

# **PSYCHOLOGICAL INSULIN RESISTANCE AMONG TYPE 2 DIABETES PATIENTS AT KENYATTA NATIONAL HOSPITAL**

**A dissertation submitted in part fulfilment of the requirements for the degree  
of Master of Medicine in Internal Medicine-University of Nairobi.**

**By:**

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## **DECLARATION**

**I certify that this dissertation is my own original work and has not been presented for a degree at any other university.**

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## **LIST OF ABBREVIATIONS**

ADA	American Diabetes Association
BIT	Barriers to Insulin Treatment
DAWN	Diabetes Attitudes Wishes and Needs Study
DCCT	Diabetes Control and Complications Trial
D-FISQ	The Diabetes Fear of Injecting and Self-Testing Questionnaire
DM	Diabetes Mellitus
DSME	Diabetes Self Management Education
ERC	Ethics and Research Committee
FBG/FPG	Fasting Blood/Plasma Glucose
FST	Fear of Self-Testing
FSI	Fear of Self-Injecting
HBA <sub>1c</sub>	Glycated haemoglobin
HLA	Human Leukocyte Antigen
IDF	International Diabetes Federation
ITAS	Insulin Treatment Appraisal Scale
KNH	Kenyatta National Hospital
MODY	Maturity Onset Diabetes of the Young
NGSP	National Glycohemoglobin Standardization Program
OHA	Oral Hypoglycemic Agent
PIR	Psychological Insulin Resistance

SPI	Survey for People who do not take Insulin
SPSS	Statistical Package for Social Sciences
T2DM	Type 2 Diabetes Mellitus
UKPDS	United Kingdom Prospective Diabetes Study
UoN	University of Nairobi
US	United States
WHO	World Health Organization



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## **ABSTRACT**

**Background:** Type 2 diabetes is progressive and over years the beta cell mass depletes leading to a lack of insulin which is key in glucose homeostasis. This necessitates the introduction of insulin as part of the patient treatment regime in order to realize optimal glycemic control. The initiation and use of Insulin is however marred by Psychological Insulin resistance (PIR) defined as the psychological barriers to initiation and persistence with insulin therapy amongst type 2 Diabetics. The prevalence of PIR among type 2 diabetics is unknown in Kenya.

**Objective:** To determine the prevalence of Psychological Insulin resistance (PIR) among type 2 diabetics attending the Diabetes Clinic at Kenyatta National Hospital (KNH) using the Insulin treatment Appraisal Scale (ITAS) and to correlate PIR with the demographic and clinical factors.

**Design:** Cross-sectional descriptive survey.

**Setting:** Diabetes Outpatient Clinic at KNH.

**Subjects:** A sample size of 167 type 2 diabetics was selected once the inclusion and exclusion criteria were met.

**Methods:** Insulin Treatment Appraisal Scale (ITAS) and a structured questionnaire were used to collect data and were investigator administered. ITAS is a validated tool used to assess the negative and positive attitudes towards insulin therapy on a Likert scale.

The ITAS scores were calculated for each subject with scores of less than 40 representing positive attitudes and scores of above 40 representing negative attitudes. Associations were drawn between the attitudes and the demographic/clinical factors. Logistic regression analysis was done to determine the factors independently associated with negative / positive attitudes towards insulin therapy. The data was analyzed using Statistical Package for Social Sciences (SPSS) version 17.0.

**Results:** One Hundred and Sixty Seven type 2 diabetes patients were studied, 68 males and 99 females with mean age of 55.5 years. Their mean duration of diabetes was found to be 10.2 years. Majority of the patients (55.6%) studied ranged in the 50-69 years age bracket. Positive family history was found in 68 (40.7%) patients. Of the 167 patients; 54(32.3%) were on insulin alone, 42 (25.1%) were on oral hypoglycemic agents and 71 (42.5%) were on both insulin and

oral hypoglycemic agents. The mean ITAS score was 52.7 with the prevalence of Psychological Insulin Resistance at 82.6%. Age, gender, family history of diabetes, duration of diabetes, duration of insulin use and ability to purchase medication did not influence the positive and or negative attitudes towards insulin therapy ( $p>0.05$ ). Insulin naïve and insulin treated patients were analyzed for positive and negative attitudes towards insulin therapy and it was found that those on insulin therapy had lower ITAS scores (50.9 versus 59) reflecting lesser degree of negative attitudes in the latter group ( $p<0.05$ ).

**Conclusion:** The prevalence of psychological insulin resistance among type 2 diabetes patients at Kenyatta National Hospital is high at 82.6%. Patients already on insulin therapy had less psychological resistance as compared to the insulin naïve patients. It is therefore vital to introduce insulin treatment as an option early in Diabetes Self Management education, at diagnosis, to enhance its utility/usefulness/acceptance in the management of Type 2 diabetes.

# INTRODUCTION

The International Diabetes Federation reported that 366 million people had diabetes in 2011 and is expected to rise to 552 million by 2030 (1). Eighty percent of people with diabetes live in low and middle income countries (1). The number of people with diabetes is increasing in every country. In Kenya the prevalence of diabetes is estimated at 4.2% (2). Africa will be the hardest hit by 2030 with the number of people living with diabetes projected to have increased by 90% (Fig.1).

Map: IDF Regions and global projections of the number of people with diabetes (20-79 years), 2011 and 2030

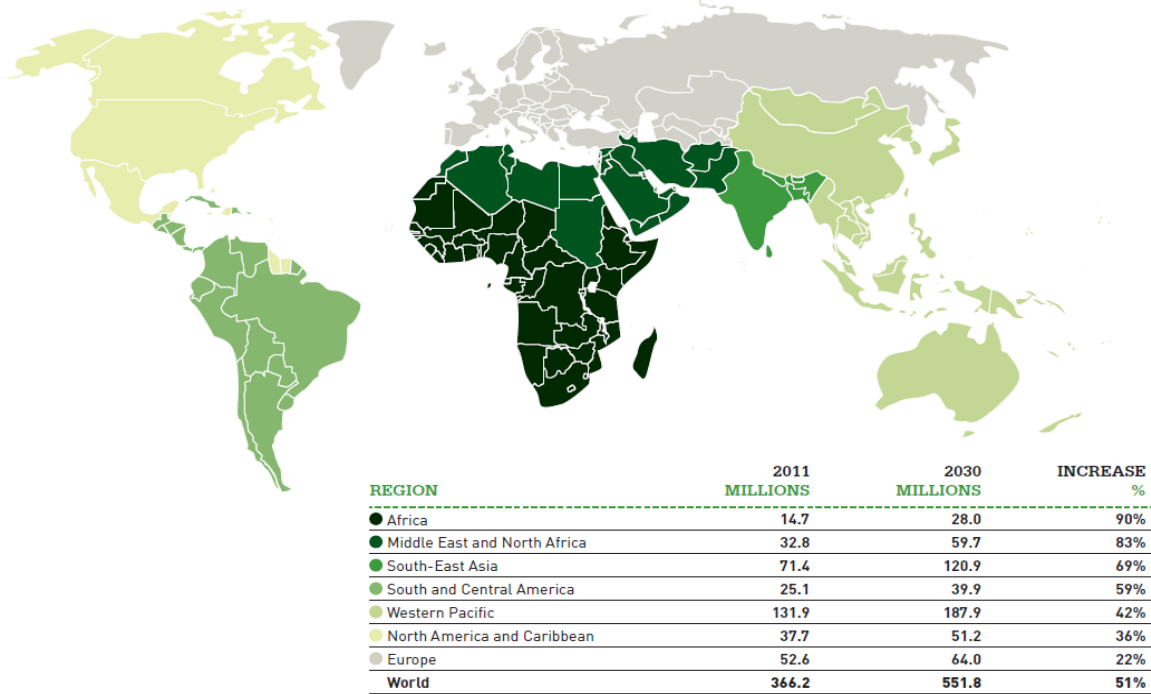


Figure 1: Representing the rising prevalence of diabetes across the globe

In 2012, 4.8 million people died and 471 billion United States (US) Dollars were spent due to diabetes. Looking at diabetes deaths against spending for diabetes care shows us the impact of a lack of investment very starkly. In countries where very little is spent on diabetes, the rate of death is almost double that in high-income countries where the vast majority of money for diabetes is spent (Fig.2).

