DRD) A score of 11 and above (moderate to severe) was categorized as having DRD ^{1,2}

3.6 Patient Selection

3.6.1 Inclusion Criteria

- Adult over 18 years
- Diagnosis of type 2 diabetes for 12 months or more.
- Informed consent

3.6.2 Exclusion Criteria

- Pregnant women
- Recent hospitalization in the preceding 6 months

3.7 Sample Size Estimation

Daniel's formula;

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

Where;

n = sample size

Z = Z statistic for a level of confidence = 1.96

P = expected proportion of diabetic patients with diabetes related emotional distress based on PAID tool (P = 0.15)

d = precision = 0.04

The calculated sample size was 281 patients; it was adjusted by 5 % to account for non-response and/or anticipated missing variables, resulting in a sample size of 296. The estimated number of patients with diabetes seen at the diabetic clinic in KNH was 3,307 in the year 2018 as per KNH records.

3.8 Sampling Method

A total sample of 298 participants attending the outpatient diabetic clinic at Kenyatta National Hospital was selected consecutively.

3.9 Patient Recruitment

Patients awaiting their scheduled appointments were recruited on diabetic clinic days (Monday-Friday) for approximately two months. The principal investigator and research assistants determined those that met the inclusion criteria. These were persons with type 2 diabetes who were 18 years or older and had not been admitted to the hospital in the

preceding 6 months. A registered clinical officer and a registered nurse worked as study assistants.

Research staff approached them and explained to them the nature and purpose of the study. Patients that met the inclusion criteria and volunteered to participate in the study were requested to sign informed consent forms, then administration of the PAID questionnaire and a study proforma questionnaire by the primary investigator and research assistants was carried out followed by drawing of a sample of blood for HBA1C. The lead investigator and research assistants were in charge of data collection. Blood pressure was taken with the patient seated on a chair with their feet on the floor and their arm supported so that their elbow was at the level of the heart. An appropriately sized blood pressure cuff was placed on bare skin and the blood pressure recorded.⁽²⁵⁾

3.10 Laboratory Methods

A blood sample was collected from the antecubital fossa using an aseptic technique. A volume of 2mls was drawn and filled into the appropriate vacutainer (purple top). Vacutainers were assigned a code to match the respective patient code. Samples were transported to the laboratory for analysis with strict adherence to laboratory handling of samples. Blood glycated hemoglobin (HbA1c) was analysed using Biolis 50i equipment from Tokyo Boeki company, using Dirui reagents on immunoturbidimetric principle concentration. Glycemic control and was used as an outcome measure of emotional distress associated with diabetes.

3.11 Study Variables

The study variables were age, gender, marital status, level of education, employment status, duration of type 2 diabetes, hypertension, treatment regimen, glycemic control (HBA1C)

3.12 Quality Assurance

Administration of the PAID instrument was done in a uniform manner with available Swahili translated versions available in print. There were no previous Swahili translations available as no previous studies have been done using the PAID tool locally. Translation from English to Swahili was done by a translator from the Linguistics Department at the University of Nairobi. Research assistants were trained to obtain information in a standardized manner. Collection, storage, and analysis of blood samples were carried out with adherence to set standards.

3.13 Ethical Considerations

The study proposal was submitted to the KNH/UON Ethics and research committee for review and approval following approval of the protocol by the department of clinical medicine and therapeutics. KNH administration approval was sought and given following approval by the Ethics and research committee.

All the patients participating in the study were given detailed explanations as to the nature of the study and laboratory investigations to be carried out. Assurance to the participating patients, that their participation was purely voluntary and that they were free to opt-out whatsoever without any consequences or explanations. Patients willing to participate in the research were requested to sign a consent form once they accepted to participate in the study. Participants' data collected by the investigator have been kept strictly confidential and will only be used for study purposes.

3.14 Data Management and Analysis

For categorical variables, demographic and clinical characteristics were provided as percentages, while continuous data was presented as means with standard deviations or medians with interquartile ranges. PAID score above 10 indicated presence of DRD and the patients with this score were categorized to show prevalence presented as a percentage. Severity of DRD was also presented as percentages.

