
**'THE IMPACT OF DEPRESSION ON TREATMENT
COMPLIANCE IN PATIENTS WITH TYPE II DIABETES
MELLITUS A CROSS-SECTIONAL STUDY'**

BY

REG NO. BQ0120002

Dissertation

Submitted to the

KLE Academy of Higher Education and Research,

Belagavi, Karnataka.

In partial fulfilment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

PSYCHIATRY

JAWAHARLAL NEHRU MEDICAL COLLEGE

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

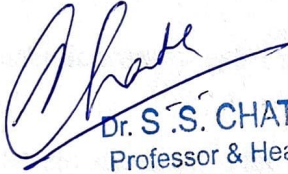
BELAGAVI- 590010, KARNATAKA, INDIA

JUNE/JULY 2023

KLE Academy of Higher Education and Research
Belagavi, Karnataka

Endorsement by the Head of Department,
Principal/ Head of the Institution

This is to certify that the dissertation entitled 'THE IMPACT OF DEPRESSION ON TREATMENT COMPLIANCE IN PATIENTS WITH TYPE II DIABETES MELLITUS- A CROSS-SECTIONAL STUDY' is a bonafide research work done by Registration No. BQ0120002.



Seal & Signature of the HOD
Dr. S.S. Chate M.D., D.P.M.
Professor & Head,
Department of Psychiatry,
J.N. Medical College, BELAGAVI - 590 010
KMC Reg No. 48918

Professor & Head,
Department of Psychiatry,
J.N. Medical College,
KLE Academy of Higher Education
and Research Belagavi – 590010.
Karnataka, India.

Date : 2/01/2023
Place : Belagavi





Seal & Signature of the Principal
Dr. (Mrs.) N. S. Mahantashetti M.D.(Paed)

Principal,
J.N. Medical College,
KLE Academy of Higher Education and
Research Belagavi – 590010.
Karnataka, India.

Date : 2/01/23
Place : Belagavi

UNDER TAKING

I, **REG NO: BQ0120002** hereby declare that the information and the data mentioned in my thesis entitled '**THE IMPACT OF DEPRESSION ON TREATMENT COMPLIANCE IN PATIENTS WITH TYPE II DIABETES MELLITUS- A CROSS-SECTIONAL STUDY**' belongs to me and is original.

I am aware of the definition of plagiarism as detailed below:

- An act or instance of using or closely imitating the language and thoughts of another author without authorization and the representation of that author's work as one's own, as by not crediting the original author.
- A piece of writing or other work reflecting such unauthorized use or imitation.
- The deliberate or reckless representation of another's words, thoughts or ideas as one's own without attribution in connection with submission of academic work, whether graded or otherwise.

I hereby declare that the thesis prepared by me is original-one and does not involve plagiarism anywhere. In case at a later stage, it is found that I have indulged in plagiarism, then I am solely responsible for the same and the Institution is at liberty to take any disciplinary action against me including cancellation of dissertation or any other penalties imposed by the University.



Date: 26/12/22

Place: Belagavi




REG NO: BQ0120002


PLAGIARISM ACCEPTANCE LETTER

	JAWAHARLAL NEHRU MEDICAL COLLEGE (Recognized by Medical Council of India, New Delhi)	
Accredited 'A+' Grade by NAAC (3 rd Cycle)		Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi- 590 010, Karnataka, INDIA		
0831 - 2471350	0831 - 2470759	www.jnmc.edu
Ref No: MDC/PG/		Date: 08-12-2022.

ACCEPTANCE LETTER

The softcopy of thesis entitled: "A CROSS-SECTIONAL DESCRIPTIVE STUDY OF THE IMPACT OF DEPRESSION ON TREATMENT COMPLIANCE IN PATIENTS WITH TYPE II DIABETES MELLITUS" has been submitted for Anti-Plagiarism check through Turnitin software. The scan has been carried out and the scanned output reveals a match percentage of 02% which is within the acceptable limits of 10% as per the guidelines given by UGC.

Guide: 



Dr. (Mrs.) N.S. Mahantashetti.
Chairperson-Antiplagiarism Committee &
Principal,
J. N. Medical College, Belagavi.

To,
Reg. No. BQ0120002,
Postgraduate Student,
2020-21 Batch,
Department of Psychiatry,
J. N. Medical College, Belagavi.

ETHICAL CLEARANCE CERTIFICATE



K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed - to-be- University)

Accredited 'A' Grade by NAAC (2nd Cycle)

Placed in Category 'A' by MHRD (GoI)

JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

Website: <http://www.jnmc.edu>

E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2472550

Principal: 2471701

Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ H2

Date: 25/01/2021

To.
REG NO. BO0120002
PG student in Psychiatry,
J. N. Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled
"THE IMPACT OF DEPRESSION ON TREATMENT COMPLIANCE IN PATIENTS
WITH TYPE II DIABETES MELLITUS : A CROSS SECTIONAL STUDY", is ethical and
justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics
Committee on Human Subjects Research.