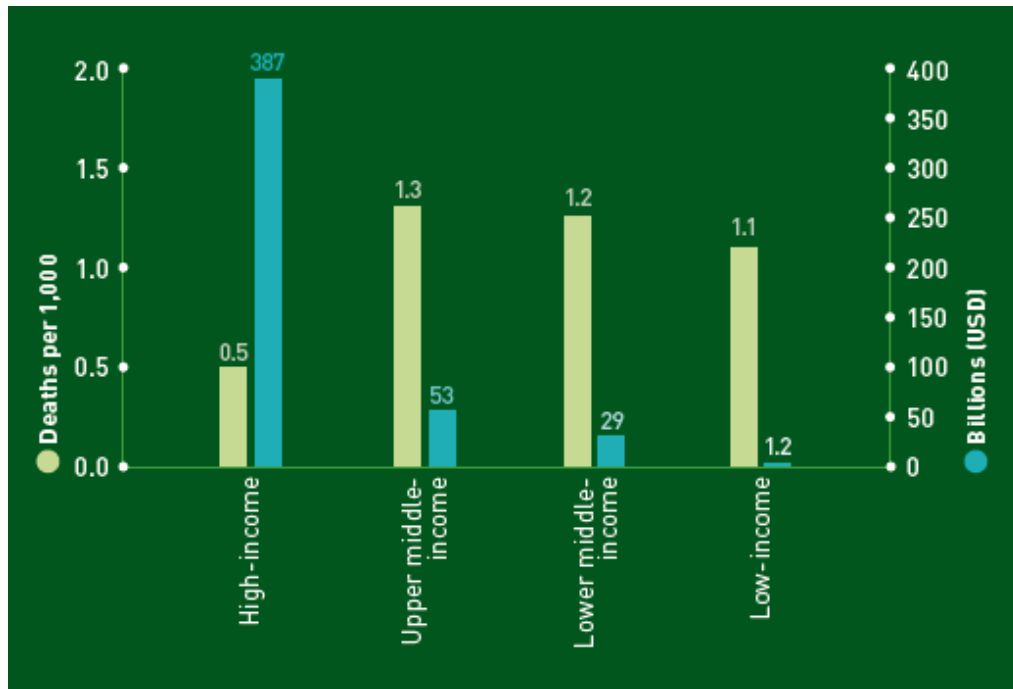


Fig.2: Health care expenditures and deaths per 1000 due to diabetes per income group (1).

The healthcare expenditures measure includes medical spending on diabetes by the health system as well as by people with diabetes.

It does not include the indirect costs to society from lost productivity, absence from work, and the associated costs of care. In other words, this is a big underestimate of the true cost of diabetes.

Glycemic targets in type 2 diabetes patients is a global challenge as its achievement revolves around the roles of both the patient and the health care providers. Despite the use of anti-diabetic medications including insulin therapy, acceptable or recommended glycemic targets are hardly achieved in good proportions in both developing and developed countries. This eventually leads to increased complications such as cardiovascular disease, diabetic nephropathy, retinopathy, neuropathy etc.

Salim Rashid et al (3) reported that 70% of their study patients had HBA<sub>1</sub>C of  $\geq 8\%$ , of these 42% of patients had HBA<sub>1</sub>C  $\geq 10\%$ . From his study it was apparent that majority of our diabetic

patients are not well controlled and therefore it is necessary to investigate factors associated with poor glycaemic controls.

An earlier study of 2001 on Cardiovascular risk factors in type 2 diabetes attending KNH, found out that the mean glycosylated haemoglobin level (HbA<sub>1c</sub>) of patients studied was 8.8%; 70.1% of these patients had HbA<sub>1c</sub> of more than 7.0%, while the mean fasting blood glucose (FBG) was 9.4 mmol/l, with 88 patients (81.5%) having FBG of more than 6.0 mmol/l (4).

The Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) have pointed to the importance of intensive blood glucose control in reducing its associated morbidity. In fact, the UKPDS, the largest and longest trial ever conducted in patients with type 2 diabetes, found that for each 1% reduction in HbA<sub>1c</sub>, there was a 21% decrease in any endpoint related to diabetes and in diabetes-related death, a 14% decrease in all-cause mortality and myocardial infarction, a 43% decrease in amputation or death from peripheral vascular disease, and a 37% decreased risk for microvascular complications, each of which was statistically significant (5,6).

The Japanese Kumamoto study also found that intensive glycaemic control reduced the risk for retinopathy, nephropathy, and neuropathy in patients with type 2 diabetes (7). Although sulfonylurea therapy has been the mainstay of treatment for type 2 diabetes for more than 40 years, the UKPDS (6) reported that over a 6-year period, about 53% of patients who were randomized to receive treatment with sulfonylureas needed additional insulin therapy, reinforcing the concept that hyperglycemia in type 2 diabetes is progressive.

It is known that most type 2 diabetics will eventually require insulin therapy several years after diagnosis in order to control their blood sugars. However, the initiation of insulin and its use is marred by psychological insulin resistance (refers to psychological barriers to initiation and persistence with insulin therapy).

In Kenya most studies have looked at complications of diabetes however focus on the use of insulin therapy –the knowledge, attitudes and practices amongst patients with type 2 Diabetes have not been studied.

Disability related to complications of diabetes affects the nation's productivity and therefore the policy makers in Kenya can use the findings of this research to identify the gaps in the attainment of optimum glycemic controls with the use of insulin therapy when oral hypoglycemic agents (OHA) have failed.

## **LITERATURE REVIEW**

### **NATURAL HISTORY OF TYPE 2 DIABETES**

The development of Type 2 diabetes can be viewed as a continuum that progresses from an early asymptomatic stage with insulin resistance to mild postprandial hyperglycemia to frank diabetes requiring pharmacological intervention. A triad of metabolic defects characterize type 2 diabetes: insulin resistance, nonautoimmune – Beta cell dysfunction, and inappropriately increased Hepatic Glucose Production (HGP).

The primary and earliest pathogenic lesion is insulin resistance, and the beta-cell is able to compensate for a variable length of time by secreting supraphysiological amounts of insulin. IGT is characterized by insulin resistance, compensatory hyperinsulinemia, and mild postprandial hyperglycemia. Over time, however, the beta-cell begins to fail, and as relative insulin deficiency occurs, fasting hyperglycemia and full-blown type 2 diabetes develop. In addition, as insulin levels fall, the inhibitory effect of insulin on HGP decreases and significant fasting hyperglycemia develops. Further progression of the disease is marked by an absolute insulin deficiency. Obesity, aging, weight gain in adulthood, and physical inactivity are some of the environmental factors that affect the natural history of diabetes, affecting its progression at all points in the continuum.

The treatment options vary across the continuum of diabetes with oral agents being able to control blood glucose in the early stages but subsequently, when absolute insulin deficiency occurs, exogenous insulin is required.

### **INSULIN THERAPY IN TYPE 2 DIABETES**

Beta-cell failure continues at a rate of about 4 percent each year (8). Therefore, patients with type 2 diabetes often benefit from insulin therapy at some point after diagnosis.

Intensive glycemic control is vital to prevent microvascular and macrovascular complications as emphasized in the Diabetes Control and Complications Trial (5) and the U.K. Prospective Diabetes Study (6). This can only be achieved if diabetes patients are staged as per the continuum of diabetes disease process and appropriate medications prescribed, with those who are insulin deficient being put on insulin therapy in a timely manner.

The American College of Endocrinology and the American Association of Clinical Endocrinologists recommend initiation of insulin therapy in patients with type 2 diabetes and an initial A1C level greater than 9 percent, or if the diabetes is uncontrolled despite optimal oral glycemic therapy (9). Insulin may be used alone or in combination with oral medications, such as metformin. This recommendation is however based on expert opinion, and not on the results of randomized controlled trials comparing different approaches in patients with an initial A1C level greater than 9 percent.



## **PSYCHOLOGICAL INSULIN RESISTANCE**

### **Introduction**

Psychological insulin resistance (PIR) refers to psychological barriers to initiation and persistence with insulin therapy.

This concept is defined in studies mostly as a diabetes management obstacle influenced by psychological factors (cognitive, emotional, relational, and cultural) and not as a psychological disorder (10).

By preventing patients from taking the insulin they need, PIR can cause patients' glycaemic levels to rise beyond recommended targets, that put patients at risk for developing complications which can in turn reduce their quality of life and increase societal burden (11). A cost analysis of patients who started insulin therapy showed that health care costs initially increased by 10%, but that expenditures were reduced by 40% in the following nine months (12).

### **Factors associated with PIR**

Insulin therapy in type 2 diabetes is associated with numerous negative connotations. These broadly include a sense of loss of control over one's life, a sense of personal failure to control their diabetes, fear of insulin use as regards needle phobia, weight gain and hypoglycemia. Furthermore, patients may face social stigma and self pity as they perceive insulin therapy would make them appear sicker before family, friends and colleagues. Misconceptions of dependence on insulin akin to injection drug abusers also hinder the initiation and use of insulin.

The Diabetes Attitudes Wishes and Needs (DAWN) study revealed that psychosocial barriers to the use of effective therapy, such as insulin, is widespread and common across countries. Among the 2,061 type 2 diabetes patients who were not using insulin, 57% were very worried about starting insulin therapy, 48% would blame themselves for having failed to manage their diabetes adequately if they were told they needed to begin insulin therapy, and only 27% believed that insulin could help them manage their diabetes better. Half of the diabetes physicians reported that they used insulin as a threat to encourage their patients to follow their existing diabetes treatment plan; which may contribute to the problem of self-blame. Diabetes physicians were generally not aware of the magnitude of the problem of self-blame associated with progression of the disease and initiation of insulin therapy (13).

Polonosky et al reported in his survey of insulin-naïve patients with type 2 diabetes that 28.2% of respondents would be unwilling to take insulin if it were prescribed (13). Interestingly, patients from ethnic minorities were significantly more likely to be unwilling to take insulin than were non-Hispanic whites (35.1% vs 22.4%).<sup>5</sup> Women also were significantly more likely to refuse insulin than were men (13). Clearly, psychological insulin resistance is common across demographic subgroups.