Factors associated with DRD were determined by associating with categorical variables using chi square test of associations. To quantify the extent of the risk associated with variables, odds ratios were determined. Means for current age, duration of diabetes and HbA1C were compared between patients with DRD versus those without using independent t test. Median duration of diabetes was compared between the two groups using Mann Whitney U test. Factors independently associated with DRD were determined using multiple logistic regression model. Statistical significance was interpreted at 5% level (p value less or equal to 0.05).

3.15 Definition of Study Variables

Problem areas in diabetes (PAID) score

Total score:

Low: 0-10

Moderate: 11-39

Severe: >40

Diabetes related distress is scores ≥ 11 (moderate to severe)

Glycemic control

HbA1C less than 7% = good control

HbA1C greater than 7% = poor control

4.0 CHAPTER FOUR: RESULTS

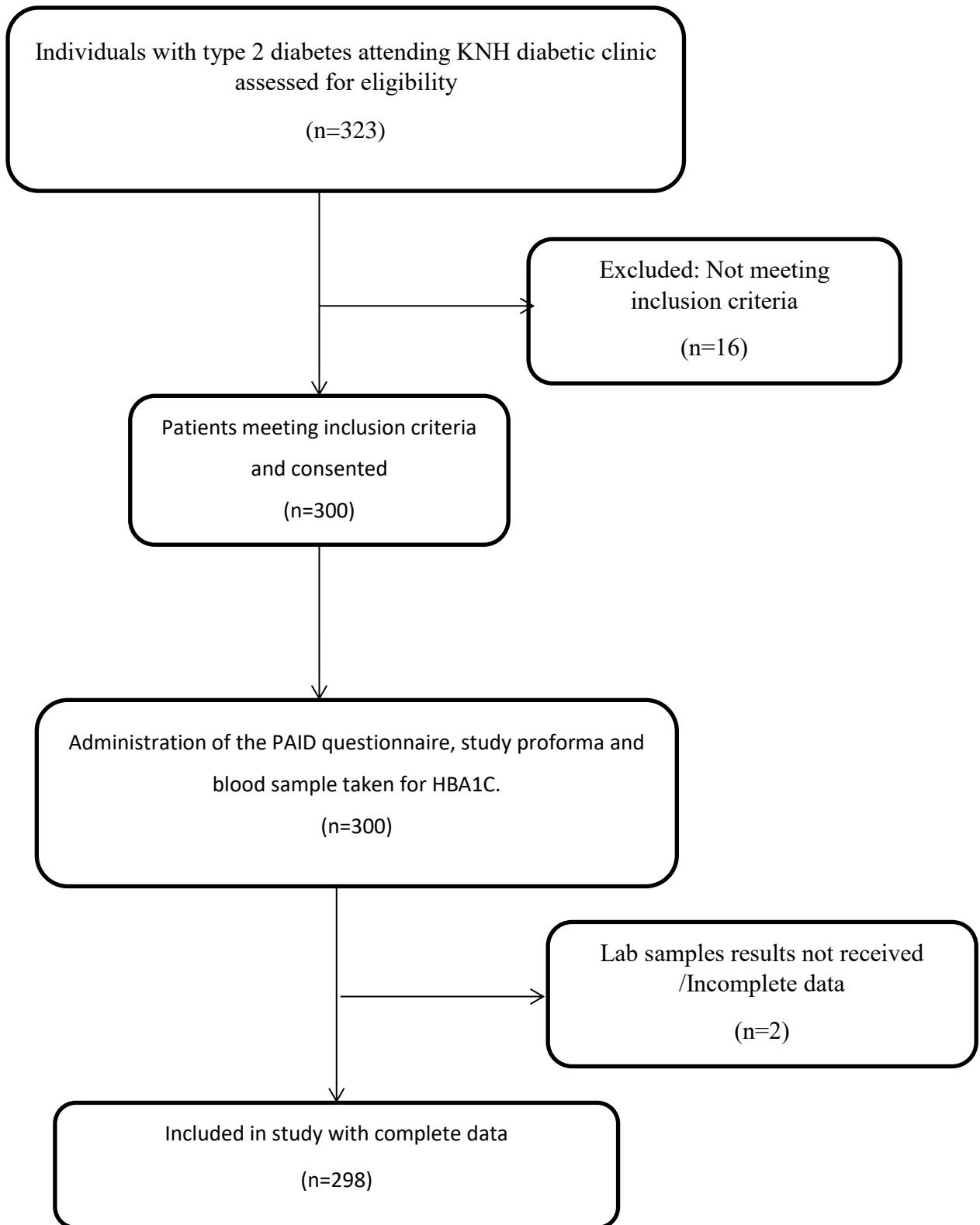


Figure 2: Flow chart on patient recruitment

Table 2: Demographic Characteristics

Variable	N=298 Frequency (%)
Gender	
Male	97 (32.6)
Female	201 (67.4)
Age in years	
Mean (SD)	59.1(11.3)
Min-Max	29.0-86.0
Category, n (%)	
≤35	3 (1.0)
36-45	30 (10.1)
46-65	174 (58.4)
>65	91 (30.5)
Marital status	
Married	246 (82.6)
Never been married	23 (7.7)
Separated	13 (4.4)
Divorced	2 (0.7)
Widowed	14 (4.7)
Level of Education	
Primary	131 (44.0)
Secondary	120 (40.3)
Tertiary	47 (15.8)
Employment status	
Unemployed	150 (50.3)
Self-employed	98 (32.9)
Employed	50 (16.8)

The demographic characteristics of the sample is demonstrated in table 3. The study included 298 participants with type 2 diabetes that consented to take part in the study. Majority of the participants were between the ages of 46-65 years (58.4%). Females made up majority of the sample at 67% (n=201). Approximately 83% (n=246) of the participants were married, the