(Dr. Smita Sonoli)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Harsha Hegde)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ABSTRACT

Introduction: Diabetes affects millions of patients worldwide and often co-exists with depression due to its higher prevalence in diabetic population as compared to general population. Treatment in diabetes is often life-long and is multimodal, that includes oral medications, injectables, dietary and lifestyle modifications. Presence of comorbid depression can interfere with maintaining compliance to the advised treatment plan

Objectives: To assess the impact of depression on treatment compliance in patients with type II diabetes mellitus. Additionally, to assess the impact of depression on quality of life in patients with type II diabetes mellitus and to assess the prevalence of depression in patients with Type II diabetes mellitus

Methods: A cross-sectional descriptive study was carried out involving 270 diabetic patients. Patient health questionnaire-9(PHQ9) was used to screen for depression. Morisky green levine scale (MGLS) was used to assess treatment compliance. World health organization quality of life scale- BREF (WHOQOL BREF) was used to assess quality of life.

Results: 34.07% of study population was found to be depressed. The treatment compliance in depressed group was found to be significantly lower than the non-depressed group. Depressed group also scored significantly lower in all domains of quality of life as compared to non-depressed group

Conclusion: One third of diabetic population was depressed. Treatment compliance and quality of life is significantly lower in depressed group, and have negative correlation with depression

Keywords: Diabetes, depression, treatment compliance, quality of life, prevalence, MGLS

ACRONYMS

WHO	World Health Organisation
BMI	Body Mass Index
ADA	American Diabetes Association
OCD	Obsessive-Compulsive disorder
ICD	International Classification of Diseases
DSM	Diagnostic and Statistical Manual of Mental Disorders
HPA axis	Hypothalamic- Pituitary-Adrenal axis
MDD	Major Depressive Disorder
T2DM	Type 2 Diabetes Mellitus
HBA1C	Glycated Haemoglobin
FBS	Fasting Blood Sugar
PHQ9	Patient Health Questionnaire-9
MGLS	Morisky Green Levine Scale
WHOQOL BREF	World Health Organisation Quality of Life- Brief Scale

WHOQOL-100	World Health Organisation Quality of Life- 100 Scale
HANDS	Harvard department of psychiatry/National depression screening scale
SF-12	Short Form Survey (12 Item)

TABLE OF CONTENTS

SR.NO.	CONTENTS	PAGE NO.
1	INTRODUCTION	1
2	OBJECTIVES	2
3	REVIEW OF LITERATURE	3-23
4	MATERIALS AND METHODS	24-26
5	RESULTS	27-39
6	DISCUSSION	40-51
7	CONCLUSION	52-53
8	SUMMARY	54
9	BIBLIOGRAPHY	55-71
10	ANNEXURES	
	Annexure I: Consent forms	72-80
	Annexure II: Proforma	81-82
	Annexure III: Tools	83-87
	Annexure IV: Master chart	88-92

LIST OF FIGURES

SR. NO.	FIGURES	PAGE NO.
1	Representation of Integrative pathogenic model of depression	10
2	Representation of bidirectionality between diabetes and depression	15
3	BMI in depressed vs non-depressed patients	30
4	Diabetic complications in non-depressed vs depressed groups	32
5	Comparison of fasting blood sugar in non-depressed vs depressed patients	33
6	Mean HBA1C in non-depressed vs depressed patients	34
7	Prevalence of depression in type II diabetic patients	35
8	Comparison of level of compliance (mean MGLS score) between non- depressed and depressed groups	36
9	Correlation between MGLS and PHQ9 scores in depressed group	37
10	WHOQOL BREF domain scores in non-depressed and depressed groups	38

LIST OF TABLES

SR. NO.	TABLE	PAGE NO.
1	American diabetic association guidelines to diagnose diabetes	4
2	Studies done on treatment compliance in type 2 diabetic mellitus with depression	22
3	PHQ-9 score and corresponding depression severity	25
4	Socio-demographic profile of study sample	27
5	Clinical factors in non-depressed and depressed groups	29
6	Diabetic complications in non-depressed and depressed groups	31
7	Comparison of fasting blood sugar (FBS) and glycated haemoglobin (HBA1C) in non-depressed and depressed groups	33
8	Prevalence of depression in diabetic patients	35
9	Comparison of level of compliance (mean MGLS score) between non- depressed and depressed groups	36
10	Correlation between severity of depression (PHQ9 score) and treatment compliance (MGLS score) in depressed group	37
11	WHOQOL BREF domain scores in non-depressed and depressed groups	38

OBJECTIVES

PRIMARY OBJECTIVE:

1. To assess the impact of depression on treatment compliance in patients with type II diabetes mellitus

SECONDARY OBJECTIVES:

1. To assess the impact of depression on quality of life in patients with type II diabetes mellitus
2. To assess the prevalence of depression in patients with type II diabetes mellitus.