Karter et al (14) reported that subjects failing to initiate prescribed insulin commonly reported misconceptions regarding insulin risk (35% believed that insulin causes blindness, renal failure, amputations, heart attacks, strokes, or early death). These participants had planned to instead work harder on behavioral goals, sense of personal failure and low self-efficacy.

Norbert et al in his study (15) reported that a negative appraisal of insulin treatment is modifiable by the initiation of insulin therapy. He further reported that the findings of his study indicate that barriers to insulin are a rather temporary than a stable phenomenon.

In Kenya, no studies have been carried out on Psychological insulin resistance and therefore the need to have one done is crucial so as to address patient concerns on insulin therapy.

### **Tools used to measure PIR**

1. Insulin Treatment Appraisal Scale (ITAS) - A validated tool that was developed to capture the T2DM patient's current appraisal of insulin therapy and assesses both positive and negative attitudes (16). It comprises 4 positive and 16 negative statements regarding insulin therapy. Participants are asked to indicate on a 5-point Likert scale to what extent he or she agrees with each statement, from 1 "strongly disagree" to 5 "strongly agree".

Scores can range from 20 to 100. Lower scores represent more positive attitudes and beliefs about insulin therapy.

Each of the ITAS statements are also analyzed and grouped into the 5 domains of PIR captured by the ITAS tool as shown in table 1 below:

DOMAIN OF PIR	STATEMENTS OF <i>ITAS</i> ADDRESSING THE DOMAIN.
Perceived personal blame	1 & 2
Fear	6,7,9,12,14.
Self pity/ social stigma	4,18,13
Perceived loss of control	5,10,11,15,16
Dependence	20

2. The Barriers to Insulin Treatment (BIT) Questionnaire – A validated easily interpretable 14 item questionnaire that is grouped into 5 components (17). These components are used to define the following subscales: fear of injection and self-testing, expectations regarding positive insulin-related outcomes, expected hardship from insulin treatment, stigmatization by insulin injections, and fear of hypoglycemia. In addition, an overall sum score of all values is calculated in order to summarize the 14 items of the BIT Questionnaire in a single score. The subscales of the BIT Questionnaire address a wide range of the most important psychological barriers to insulin treatment.
  3. The Survey for People who do not take Insulin (SPI) - is a questionnaire designed to identify reasons why people are reluctant to start insulin, including risk of side effects or complications and changes in lifestyle (18).
  4. The Diabetes Fear of Injecting and Self-Testing Questionnaire (D-FISQ) - is a 30-item self-report questionnaire consisting of two subscales that measure fear of self-injecting insulin (FSI) and fear of self-testing (FST), the latter measuring fear of blood glucose testing (19).
- No studies have been done on PIR in Kenya and therefore the aforementioned tools used to measure PIR have not been validated in Kenya. The ITAS tool was used in the study as it captures the patients' concerns on Insulin therapy and it can be administered to both Insulin naïve as well as to Insulin treated patients (16). The ITAS tool was adopted & adapted through translation into Kiswahili for ease of administration to our study patients.

### **Strategies for reducing PIR**

Studies on PIR have recommended guidelines on overcoming it (20, 21, 22). However, none of these strategies have been tested in a longitudinal manner to check on their effectiveness.

Patient education is vital and it includes teaching patients on the natural history of diabetes and introducing the the concept of insulin use from the onset. The progressive nature of diabetes

should be stressed and the complications associated with poor glycemic control. Patient Education should be tailored to address concerns regarding hypoglycemia, weight gain and misconceptions with insulin therapy.

Psychological techniques can also be used to overcome PIR (21,22). These include desensitizing the patient against insulin use by exposing them to an insulin injection under medical supervision. Motivational interviewing with success stories of diabetes patient on insulin can also be employed.

## **STUDY JUSTIFICATION**

Type 2 diabetes is a progressive disease with eventual pancreatic beta cell failure therefore necessitating insulin therapy.

By preventing patients from taking the insulin they need, PIR can cause patients' glycemia levels to fall beyond recommended targets, and can put patients at risk for developing complications which can in turn reduce their quality of life and increase societal burden. At Kenyatta National Hospital previous studies (3, 4) have shown that type 2 diabetes patients have poor glycemic control and develop complications early into their diagnosis.

There is no local data on the prevalence of Psychological Insulin resistance amongst our diabetic population. Most data on PIR emanates from the developed world and this might not directly reflect on our situation due to major socio-cultural, economic and environmental differences.

This study was designed to determine the prevalence of PIR amongst type 2 diabetics and to correlate with clinical and demographic factors. The data generated from this study will therefore establish the magnitude of PIR and assist health care providers in addressing patients' concern to the initiation and use of insulin therapy amongst type 2 diabetics with a view of achieving optimum glycemic controls when oral hypoglycaemic agents have failed to control blood sugars effectively. Patients' apprehensions on insulin therapy need to be identified and Diabetes Self Management Education (DSME) focussed on these concerns.

## **BROAD OBJECTIVE**

- To determine the prevalence of psychological insulin resistance and to correlate it with demographic and clinical factors amongst Type 2 diabetes patients attending DM clinic at KNH.

## **SPECIFIC OBJECTIVE**

- ✓ To determine the prevalence of Psychological Insulin Resistance amongst Type 2 diabetes patients attending the Diabetes clinic at KNH using the ITAS Tool.

## **SECONDARY OBJECTIVE**

- ✚ To correlate demographic and clinical factors with PIR amongst Type 2 diabetes patients attending the Diabetes clinic at KNH.

## **METHODOLOGY**

### **Study site**

This study was conducted at the Diabetes Clinic of Kenyatta National Hospital. Kenyatta National Hospital is a tertiary (level VI) and national referral hospital situated in the Nairobi City County. It also facilitates medical training and thus serves as a teaching hospital for University of Nairobi (UoN) College of Health Sciences and Kenya Medical Training College (KMTC).

The hospital runs a number of specialized clinics including the Diabetes Clinic. The Diabetes Clinic runs throughout the week from Monday to Friday from 8am to 5pm. There are two types of clinics; the Mini-clinic which operates from Monday to Thursday while the major Diabetes Clinic operates every Friday. The major clinic serves an average of 120 patients and is run by Consultant Diabetologists and postgraduate students in Internal Medicine, while the Mini-clinic attends to 50 patients per day and is run by Clinical Officers. Other medical health care professionals that assist in running the clinic are nutritionists, diabetic nurses and foot care specialist nurses.

The patients with diabetes attending the clinic are from Nairobi County, neighboring counties and those referred for specialized treatment from across the country.

The clinic sees booked patients on a first come first served basis. Patients booked for the day are assigned numbers serially and in chronological order as they report to the clinic by the triage nurse. The patients' files are retrieved by a nurse from the records office which is located in the clinic. The retrieved files are kept at the nursing desk. Using the numbers assigned patients go to pay for the services, that is, consultation fee and blood sugar testing. Once payment has been made, the patients proceed to the biochemistry laboratory for blood sugar testing. With the recorded blood sugar levels, the patients return to the Diabetes Clinic where vital signs are taken and recorded in the patients' file. After vital signs have been taken, the patients (with their files) are either directed to the clinician or to the foot care specialist nurse for wound dressing (if required). The Clinician or the foot care specialist might refer some of the patient to the nutritionist when the need arises. Some patients, after wound dressing might be referred to see the clinician. The clinician can also refer some patients to the diabetic foot care specialist nurse.

Once the patient has been attended to, he/she books at the records office his/her next visit and proceeds to the pharmacy to buy medication (if any was prescribed) and leaves the hospital.

### **Study design**

Descriptive Cross-Sectional study.

### **Study population**

Type 2 diabetes patients attending routine care in the Diabetes Clinic.

### **Inclusion criteria:**

- 1) Patients with confirmed file diagnosis of type 2 diabetes based on the following American Diabetes Association criteria 2013(Appendix 1).
- 2) Age at diagnosis of Diabetes  $\geq$  25 Years.
- 3) Patients who can communicate in English or Kiswahili.

### **Exclusion criteria:**

1. Patients on follow up for any psychiatric illness and dementia.  
Psychiatric illness was defined as a medical condition that is characterised by a significant disturbance of thought, mood, perception or memory and therefore making it difficult for such a patient to participate in the study which entails obtaining accurate responses to the ITAS tool and the structured questionnaire.
2. Patients with type 1 Diabetes mellitus.