rest were classified as others which included those that have never been married, those that were separated, divorced, or widowed. Majority had the standard of education as having had at least a primary education. Of these, 40% had attained secondary education and 16% had completed tertiary education. Half of the respondents (50%) were unemployed, while the other half were either employed or self-employed. Of note is that the level of unemployment was significantly higher than in a previous study by Genga in 2010.⁽²⁶⁾

Majority of the participants (61%) have been living with type 2 diabetes for 6 years or more (table 4). Approximately 48% of the participants were on oral glucose lowering agents (OGLAs) only and 44% were on a combination of oral agents and insulin. Those with hypertension as a comorbidity were 70% of the participants. Majority of the participants had suboptimal glycaemic control. Approximately 53.3% had HBA1C \geq 7.1%.

The results of the study showed that 45% of the participants had moderate to severe levels of diabetes-related emotional distress while 56% had low levels of emotional distress as shown in Table 5.

Table 3: Clinical Characteristics

Variable	N=298 Frequency (%)
Duration of T2DM in years Category, n (%) 1-5 6-10 >10	115 (38.6) 73 (24.5) 110 (36.9)
Treatment Regimen Oral medication Insulin Oral & Insulin Diet	142 (47.7) 24 (8.1) 131 (44.0) 1 (0.3)
Hypertension Hypertensive Not hypertensive	209 (70.1) 89 (29.9)
HbA1c results Mean (SD) Category, n (%) ≤7: Good 7.1-8.0: Moderate >8.0: Poor	8.3 (3.7) 139 (46.6) 40 (13.4) 119 (39.9)

Table 4: The prevalence and severity of diabetes-related emotional distress

	Median/ frequency	IQR/%
Diabetic Distress (PAID)	10	6.25,16.25
PAID IN CATEGORIES		
Low	166	56%
Moderate	124	41%
Severe	8	3 %

Diabetes-related emotional distress (DRD) consists of scores ≥ 11 (moderate-severe). The prevalence in our population is 44%.