## Sample size determination

Using the Cochran formula (1977) to calculate the sample size

$N = z^2 pq / d^2$  where:

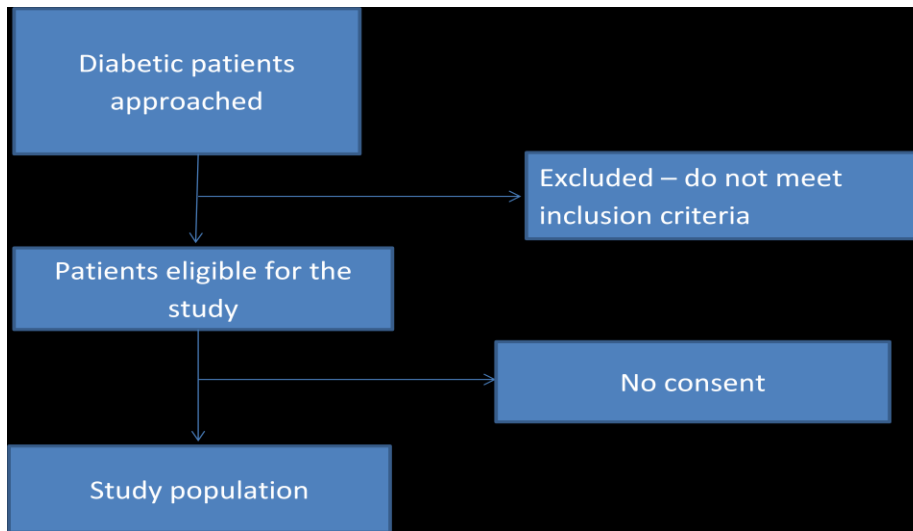
- **N**= required sample size of Type 2 Diabetes patients
- **z** = confidence level at 95% (standard value of 1.96)
- **p** = Proportion of patients having apprehension of using insulin (57%) *\*based on the DAWN study\**
- **d** = margin of error at 7.5% (standard value of 0.075)
- The minimum sample size required was **167** type 2 diabetic patients

## SAMPLING PROCEDURE

- Once all approvals were in place systematic random sampling procedure was used to select and enrol the study participants from all type 2 diabetes patients coming to the clinic for routine follow up.
- The list of patients registered for the day formed a sampling frame for drawing a study sample.
- The hospital has a Diabetes Clinic that runs throughout the week from Monday to Friday with a major Diabetes Clinic every Friday.
- The Major Clinic serves an average 120 patients per week while the Mini-clinic attends to about 50 patients per day.
- Approximately 40 patients were enrolled per week and were distributed equally across the days of the week (8 patients per day).
- Based on the systematic random sampling, every 6th patient was selected into the study on Monday to Friday clinic days.



Figure 3: *Patient Recruitment flow chart*



Recruitment took place at the Diabetes Clinic of Kenyatta National Hospital as shown in figure 3 above.

All files of the patients booked for that day of clinic were checked at the nursing desk by the Principal Investigator or his assistants with the help of the nurse stationed at the desk.

Those patients whose medical records showed that they have type 2 DM were listed chronologically as they registered for the clinic by the Principal investigator or his assistants helped by the nurse at the nursing desk.

Every sixth patient in the diabetes clinic list was identified by the Principal Investigator or his research assistants.

Those patients identified for participation, after vital signs are taken, and could speak English or Kiswahili, were introduced to the Principal Investigator or his assistants by the nurse taking vital signs.

The Principal investigator or his assistants took the identified patients, one at a time, to one of the consultation rooms which was designated for interview and to offer privacy.

The Principal investigator or his assistants introduced themselves, explained the study and requested the patients to voluntarily participate in the study.

Once the patient agreed to participate, he/she gave a written consent by signing the consent form (Appendix 2 & 3).

### **DATA COLLECTION PROCEDURE**

Data collection was done by the principal investigator, assisted by trained research assistants once consent had been sought.

The patients enrolled in the study were interviewed using a structured questionnaire and a standard validated tool called Insulin Treatment Appraisal Scale (ITAS) to collect data on insulin therapy in type 2 diabetes (Appendices 4-7). Both the questionnaire and the ITAS tool were interviewer administered.

Medical information was also retrieved from the medical records, which included patient's file and diabetic diary which all patients in the diabetic clinic possessed. Medical records also helped in correlating information given by participants to minimize on recall bias.

The daily log of patient numbers with the name and the study number assigned to each patient enrolled were kept to countercheck when doing subsequent interviews to avoid double enrolment.

The Principal Investigator (PI) and his assistants ensured the data collected was of high quality by checking through the questionnaire immediately after every interview, before the study participant left the hospital.

Any missing or unclear response on the questions were corrected by requesting the patient for additional time to clarify the responses.

## **STUDY VARIABLES** (Appendix 4 & 5)

- Age
- Sex
- Family history of DM
- Level of formal education
- Duration of Diabetes
- DM Medication
- Duration of Insulin use
- Ability to purchase medication

## **DATA MANAGEMENT**

- ✓ Data collected during the study was entered into computerized data entry sheets.
- ✓ The data did not bear the names of the participants.
- ✓ Serial numbers were used.

## **DATA ANALYSIS**

- Statistical analysis was done using statistical package for social scientists (SPSS) version 17.0.
- Continuous data such as age and duration of diabetes was presented as means, standard deviations and medians.
- After analysis, data was presented in the form of tables, pie-charts and graphs.
- The 20 point (4 positive and 16 Negative statements) ITAS scores calculated with the four positive statements being reverse-scored before totalling. Scores can range from 20 to 100. Lower scores represent more positive attitudes and beliefs about insulin therapy.  
Analysis of the ITAS score:
  - Patients were categorized into those with predominantly positive and/ negative attitudes:
    - Scores of 40 and below representing positive attitudes.
    - Scores above 40 representing negative attitudes.
  - Each of the ITAS statements were also analyzed and grouped into the 5 domains of PIR captured by the ITAS tool i.e. Perceived personal blame, fear, self pity/social stigma, Perceived loss of control and dependence.

- Mean Age and duration of diabetes was compared between patients with positive and negative attitudes using Student's t-test.
- Also, age (<40, 41-50, 51-60, >60 years) and duration of diabetes (10 year intervals) were categorized and associated with attitudes using Chi square test.
- Gender, education levels, family history of DM, DM medications used and ability to purchase drugs were associated with attitudes using Chi-square test.

Multivariate Analysis:

- Logistic regression analysis was done to determine the factors independently associated with negative / positive attitudes towards insulin therapy.
- Odds ratios were presented to show the likelihood of associations between variables.

\*All statistical tests will be performed at 5% level of significance (95% confidence interval). \*

## **QUALITY ASSURANCE**

- The research assistants underwent training.
- Filled questionnaires were checked by the PI and research assistant to minimize errors before data entry.

## **ETHICAL CONSIDERATIONS**

Consent was obtained from the study participants before administering the questionnaire and ITAS Tool. The consent form contained a signature form for the participant and witnesses. The witness signed and dated the consent form attesting that the requirements for informed consent have been satisfied; that the consent was voluntary and freely given by the participant without coercion.

The research assistants and the principal investigator were introduced to the patient by the primary nurse attending to the patient. The principal investigator and research assistants informed the patient on the objectives of the study and the patient was asked to voluntarily participate by providing an informed consent.

Information on the Principal Investigator and the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee (KNH/UoN ERC) and their telephone numbers were availed to the patients in case they needed to contact them at any given time.

All interviews were conducted in private and confidentiality maintained throughout the study. Data was de-identified. The participants were assured of confidentiality and informed that their names were not going to be used.

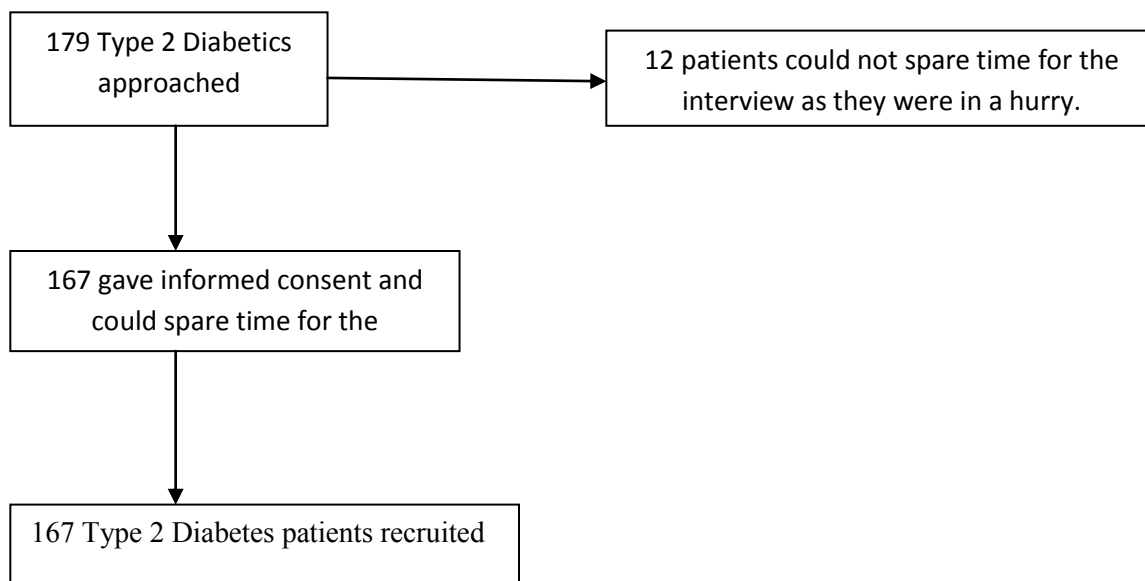
No drug was administered and no procedures were undertaken. Also no specimen was collected from the participants.

This study was conducted following the approval of the KNH/UoN Ethics and Research Committee.

## RESULTS

A total of 167 Type 2 diabetes patients who met the eligibility criteria were enrolled into the study between March 2014 and April 2014. Of the 179 type 2 diabetes patients approached, 12 patients could not spare time for the interview as they were in a hurry. The remaining 167 patients fulfilled the inclusion criteria and gave informed consent. Figure 4 below represents the flow of patients.

**Figure 4: Patient flow chart**



**Table 2: Socio-demographic characteristics of the study population**

<b>Variable</b>	<b>Frequency (%)</b>
<b>Age (years)</b>	
Mean (SD)	55.5 (13.8)
Median (IQR)	56 (48-64)
Min-Max	30-84
<b>Age categories, n (%)</b>	
Below 40	22 (13.2)
40-49	29 (17.4)
50-59	47 (28.1)
60-69	46 (27.5)
70 and above	23 (13.8)
<b>Sex</b>	
Male	68 (40.7)
Female	99 (59.3)

Table 2 above represents the socio-demographic characteristics of the study population. The mean age of the study population was 55.5 years. Male to female ratio was 0.69:1. The age range of the sample was between 30-84 years. Majority of the patients (55.6%) studied were between 50-69 years of age.

**Table 3: Clinical characteristics of the study participants**

<b>Variable</b>	<b>Frequency (%)</b>
<b>Duration of diabetes in Years</b>	
Mean (SD)	10.2 (8.7)
Median (IQR)	8 (3-16)
Min-Max	0-49
<b>Duration categories in years, n (%)</b>	
0-9	93 (55.7)
10-19	47 (28.1)
20-29	23 (13.8)
30 and above	4 (2.4)
<b>DM Medication used</b>	
Insulin only	54 (32.3)
OHA only	42 (25.1)
Both -Insulin & OHA	71 (42.5)
<b>Duration of insulin use in years</b>	
Median (IQR)	5.0 (1.0-11.0)
Min-Max	<1 – 27
<b>Ability to purchase DM Medication</b>	
Self	115 (68.9)
Relative	47 (28.1)
Friend	1 (0.6)
No means	4 (2.4)
<b>Family history of DM</b>	
Yes	68 (40.7)
No	99 (59.3)

Table 3 above represents the clinical characteristics of the study population. The mean duration of type 2 diabetes was noted to be 10.2 years with a range of between 3 months to 49 years. Majority of the patients (55.7%) studied were living with diabetes for the past 0-9 years while 2.4% had lived with diabetes for 30 years and above.

Majority of patients (42.5%) were noted to be on both Insulin and Oral Hypoglycemic agents (OHA) followed by those on only insulin at 32.3 %. 25.1% of the patients were on OHA alone.

Those on Insulin therapy had used insulin ranging from <1 to 27 years. It was noted that a majority of patients (68.9%) could afford their medication. 28.1 % are assisted by a relative to purchase their medication.

Of the 167 study subjects with type 2 diabetes, 40.7% reported a positive family history of diabetes.



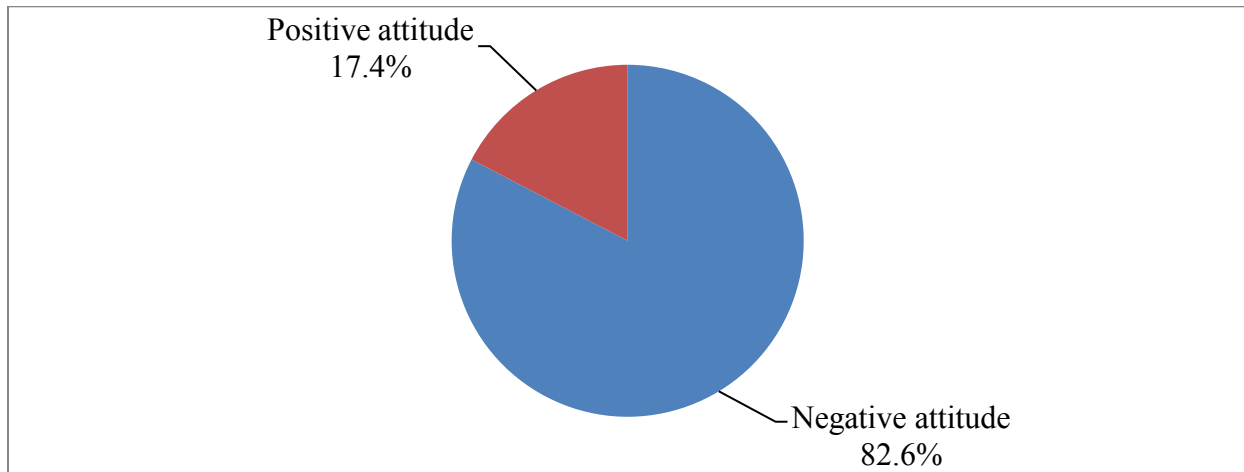
**Table 4: Psychological insulin resistance using ITAS score for the study subjects**

Variable	
<b>ITAS score</b>	
Mean (SD)	52.7 (13.1)
Median (IQR)	51 (43-61)
<b>ITAS category, n (%)</b>	
Negative attitude	138 (82.6)
Positive attitude	29 (17.4)

Table 4 above shows the ITAS Scores for the study population.

The mean ITAS score for the study population is 52.7 as represented in table 5 above. The prevalence of Psychological Insulin Resistance noted to be at 82.6% (figure 5 below).

**Figure 5: Psychological insulin resistance (ITAS score)**



**Table 5: Insulin Treatment Appraisal Scores (ITAS) for the study participants**

Question		Strongly Disagree	Disagree	Agee nor Disagree	Agree	Strongly Agree	Mean	
Q1	Taking insulin means I have failed to manage my diabetes with diet and tablets	n	22	34	9	43	59	3.5
		%	13.2	20.4	5.4	25.7	35.3	
Q2	Taking insulin means my diabetes has become much worse	n	28	45	10	33	51	3.2
		%	16.8	26.9	6.0	19.8	30.5	
Q3	Taking insulin helps to prevent complications of diabetes	n	7	7	16	57	80	1.8
		%	4.2	4.2	9.6	34.1	47.9	
Q4	Taking insulin means other people see me as a sick person	n	51	39	7	38	31	2.8
		%	30.7	23.5	4.2	22.9	18.7	
Q5	Taking insulin makes life less flexible	n	38	40	11	47	30	2.9
		%	22.9	24.1	6.6	28.3	18.1	
Q6	I'm afraid of injecting myself with a needle	n	57	46	6	33	22	2.5
		%	34.8	28.0	3.7	20.1	13.4	
Q7	Taking insulin increases the risk of low blood glucose levels (hypoglycaemia)	n	25	45	18	51	27	3.1
		%	15.1	27.1	10.8	30.7	16.3	
Q8	Taking insulin helps to improve my health	n	10	21	10	55	71	2.1
		%	6.0	12.6	6.0	32.9	42.5	
Q9	Insulin causes weight gain	n	28	47	33	27	31	2.9
		%	16.9	28.3	19.9	16.3	18.7	
Q10	Managing insulin injection takes a lot of time and energy	n	43	59	16	28	20	2.5
		%	25.9	35.5	9.6	16.9	12.0	
Q11	Taking insulin means I have to give up activities I enjoy	n	54	53	7	25	27	2.5
		%	32.5	31.9	4.2	15.1	16.3	
Q12	Taking insulin means my health will deteriorate	n	74	54	10	13	16	2.1
		%	44.3	32.3	6.0	7.8	9.6	
Q13	Injecting insulin is embarrassing	n	60	43	17	24	23	2.4
		%	35.9	25.7	10.2	14.4	13.8	
Q14	Injecting insulin is painful	n	44	38	11	46	28	2.9
		%	26.3	22.8	6.6	27.5	16.8	
Q15	It is difficult to inject the right amount of insulin correctly at the right time every day	n	43	49	6	35	33	2.8
		%	25.9	29.5	3.6	21.1	19.9	
Q16	Taking insulin makes it more difficult to fulfil my responsibilities (at work, at home)	n	55	61	8	21	20	2.3
		%	33.3	37.0	4.8	12.7	12.1	
Q17	Taking insulin helps to maintain good control of blood glucose	n	6	13	8	57	83	1.8
		%	3.6	7.8	4.8	34.1	49.7	
Q18	Being on insulin causes family and friends to be more concerned about me	n	28	32	10	54	43	3.3
		%	16.8	19.2	6.0	32.3	25.7	
Q19	Taking insulin helps to improve my energy level	n	16	13	16	70	52	2.2
		%	9.6	7.8	9.6	41.9	31.1	
Q20	Taking insulin makes me more dependent on my doctor	n	25	43	7	46	46	3.3
		%	15.0	25.7	4.2	27.5	27.5	

*\*Highlighted statements represent the positive attitudes\**

Table 5 represents the scores for each of the 20 questions. The highlighted 4 positive statements were reverse scored before analysis.

Results of each of the ITAS statements were grouped into the various domains of Psychological insulin resistance as follows:

✓ **Perceived Personal blame**

1. 61% believed that taking insulin means that they had failed to manage their diabetes with diet and tablets.
2. 43.7% believed that taking insulin means their diabetes has become much worse.

✓ **Fear**

1. Injection phobia was noted in 33.5 % of the patients studied.
2. 47% cited risk of hypoglycemia with insulin therapy.
3. 35% cited weight gain with Insulin use.
4. 17.4 % believed that their health will deteriorate with insulin use.
5. 44.3% believed that Insulin injections were painful.

✓ **Self Pity/Social stigma**

1. 41.3% believed Insulin use will make other people see them as more sick.
2. 28.2% believed injecting insulin is embarrassing.
3. 58% believed that being on Insulin causes family and friends to be more concerned about them.