Table 5: Factors associated with DRD

Variable	DRD		OR (95% CI)	P value
	Present	Absent		
Gender				
Male	40 (41.2)	57 (58.8)	0.8 (0.5-1.4)	0.460
Female	92 (45.8)	109 (54.2)	1.0	
Mean age in years (SD)	56.4 (11.5)	61.3 (10.7)	-	<0.001
Category, n (%)				
≤35	2 (66.7)	1 (33.3)	3.9 (0.3-44.4)	0.227
36-45	20 (66.7)	10 (33.3)	3.9 (1.6-9.3)	0.002
46-65	79 (45.4)	95 (54.6)	1.6 (1.0-2.7)	0.076
>65	31 (34.1)	60 (65.9)	1.0	
Marital status				
Married	101 (76.5)	145 (87.3)	1.0	
Never been married	17 (12.9)	6 (3.6)	4.1 (1.6-10.7)	0.002
Separated	10 (7.6)	3 (1.8)	4.8 (1.3-17.8)	0.011
Divorced	2 (1.5)	0	-	0.092
Widowed	2 (1.5)	12 (7.2)	0.2 (0.1-1.1)	0.052
Level of Education				
Primary	49 (37.4)	82 (62.6)	0.7 (0.4-1.5)	0.382
Secondary	62 (51.7)	58 (48.3)	1.3 (0.7-2.6)	0.417
Tertiary	21 (44.7)	26 (55.3)	1.0	
Employment status				
Unemployed	57 (38.0)	93 (62.0)	0.6 (0.3-1.1)	0.084
Self-employed	49 (50.0)	49 (50.0)	0.9 (0.5-1.8)	0.818
Employed	26 (52.0)	24 (48.0)	1.0	
Median duration of T2DM in years (IQR)	6.0 (3.0-14.0)	10.0 (4.0-17.0)	-	0.060
Category, n (%)				
1-5	57 (49.6)	58 (50.4)	1.7 (1.0-2.8)	0.064
6-10	34 (46.6)	39 (53.4)	1.5 (0.8-2.7)	0.211
>10	41 (37.3)	69 (62.7)	1.0	
Treatment regimen				
Oral medication	63 (44.4)	79 (55.6)	1.0	
Insulin	10 (41.7)	14 (58.3)	0.9 (0.4-2.2)	0.896
Oral & Insulin	58 (44.3)	73 (55.7)	1.0 (0.6-1.6)	0.996
Diet	1 (100.0)	0	-	1.000
Hypertension				
Yes	92 (44.0)	117 (56.0)	1.0 (0.6-1.6)	0.883
No	40 (44.9)	49 (55.1)	1.0	
Mean HbA1C (SD)	8.4 (3.7)	8.2 (3.7)	-	0.674
Glycaemic control				
≤7: Good	61 (43.9)	78 (43.9)	1.0	
7.1-8.0: Moderate	21 (52.5)	19 (47.5)	1.4 (0.7-2.9)	0.336
>8.0: Poor	50 (42.0)	69 (58.0)	0.9 (0.6-1.5)	0.163

DRD showed statistical significance in only age ($p < 0.001$) and marital status ($p = 0.002$). The remaining variables gender, level of education, employment status, duration of type 2 diabetes, treatment regimen and hypertension were not significantly associated with DRD.

5.0 CHAPTER FIVE: DISCUSSION

The purpose of this study was to investigate the prevalence and severity of diabetes-related emotional distress in patients with type 2 diabetes who visited the Kenyatta National Hospital's diabetes clinic. The prevalence of DRD was 44% (as defined by moderate to severe scores on PAID). Of these 3% had severe distress and 41% had moderate distress. These findings were comparable to those found in other studies. According to the Diabetes, Attitudes, Wishes and Needs (DAWN-2), a study with 16,000 participants across 17 countries, the prevalence of emotional distress related to diabetes was 44.6%.¹²

A multicentre study in KwaZulu-Natal, South Africa, carried out by Ramkisson et al on 401 patients with type 2 diabetes the study's results showed that 44 per cent of the study participants had moderate to high levels of distress. This study was done using the Questionnaire on Stress in Diabetes (QSD-R).

The results of this study are comparable to those of other studies assessing the prevalence and severity of DRD. The goal of this research was also to see if there was a link between diabetes-related emotional distress and the level of education, duration of type 2 diabetes, treatment regimen, comorbidities (hypertension), and glycemic control. In our research, these factors did not show a statistically significant relationship with diabetes-related emotional distress.

Younger age was associated with higher levels of diabetes-related emotional distress (table 5) which is consistent with the findings of other studies. Those with DRD were significantly younger. As age increased, the level of diabetes-related emotional distress decreased.