✓ **Perceived Loss of Control**

1. 46.4% believed Insulin makes life less flexible.
2. 28.9% believed that insulin use takes a lot of time and energy.
3. 31.4% believed that they would have to give up activities that they enjoy.
4. Injecting the correct amount of Insulin everyday was noted to be a problem with 40.7%.
5. 24.8% believe that insulin use makes it more difficult to fulfill responsibilities.

✓ **Dependence**

1. Insulin use was associated with more dependence on their doctor in 55%.

**Table 6a: Factors associated with psychological insulin resistance in the study subjects**

Variable	Attitude		OR (95% CI)	P value
	Negative	Positive		
<b>Age</b> Mean (SD)	54.8 (14.1)	59.0 (11.5)	-	0.163
<b>Categories</b> 40 and below	24 (92.3)	2 (7.7)	4.1 (0.9-19.2)	0.059
41-50	26 (81.3)	6 (18.8)	1.5 (0.5-4.2)	0.468
51-60	41 (89.1)	5 (10.9)	2.8 (0.9-8.3)	0.058
Above 60	47 (74.6)	16 (25.4)	1.0	
<b>Gender</b> Male	57 (83.8)	11 (16.2)	1.2 (0.5-2.6)	0.737
Female	81 (81.8)	18 (18.2)	1.0	
<b>Family history</b> Yes	82 (82.8)	17 (17.2)	1.0 (0.5-2.3)	0.936
No	56 (82.4)	12 (17.6)	1.0	
<b>Duration of DM</b> Median (IQR)	8 (3-15)	10.5 (6-19)	-	0.069
<b>Categories</b> 0-9	80 (86.0)	13 (14.0)	1.8 (0.6-5.2)	0.302
10-19	38 (82.6)	8 (17.4)	1.4 (0.4-4.4)	0.613
20 and above	21 (77.8)	6 (22.2)	1.0	
<b>DM medication used</b> Insulin	98 (78.4)	27 (21.6)	1.0	
OHA	40 (95.2)	2 (4.8)	5.5 (1.3-24.3)	<b>0.013</b>
<b>Duration of insulin</b> 5 and below	77 (84.6)	14 (15.4)	1.3 (0.5-3.4)	0.597
6-10	28 (81.6)	6 (18.4)	1.1 (0.3-3.5)	0.876
Above 10	34 (80.3)	8 (19.7)	1.0	
<b>Ability to purchase DM medication</b> Self	94 (81.7)	21 (18.3)	1.0	
Other	42 (84.0)	8 (16.0)	1.2 (0.5-2.9)	0.726

Table 6a above shows the factors associated with psychological insulin resistance in the study population. The associated factors are discussed below:

### **Age and gender**

Age of the patients was not significantly associated with psychological insulin resistance ( $p>0.05$ ) though there was a higher chance of younger patients exhibiting negative attitude towards insulin compared to those who were above 60 years – this finding however was not statistically significant ( $p=0.059$ ). Both genders showed similar attitude towards insulin ( $p=0.737$ ).

### Family history and duration of diabetes

Family history and the duration of diabetes had no significant influence on patients' attitude towards insulin. Both groups of patients with family history and those without a history exhibited similar levels of attitudes ( $p=0.936$ ). Though a lower proportion (77.8%) of patients in 20 years and above duration category had negative attitude compared to >80% among those who had had diabetes for less than 20 years, this was not statistically significant ( $p>0.05$ ).

### DM medications

A higher proportion (95.2%) of patients using OHA had negative attitude compared to 78.4% of those using insulin, OR 5.5 (1.3-24.3),  $p=0.013$ . Duration of insulin use was not associated with psychological insulin resistance ( $p>0.05$ ). Similarly, ability to purchase medications was not associated with psychological insulin resistance ( $p=0.726$ ).

**Table 6b: Factors associated with psychological insulin resistance in the study subjects**

Variable	ITAS score, mean (SD)	P value
<b>Age categories</b>		
40 and below	54.4 (10.7)	0.075
41-50	53.7 (14.4)	
51-60	56.1 (14.6)	
Above 60	49.7 (12.0)	
<b>Gender</b>		
Male	53.2 (13.9)	0.825
Female	52.8 (12.8)	
<b>Family history</b>		
No	53.4 (13.4)	0.607
Yes	52.3 (13.0)	
<b>Duration of DM</b>		
0-9	54.8 (13.6)	0.181
10-19	50.7 (12.0)	
20 and above	51.5 (12.6)	
<b>DM medication used</b>		
Insulin	50.9 (12.6)	<b>0.001</b>
OHA	59.0 (13.3)	
<b>Duration of insulin</b>		
5 and below	52.6 (11.9)	0.205
6-10	52.9 (13.8)	
Above 10	46.2 (10.8)	
<b>Ability to purchase DM medication</b>		
Self	53.2 (14.0)	0.761
Other	52.5 (11.4)	

Table 6b above shows the correlation of the study variables with the mean ITAS Score. Type of diabetes medication used as a variable is noted to be the only significant variable.

### Multivariate analysis

Age and type of DM medications were applied in the logistic regression model.

**Table 7: Predictors of psychological insulin resistance among the study participants**

Variable	OR (95% CI)	P value
<b>Age categories</b>		
40 and below	4.3 (0.9-20.6)	0.067
41-50	1.3 (0.4-3.7)	0.680
51-60	2.6 (0.9-8.0)	0.085
Above 60	1.0	
<b>DM medication used</b>		
Insulin	1.0	
OHA	5.7 (1.3-25.3)	<b>0.023</b>

As shown in table 7 above, type of DM medications used remained to be significantly associated with psychological insulin resistance with those not using insulin showing a higher chance of PIR, OR 5.7 (95% CI 1.3-25.4), p=0.023 (Table 8). However, age was not significantly associated with psychological insulin resistance.

## DISCUSSION

This study was the first of its kind that set out to determine the prevalence of Psychological Insulin Resistance (PIR) and to correlate it with demographic and clinical factors amongst type 2 diabetes patients at Kenyatta National Hospital. No local data is available on Psychological Insulin Resistance and literature on the same is also not available from other African countries. Further, there is paucity of data on PIR from developing nations.

Our study found a high prevalence (82.6%) of PIR in both Insulin naïve and insulin treated patients comparable to the Iranian study by Ghadiri et al (23) who found a prevalence of 77% . In comparison to studies (13,24,25) done in developed nations, the PIR ranged from 30-50%, therefore our prevalence was much higher. However, two of these studies (13,24) reported that the actual prevalence of PIR would be much higher probably because their sample population was relatively motivated and had fair glycemic control. These studies used different tools to determine PIR. Overall, the prevalence of PIR has been found to be high and the differences in magnitude of PIR was emphasized in the DAWN study (26) which showed that attitudes towards insulin therapy were related to culture and health care systems of different countries.

Insulin naïve when compared to insulin treated patients demonstrated a much more negative appraisal of insulin therapy. This finding compares well with previous findings of cross-sectional studies (13-15). A better appraisal of insulin amongst insulin treated patient is likely to be a consequence of adaptation to the demands of insulin therapy coupled with a better understanding of this treatment modality. This study was cross-sectional and therefore limited in capturing the critical times when predictors of PIR influence insulin acceptance. Norbert et al (15) in his longitudinal study reported that a negative appraisal of insulin therapy is modifiable by the initiation of insulin therapy. He further emphasized that the barriers towards insulin therapy are rather temporary than a stable phenomenon.

The proportion of younger patients, of 40yrs and below, in our study exhibited more negative attitude towards insulin compared to those who were above 60 years, however this was not statistically significant. This preponderance possibly is due to the duration of diabetes, with the over 60 years old having acquired better understanding and skills on insulin.

Both genders showed similar attitudes towards insulin this was in contrast to a study done by Soohyun et al (27) that demonstrated that women had more negative attitudes/reluctance towards insulin therapy compared to men. A Malaysian study by Nur et al (25) also found that PIR was higher in females as compared to men. The disparity in attitudes to insulin therapy between the genders in various studies requires further evaluation, especially on the background of standard Diabetes Self Management Education.

Personal blame/failure was noted to be a major barrier to insulin therapy amongst our patients where 61% blamed themselves for having failed to manage their diabetes with diet and exercise. This was comparable to earlier studies on PIR (13,26,28), where self-blame occurred in 43-58%.

Patients may receive subtle messages from their health care provider that insulin will be initiated only if/when the patient fails to control the disease with diet, exercise, and oral agents (29). Thus, they may view insulin therapy as a threat or as a punishment for their failure. Indeed, the earlier treatment algorithms (guidelines) relegated insulin to the last phases of disease continuum, when OHA were presumed to have failed. It is crucial to educate our patients on the natural history of diabetes with the need for insulin in their disease continuum.

Our study reveals fear of insulin therapy is common in our setup. This includes injection phobia, fear of hypoglycemia and weight gain and is comparable to earlier studies (25,26). While these are genuine concerns, patients need to be counseled and their anxieties allayed. The newer insulin formulations have less hypoglycemic episodes and the ultrafine needles are less painful. Patients can be desensitized, if injection phobia exists, by exposing them to insulin injections under medical supervision.