There was a statistically significant difference in perceived levels of diabetes-related emotional distress based on marital status. Those categorized as married had lower levels of distress than those listed as others. This included those that have never been married, are separated, divorced, or widowed. This may be due to better social support among those that are married.

There was no statistically significant link between glycemic control and diabetes-related emotional distress in this investigation. This outcome was surprising in that it deviated from the results found in other studies that suggested an increase in HBA1C with rising PAID scores.^{27,28} In other studies Glycemic control showed bidirectional outcomes with Diabetes related distress. HBA1c fluctuated in relation to DRD. Reduction in DRD resulted in clinically significant improvements in HBA1c.²⁴

A prospective study by Aikens et al revealed correlations between Diabetes distress and poor outcomes. This revealed that DRD predicts glycemic control.⁵ Observational studies have suggested that diabetes distress has bigger impact on diabetes outcomes is greater than depression. Research by Zagarins et al that aimed to evaluate the impact of changes in diabetes distress and depressive symptoms on glycemic control revealed that changes in depressive symptoms in multiple linear regression did not result in change in glycemic control however change in diabetes distress was significantly associated with change in HBA1c.²⁶

The findings of this study indicate that there are probably other factors in our population that have significant effect on glycemic control, and they may bear more weight than diabetes-related emotional distress.

Diabetes Mellitus is a disease that results in significant physical and psychological challenges. According to the findings of this study diabetes-related emotional distress is prevalent in our population. Mental wellbeing is important among those living with diabetes as it has critical impact on healthcare results. Regular assessment for DRD in people with diabetes would be beneficial as psychological problems are significantly underdiagnosed. Effective diabetes distress awareness will encourage early intervention and prevent further adverse healthcare effects.

It is noteworthy that healthcare professionals will tend to prioritize physical health and achieving glycemic targets however the psychological well-being of people living with diabetes is overlooked and not addressed. Efforts to identify and mitigate emotional distress would be of benefit in the management of all individuals with diabetes.

The DAWN2 study, that showed similar prevalence of DRD as our population, supported a paradigm shift in the management of diabetes to incorporate a person-centered chronic care model that emphasises the need for psychosocial support.¹² The study identified several gaps in the management of diabetes. The findings showed that self-management in individuals with diabetes were inadequate and was often a result of DRD. These findings raise key issues that suggest that diabetes related distress is an important concept that has been insufficiently addressed in clinical practice.

6.0 CHAPTER SIX: STUDY STRENGTHS, LIMITATIONS, CONCLUSION & RECOMMENDATIONS

6.1 Study Strengths

The study provides valuable information on patient's psychological state and perceived DRD and factors associated to the perceived distress.

6.2 Limitations

There may have been response bias as some of the participants may have considered the questions to be too personal. A response bias from the participants may be reflected in the perceived DRD levels. Some of the responses to questions asked may have been skewed towards a positive result, such as whether healthcare services offered at the diabetes clinic was satisfactory to patients. However, the participants were reassured of confidentiality of the information they provided and that there would be no negative consequences on the responses given. This may have minimised the response bias.

The study was conducted at a single facility, which is a tertiary facility and may not reflect the level of diabetes distress among patients from different populations within the country especially patients that may be attending private healthcare facilities.

6.3 Conclusion

The prevalence of DRD in our population is significant enough to warrant change in how healthcare is delivered to our patients with type 2 diabetes. Approximately 44% of the participants had moderate to high levels of emotional distress, interventions to target specific demographic groups may result in reduced levels of DRD. Regular screening and assessment of diabetes distress at an individual level could be scheduled annually. It would be of great interest to have a study that compares DRD levels between individuals with type 1 diabetes and those with type 2 diabetes. It would be of great additional value to assess the perceived level of distress in individuals with type 1 diabetes, given not only their age but the different treatment regimen requiring insulin injections. Since the younger population had higher DRD, the prevalence in this population would be of added value.

6.2 Recommendations

A study that compares the DRD score at the onset of diagnosis and the levels after 1 year of diagnosis and treatment may give additional and useful data. This study did not include participants with a diagnosis of T2DM for less than 1 year. It was notable during data collection that several participants in the study mentioned that their level of acceptance of diagnosis with diabetes had increased over time and that their distress concerning the diagnosis had also reduced over time. This would be a good indicator that the ongoing patient education and management is resulting in reduction of emotional distress.

Following the findings of this study I recommend;

- a) Routine screening for DRD and determinants of DRD
- b) Intervention to reduce DRD through multidisciplinary approach methods
- c) Further research on establishing the impact of DRD on patient outcomes and interventions to mitigate these.
- d) Further research on models of care that would improve healthcare service delivery to individuals with diabetes and minimize levels of diabetes-related distress.

The results of this research will be shared with the staff at the diabetes clinic to facilitate improved healthcare service delivery.

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APPENDICES

Appendix I: Study Proforma

1. Gender Male Female

2. Age (in years)

Marital status

Married

Never been married.

Separated

Divorced

3. Level of Education

Primary

Secondary

Tertiary

4. Employment status

Unemployed

Self-employed

Employed

5. Age of onset of T2DM

6. Duration of T2DM

Treatment Regimen

Oral medication	<input type="checkbox"/>
Insulin	<input type="checkbox"/>

7. Hypertension

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

8. Smoking

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

9. HBA1c

<6.5%	<input type="checkbox"/>
> 6.5%	<input type="checkbox"/>

LMP

(Where applicable)

.....

Appendix II: Informed Consent form

STUDY: ASSESSMENT OF THE BURDEN AND IMPACT OF DIABETES-SPECIFIC EMOTIONAL DISTRESS IN TYPE 2 DIABETIC PATIENTS ATTENDING THE DIABETES CLINIC AT KENYATTA NATIONAL HOSPITAL

Introduction

This research is being conducted by Dr. Ciku Nyambura, a postgraduate resident in the department of Clinical Medicine and Therapeutics at the University of Nairobi.

This objective of this consent form is to provide you with the necessary information concerning the study to help you decide whether you would want to participate in the research. Feel free to ask any questions concerning the study and once your questions have been answered to your satisfaction you may decide whether to participate in the study. The process is called “informed consent”. Once you agree to participate in this study, we shall request that you sign your name on this form. It is voluntary participation and refusal to participate will not affect the healthcare services provided to you.

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

Study

The purpose of the research is to determine the severity of diabetes related emotional distress and its associations at Kenyatta National Hospital.

Procedures

You will be requested to complete a questionnaire and a study proforma. The questionnaire has 20 questions. The questions will include details on your demographics and your personal views on living with diabetes. A blood sample will be drawn to measure glycated hemoglobin level as a measure of blood sugar control.

Confidentiality

All information obtained will be kept confidential and reported as group data without any identifying factors. The information will be stored in a secure location accessible only to those involved in the research.

Compensation

There will be no monetary compensation for participating in the study.

Benefits

The information obtained will be communicated back to the healthcare service providers with the including the HBA1c results.

Risks

Minimal risk on competing the questionnaire. Some discomfort may be experienced on obtaining a blood sample for glycated hemoglobin.

If you have any questions, please feel free to contact me.

Dr. Ciku Nyambura Gacanja

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Dr. Thomas.O. Kwasa

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P.O. Box 30197

Nairobi

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

I confirm that I have received detailed information concerning the above study. I have understood the subject information. I confirm that I have had the opportunity to ask questions and they have been fully answered.

I understand that my participation is voluntary.

I agree to take part in the above study Yes No

Name of participant/patient Date Signature/Thumb stamp

Name of research assistant taking consent Date Signature.

Principal investigator Date Signature

Appendix III: Problem Areas in Diabetes (PAID) Questionnaire (English)