Perceived loss of control was noted to be a significant contributor to PIR amongst our patients with almost half of them believing that insulin would make life less flexible and one third believing that they would have to give up the activities they enjoy. These findings were comparable to earlier studies (13,28). Patients believed their lifestyle would be restricted by insulin therapy; for example, they would have to eat at specific times, they would not be able to travel or eat out, and they would not be able to be left alone. One quarter of our study patients believed that insulin use makes it more difficult to fulfill responsibilities. Educating the patients and tailoring of insulin regimen to suit their daily routines is a strategy to help overcome this barrier as recommended by earlier studies such as the DAWN study (26). These recommendation have however not been studied in a longitudinal manner to assess their efficacy.

Data from our study reveals that our type 2 diabetes patients face social stigma and self pity as a barrier to insulin therapy. Close to half of them believed that insulin use would make them appear sicker before others and a third reported that insulin injections are embarrassing. Sharing success stories of patients already on insulin can help alleviate social stigmatization as has been recommended in earlier studies (26).

Based on the results of our study, it is noted that Diabetes Self Management Education should lay emphasis on changing attitudes towards insulin therapy. Interventions need to be put in place to assist the patients overcome psychological insulin resistance. One type of intervention should focus on patients who are at the onset of diabetes and start an early process of education/counseling as a preparation for the initiation of insulin therapy when necessary; another type should focus on how to help patients accept insulin as soon as possible; and another on how to help patients adhere to their prescribed insulin plan. These strategies have however not been studied in a longitudinal manner. Furthermore, interventions should also focus on health care providers and train them in these techniques in order to reach a greater number of patients.



## **CONCLUSION**

The prevalence of psychological insulin resistance among type 2 diabetes patients at Kenyatta National Hospital is high at 82.6%. Patients already on insulin therapy had less psychological resistance compared to the insulin naïve patients. There was no association between the Age, sex, duration of diabetes, duration of insulin use, ability to purchase diabetes medication and family history of diabetes with Psychological Insulin Resistance. Self blame/Personal failure was noted to be a significant contributor to Psychological Insulin resistance in our study subjects.

## **RECOMMENDATIONS**

1. In view of the high prevalence of Psychological insulin resistance amongst patients with type 2 diabetes, there is an urgent need to evaluate the Diabetes Self Management education content and delivery at Kenyatta National Hospital.
2. The beneficial use of Insulin therapy in the management of diabetes should be emphasized from the point of diabetes diagnosis.
3. Diabetes counseling should be focused on the issues of: Personal failure/Self blame, Patients' fears of insulin therapy, and misconceptions regarding Insulin therapy.
4. Longitudinal studies are required in order to capture the most salient predictors of PIR and the best strategies to overcome psychological insulin acceptance.
5. There is a great need of randomized controlled interventions to show which techniques or combination of techniques bring the fastest and less resource-consuming decrease in these psychological barriers.
6. Future studies are required to assess the provider barriers/ clinical inertia as an important contributor to Psychological Insulin Resistance.

## **STUDY LIMITATIONS**

- Response bias.
- The result showed an association and not causal relationship.
- The pool of attitudinal items was limited and there are other important contributors to PIR that were not assessed, for example, religious and cultural beliefs, use of herbal medications etc.
- The Insulin Treat Appraisal Scale (ITAS) has not been validated in the socio-cultural setting and diabetes care practice in Kenya.

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## **Appendix 1: Criteria for Diagnosis of Diabetes Mellitus**

The American Diabetes Association (ADA) Guidelines 2013 recommend:

- Glycated haemoglobin (HBA<sub>1C</sub>)  $\geq 6.5\%$  <sup>\*\*†</sup> OR
- Fasting plasma glucose<sup>‡</sup>  $\geq 126$  mg/dL (7.0 mmol/L)<sup>†</sup> OR
- 2-hour plasma glucose  $\geq 200$  mg/dL (11.1 mmol/L) during an oral glucose tolerance test; 75-g glucose load should be used<sup>†</sup> OR
- Random plasma glucose concentration  $\geq 200$  mg/dL (11.1 mmol/L) in persons with symptoms of hyperglycemia or hyperglycemic crisis

\*Test should be performed in a lab using a National Glycohemoglobin Standardization Program (NGSP)-certified method and standardized to the Diabetes Control and Complications Trial (DCCT) assay; <sup>†</sup>In the absence of unequivocal hyperglycemia results should be confirmed using repeat testing; <sup>‡</sup>Fasting defined as no caloric intake for  $\geq 8$  hours

**Appendix 2:      CONSENT FORM** (English Version)

This is a research study being conducted by Dr. Asif Gulam, a postgraduate student in the Department of Clinical Medicine & Therapeutics, University of Nairobi. This study is carried out at the Diabetic Clinic, Kenyatta National Hospital (KNH). The title of the study is **‘PSYCHOLOGICAL INSULIN RESISTANCE AMONG TYPE 2 DIABETICS AT KENYATTA NATIONAL HOSPITAL’**.

Diabetes is a very common disease and affects many people in Kenya. If not well treated, it can lead to very dangerous complications. One way of treating diabetes well is by using insulin injection. Some diabetic patients might have negative attitudes towards using insulin injection. Thus, the purpose of conducting this research study is to find out the fraction of type 2 diabetes patients with a negative attitude towards starting and continuing insulin injection for the treatment of their diabetes which sometimes is very necessary and better than other methods of treating diabetes.

You will be subjected to an interview that will be carried out by the principal investigator or his research assistants.

No health risks will be encountered by participating in the study. There is no intervention administered nor is there any sample of tissue or material that will be obtained from your body. Thus, there is no risk to your health by participating in this study and your routine care at the diabetic clinic will still be given as scheduled.

There are no direct or immediate benefits to the participants. However, the information gathered in this study will help identify (if any) the negative attitudes that some type 2 diabetic patients have towards insulin and thus come up with solutions to address them to optimize their treatment.

The information obtained in this study will be handled with confidentiality throughout the study period. You shall be interviewed in privacy. No names shall be used to identify the participants.

No monetary compensation shall be given to the participants.

Participation in this study is voluntary. Accepting or declining to participate in this study will not in any way influence the treatment you receive in this clinic. Dropping out of this study carries no consequences and you are free to do so at any stage of the study without fear of victimization.

Once you agree to participate in the study, the procedure will be as follows:

1. Give a written informed consent
2. You will then be interviewed by the Principal Investigator or his research assistants. The interview is in two sections.
  - The first section will require you to give information on your socio-demographic details and your medical condition (diabetes)
  - The second section is an interview on insulin treatment for diabetes.  
If you are already on insulin, you will be asked questions about your perception of taking insulin for your diabetes.  
If you are not already on insulin, you will still be asked the same questions and your answers should be based on your current knowledge and thoughts about how insulin treatment would be like.
3. Once the interview has been conducted, you will go back to the nursing desk and then directed to see the clinician.
4. In case you disapprove to participate in the study, you will still receive the same diabetic care like those who participate.

I hereby, without enticement or coercion, agree to participate in this study.

Participant's signature: \_\_\_\_\_ Date: \_\_\_\_\_.

Witness's signature: \_\_\_\_\_ Date: \_\_\_\_\_.

In case of queries or further information, please contact the following persons:

1) **Principal investigator:-**

Dr. Asif Gulam

Telephone: 0733588148

2) **Supervisors: -**

Prof. C. F. Otieno

Associate Professor and Consultant Physician/Diabetologist

Department of Clinical Medicine and Therapeutics

University of Nairobi

Telephone: 020-2726360

Dr. Omondi Oyoo

Senior Lecturer and Consultant Physician

Department of Clinical Medicine and Therapeutics

University of Nairobi

Telephone: 020-2726360

3) **KNH/UoN Ethics and Research Board**

Kenyatta National Hospital

Telephone: 020-2726300 Ext 44102

**Appendix 3: Consent form (Kiswahili version).**

**FOMU YA IDHINI**

Huu ni utafiti ambao unafanywa na Dr. Asif Gulam, mwanafunzi wa masomo ya juu katika idara ya magonjwa ya ndani, Chuo Kikuu cha Nairobi. Uchunguzi huu utafanywa kwenye kliniki ya kisukari, Hospitali Kuu ya Kitaifa ya Kenyatta. Jina la utafiti huu ni **‘VIZUIZI VYA KISAIKOLOJIA KWA UTUMIAJI WA DAWA YA INSULIN KWA WALE WENYE KISUKARI AINA 2 KATIKA HOSPITALI KUU YA KITAIFA YA KENYATTA’**.

Ugonjwa wa kisukari unaathiri watu wengi Kenya. Kama hautibiwi vizuri basi inaleta athari mbaya kwa maisha ya mgonjwa. Njia moja ya kutibu ugonjwa huu ni kutumia njia ya sindano ya insulin. Baadhi ya wenye ugonjwa wa kisukari wako na mawazo mabaya kuhusu utumiaji wa insulin. Kwa hivyo, sababu ya kufanya utafiti huu ni kuangalia na kutambua kiasi cha wagonjwa wenye kisukari wenye mawazo mbaya kwa utumiaji wa sindano ya insulin. Utumiaji wa insulin ni bora kwa matibabu ya ugonjwa wa kisukari na mara nyengine utumiaji wake unakuwa wa dharura na lazima.

Utafiti huu unaangalia vizuizi vya kisaikolojia katika kuanzisha na kuendeleza utumiaji wa dawa ya insulin kwa wale wenye kisukari aina 2.