PROBLEM AREAS IN DIABETES (PAID) QUESTIONNAIRE

INSTRUCTIONS: Which of the following diabetes issues are currently a problem for you?
 Circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
1. Not having clear and concrete goals for your diabetes care?.....	0	1	2	3	4
2. Feeling discouraged with your diabetes treatment plan?.....	0	1	2	3	4
3. Feeling scared when you think about living with diabetes?.....	0	1	2	3	4
4. Uncomfortable social situations related to your diabetes care..... (e.g., people telling you what to eat)?	0	1	2	3	4
5. Feelings of deprivation regarding food and meals?.....	0	1	2	3	4
6. Feeling depressed when you think about living with diabetes?.....	0	1	2	3	4
7. Not knowing if your mood or feelings are related to your diabetes? ..	0	1	2	3	4
8. Feeling overwhelmed by your diabetes?.....	0	1	2	3	4
9. Worrying about low blood sugar reactions?.....	0	1	2	3	4
10. Feeling angry when you think about living with diabetes? ..	0	1	2	3	4
11. Feeling constantly concerned about food and eating?.....	0	1	2	3	4
12. Worrying about the future and the possibility of serious complications?.....	0	1	2	3	4
13. Feelings of guilt or anxiety when you get off track with your diabetes management?.....	0	1	2	3	4
14. Not "accepting" your diabetes?.....	0	1	2	3	4
15. Feeling unsatisfied with your diabetes physician?.....	0	1	2	3	4
16. Feeling that diabetes is taking up too much of your mental and physical energy every day?.....	0	1	2	3	4
17. Feeling alone with your diabetes?.....	0	1	2	3	4
18. Feeling that your friends and family are not supportive of your diabetes management efforts?.....	0	1	2	3	4
19. Coping with complications of diabetes?.....	0	1	2	3	4
20. Feeling "burned out" by the constant effort needed to manage diabetes?.....	0	1	2	3	4

PATIENT LABEL

Appendix IV: Problem Areas in Diabetes (PAID) Questionnaire (Swahili)

Hojaji kuhusu sehemu zilizizo na utata katika ugonjwa wa Kisukari

Maagizo: Ni masuala yapi ambayo yanafanya ugonjwa wa kisukari kuwa tatizo kwako? Chagua jibu bora kwa kuliweka kwa duara.

		Sio shida	Shida kidogo	Shida ya wastani	Kwa namna shida kubwa	Shida kubwa
1	Kutokuwa na malengo mazuri kuhusu ugonjwa wako wa sukari?	0	1	2	3	4
2	Kukata tamaa kutokana na mpango wa matibabu yako ya kisukari?	0	1	2	3	4
3	Kushtuka unapofikiria kuwa wewe ni mgonjwa wa kisukari?	0	1	2	3	4
4	Hali za kijamii ambazo hazikusaidii kuhusu matibabu yako ya kisukari?	0	1	2	3	4
5	Kujihisi umefinyiliwa kutokana na chakula au mlo?	0	1	2	3	4
6	Kufikiria sana kuwa una ugonjwa wa kisukari kwa Maisha yako?	0	1	2	3	4
7	Kutojua iwapo hisia zako zinaathiriwa na ugonjwa wako wa kisukari?	0	1	2	3	4
8	Kulemewa na ugonjwa huu wa kisukari?	0	1	2	3	4
9	Kuogopa matokeo ya kiwango cha chini cha kisukari?	0	1	2	3	4
10	Kuwa na hasira unapofikiria kuhusu ugonjwa wa kisukari maishani mwako?	0	1	2	3	4
11	Kila wakati kufikiria kuhusu chakula na kile unachokula?	0	1	2	3	4
12	Kogopa Maisha ya usoni haswa uwezekano wa kutokea kwa matatizo makubwa ya kiafya?	0	1	2	3	4
13	Kujihurumia na kujichukia unapoacha mpago wa kutibu ugonjwa wako wa kisukari?	0	1	2	3	4
14	Kutokubali kuwa unaugua kisukari?	0	1	2	3	4
15	Kutofurahishwa na daktari wako wa kisukari?	0	1	2	3	4
16	Kujisi kuwa ugonjwa wa kisukari unachukua nguvu zako nyingi kiakili na kimwili kila siku?	0	1	2	3	4
17	Kujihisi uko pekee katika ugonjwa huu a kisukali?	0	1	2	3	4
18	Kuhisi kuwa marafiki na familia hawakusaidii katika juhudi zako za kupigana kisukari?	0	1	2	3	4
19	Kupigana na matatizo yatokanayo na kisukari?	0	1	2	3	4
20	Kuishiwa na nguvu kwa sababu ya juhudi za kila mara zinazohitajika kupigana na kisukari?	0	1	2	3	4

Appendix V: KNH/UoN-ERC Letter of Approval