Utahojiwa na mtafiti mkuu ama wasaidizi wake.

Hakuna hatari yoyote ya kiafya utakayopata kwa kuhusika kwenye utafiti huu. Hutatulewa damu au kiungo chochote cha mwili. Hakuna matibabu zaidi utakayopewa. Matibabu yako ya ugonjwa wa kisukari utaendelea kama ulivyopangwa hapo awali.

Hakuna faida yoyote ya sasa hivi ama ya kibinafsi itakayopatikana kwa kushiriki kwenye uatafiti huu. Lakini, utafiti huu utatambua kama kuna vizuizi vovote vya kisaikolojia katika kuanzisha au kuendeleza utumiaji wa dawa ya insulin ili vipate kutatuliwa.

Taarifa itakayopatikana kwenye utafiti huu itaangaliwa kwa njia ya kisiri kwa muda wote wa utafiti. Utahojiwa kwa njia ya kisiri. Majina ya washiriki hayatotumiwa kuwatambua.

Hakuna fidia ya kifedha itakayolipwa washiriki.



Kushiriki kwenye utafiti huu ni hiyari. Kukubali au kukataa kushiriki kwenye utafiti huu hakutabadilisha kwa njia yoyote ile matibabu utakayopewa hapa kliniki. Kuamua kutoka kwenye utafiti huu hauna na uko huru kujiondoa wakati wowote bila hofu.

Ukikubali kushiriki kwenye utafiti huu, utahitajika kufuata utaratibu ufuatao:

1. Kutoa idhini kwa kuandika
2. Baadaye utahojiwa na mtafiti mkuu au wasaidizi wake. Mahojiano yatagawanywa sehemu mbili.
  - Sehemu ya kwanza, itakuhitaji utoe maelezo kuhusu na ugonjwa wako wa kisukari.
  - Sehemu ya pili utahojiwa kuhusu sindano ya insulin kutibu ugonjwa wa kisukari.  
Ikiwa tayari unatumia sindano ya insulin, utaulizwa maswali kuhusu utumiaji wa sindano ya insulin kutibu ugonjwa wako wa kisukari.  
Ikiwa bado hujaanza kutumia sindano ya insulin, utaulizwa maswali yayo hayo. Majibu yako yalingane na elimu yako ya sasa hivi au mawazo yako kuhusu vile ungetumia sindano ya insulin
3. Baada ya mahojiano, utarudi kwa muuguzi ili akupeleke kwa daktari.
4. Ikiwa hutakubali kujiunga na utafiti huu, basi utapata huduma ile ile watakaopata wale waliojiunga kwa utafiti

Mimi, bila kulazimishwa au kulaghaiwa, nakubali kushiriki kwenye utafiti huu.

Sahihi ya mshiriki: \_\_\_\_\_ .Tarehe: \_\_\_\_\_ .

Sahihi ya shahidi: \_\_\_\_\_ .Tarehe: \_\_\_\_\_ .

Ikiwa kuna utata wowote au kutaka maelezo zaidi, tafadhali wasiliana na watu wafuatayo:

1) **Mtafiti mkuu:-**

Dr. Asif Gulam  
Simu: 0733588148

2) **Wahadhiri: -**

Prof. C. F. Otieno  
Associate Professor and Consultant Physician  
Department of Clinical Medicine and Therapeutics  
Chuo Kikuu cha Nairobi  
Simu: 020-2726360

Dr. Omondi Oyoo  
Mhadhiri mkuu and Consultant Physician  
Department of Clinical Medicine and Therapeutics  
Chuo Kikuu cha Nairobi  
Simu: 020-2726360

3) **KNH/UoN Ethics and Research Board**

Hospitali Kuu ya Kitaifa ya Kenyatta  
Simu: 020-2726300 Ext 44102

Appendix 4: QUESTIONNAIRE (English Version)

**PSYCHOLOGICAL INSULIN RESISTANCE AMONG TYPE 2 DIABETICS AT KENYATTA NATIONAL HOSPITAL.**

1. Name .....
2. Age.....
3. Sex.....
4. Hospital No. ....
5. Residence.....
6. Occupation.....
7. Year of Diagnosis/duration of DM.....
8. DM Medication used (Insulin/OHA/Both) .....
9. Duration of insulin use (if on insulin) .....
10. Ability to purchase DM Medication (self/relative/friend/No means) .....
11. Family history of DM.....

Appendix 5: MASWALI (Kiswahili version).

**PSYCHOLOGICAL INSULIN RESISTANCE AMONG TYPE 2 DIABETICS AT KENYATTA NATIONAL HOSPITAL.**

1. Jina.....  
.....
2. Umri.....  
.....
3. Jinsia.....  
.....
4. Nambari ya hospitali.....
5. Makao.....  
.....
6. Kazi.....
7. Mwaka uliojulikana kuwa na kisukari/muda wa kisukari.....
8. Dawa ya kisukari uliotumia (insulin/tembe/zote mbili).....
9. Muda wa utumiaji wa insulin (kama unatumia).....
10. Uwezo wa kununua madawa ya kisukari (mwenyewe/jamaa/marafiki/hakuna uwezo).....
11. Ugonjwa wa kisukari kwenye ukoo.....

Appendix 6 (English Version)

### Insulin Treatment Appraisal Scale (ITAS)

The following questions are about your perception of taking insulin for your diabetes. If you have not yet initiated insulin therapy, please answer each question from your current knowledge and thoughts about what insulin therapy would be like. Please indicate to what extent you agree or disagree with each of the following statements. Tick one box for each statement that best describes your own opinion.

	strongly disagree	disagree	agree nor disagree	agree	strongly agree
1. Taking insulin means I have failed to manage my diabetes with diet and tablets.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Taking insulin means my diabetes has become much worse.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Taking insulin helps to prevent complications of diabetes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Taking insulin means other people see me as a sicker person.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Taking insulin makes life less flexible.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I'm afraid of injecting myself with a needle.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Taking insulin increases the risk of low blood glucose levels (hypoglycaemia).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Taking insulin helps to improve my health.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Insulin causes weight gain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Managing insulin injections takes a lot of time and energy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Taking insulin means I have to give up activities I enjoy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Taking insulin means my health will deteriorate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Injecting insulin is embarrassing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Injecting insulin is painful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. It is difficult to inject the right amount of insulin correctly at the right time every day.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Taking insulin makes it more difficult to fulfil my responsibilities (at work, at home).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Taking insulin helps to maintain good control of blood glucose.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Being on insulin causes family and friends to be more concerned about me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Taking insulin helps to improve my energy level.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Taking insulin makes me more dependent on my doctor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*Highlighted statements represent the positive attitudes\*

Appendix 7: ITAS-Kiswahili version

**Insulin Treatment Appraisal Scale (ITAS)**

Maswali yafuatayo ni kuhusu mtazamo wako wa utumiaji wa dawa ya insulin kwa ugonjwa wako wa kisukari. Kama bado hujaanza utumiaji wa dawa ya insulin, tafadhali jibu kila swali kutumia elimu na mawazo yako ya sasa hivi kuhusu vipi utumiaji wa matibabu ya insulin utakuwa. Tafadhali onyesha/weka ishara ni kwa kiwango gani unakubaliana au hukubaliani na kila maneno yafuatayo. Weka alama ya sahihi kwa kisanduku kimoja kwa kila neno ambayo inaelezea vizuri zaidi oni lako.

	Nakataa Kata Kata	Nakataa	Sikubali na Sikatai	Nakubali	Nakubali Kabissa
1. Kuchukua insulin inamaanisha sijafaulu kuchunga ugonjwa wangu wa kisukari kwa chakula na tembe.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Kuchukua insulin inamaanisha ugonjwa wangu wa kisukari umekuwa mbaya zaidi.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Kuchukua insulin inasaidia kukinga maafa ya ugonjwa wa kisukari.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Kuchukua insulin inamaanisha watu wengine wananiona mimi kama mtu mgonjwa zaidi.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Kuchukua insulin inafanya maisha kuwa magumu zaidi.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Naogopa kujidunga mwenyewe na sindano.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Kuchukua insulin inaongeza hatari ya kushuka kwa kiwango cha sukari mwilini.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Kuchukua insulin inasaidia kuboresha afya yangu.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Insulin inasababisha kuongezeka kwa kilo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Kumudu sindano ya insulin inachukua wakati na nguvu nyingi.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Kuchukua insulin inamaanisha lazima niwache shughuli ninazozifurahia.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Kuchukua insulin inamaanisha afya yangu itazorota.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Kudunga insulin ni jambo la kuaibisha.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Kudunga insulin ni uchungu.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Ni vigumu kudunga kiwango kinachotakikana cha insulin kisawasawa kwa wakati unaofaa kila siku.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16. Kuchukua insulin inafanya kuwa vigumu zaidi kutekeleza wajibu wangu (kazini, nyumbani).
17. Kuchukua insulin inasaidia kusawazisha kiwango cha sukari vizuri.
18. Kuwa kwa insulin inasababisha familia na marafiki kuwa na wasiwasi zaidi kunihusu mimi.
19. Kuchukua insulin inasaidia kuimarisha kiwango changu cha nguvu.
20. Kuchukua insulin inanifanya mimi kutegemea zaidi daktari wangu.