INTRODUCTION

Diabetes is an extremely common, chronic illness that affects millions of patients worldwide. India is burdened with 77 million people with diabetes with an expected rise to 134 million by 2045^[1]. One of the often-missed finding in diabetic patients is the comorbid depression. Various studies^{[2] [3] [4]} have found that depression co-exists with diabetes, which could be due to underlying biological mechanisms^[5], predisposing to depressive disorders that are highly prevalent in diabetic population as compared to general population. Screening diabetic patients for depression is not a common practice and the symptoms like easy fatiguability or poor appetite is seen in patients with both depression and diabetes, causing a diagnostic overlap in the absence of detailed evaluation.

Treatment for diabetes usually includes oral drugs, insulin, physical exercise, and dietary modification. Adherence to all forms of treatment is rarely seen as diabetes is a long-term illness and only few patients are seen to be adherent over the long course of illness^[6]. Although previous studies have established the higher prevalence of depression in diabetic patients^{[7][8][9]}, the impact of depression is not studied extensively on various components of diabetes. Our study aims to study the prevalence of depression, various demographic and clinical factors in the study groups, the impact of depression on treatment compliance in diabetic patients, the quality of life in patients with comorbid diabetes and depression and compare it with the non-depressed group. This study intends to provide insight on the above-mentioned aspects in Indian population and establish the need for screening diabetic patients for depression as a common practice and intervene as required.

REVIEW OF LITERATURE

Diabetes

Diabetes is a worldwide burden and is a chronic disease that occurs when there is insufficient insulin produced by pancreas or when the body does not use the produced insulin effectively in order to regulate the blood sugar. It is a chronic endocrinological disorder that alters the metabolism of carbohydrates, fat, proteins, electrolytes and water, causing changes in the organ systems of the body and has a multifactorial aetiology with significant contribution from genetic and environmental factors ^[10]As per WHO, there were 537 million individuals with Diabetes in year 2021, with over 5% premature mortality and caused 6.7 million deaths in 2021^[11]. It is known to cause multiple complications like blindness, renal complications, cardiovascular complications, and amputations. Diagnosis is done by cost effective methods like blood sugar testing, and treatment mainly is blood glucose control aided by medications, diet, and physical activity ^[12]

About 1 in every 11 adults have diabetes with 90%- 97% of them having type 2 diabetes^[13] which has a higher genetic susceptibility and additional phenotypic variations within sub-populations^[10], with these phenotypic subtypes within populations showing ethnical and regional variations.^[10] As a result, the prevalence rates are higher in low- and middle-income regions, as 3 in every 4 adults with diabetes live in these regions.^[11] However, urbanisation was also said to influence the disease, where some studies have reported that there are twofold higher number of patients in urban setting as compared to rural centres, with factors like income status affecting the prevalence of the disease ^[14] The aetiological factors causing diabetes are numerous. Common causes are genetic and environmental variations, nutritional factors, toxic agents, infections, body weight, stress, substance use and sedentarism^[10,15] Gender

differences were also found to influence the presentation of diabetes mellitus. Female gender was found to have significantly impaired glucose tolerance at a higher frequency while males were found to have impaired fasting glucose more than females. Stress contributes to diabetes in a way that prolonged and severe stress is found to be associated with glucose intolerance by activation of glucocorticoids.^[10] Due to the staggering prevalence of diabetes in all parts of the globe, the worldwide human, social and economic burden is extremely high^[16]

DIAGNOSING DIABETES-

As per American Diabetes Association,

HBA1C	
<5.7%	NORMAL
≥5.7% TO <6.5%	PREDIABETES
≥ 6.5%	DIABETES

FASTING PLASMA GLUCOSE	
<100mg/dl	NORMAL
≥ 100mg/dl TO <126mg/dl	PREDIABETES
≥ 126mg/dl	DIABETES

ORAL GLUCOSE TOLERANCE TEST	
<140 mg/dl	NORMAL
≥ 140mg/dl TO 200mg/dl	PREDIABETES
≥ 200mg/dl	DIABETES

Table 1: Showing ADA guidelines to diagnose diabetes^[17]

The diagnosis of diabetes usually occurs years after the onset of the illness. Every year worldwide, about 45.8% of patients with diabetes mellitus were said to be undiagnosed^[11]

India, the diabetic capital of world, is now considered an epicentre for T2 DM along with China where the patients were found to have the disease onset at younger age and lower BMI as compared to the west. According to International diabetes federation, India is said to have 74 million diabetic patients, with every 1 in 12 adults having diabetes and an estimated 123.5 million diabetic patients by the year 2040^[11]

Indian diabetics are found to be more insulin resistant as compared to Caucasians due to various genetic predispositions.^[2] The complications associated with diabetes like adverse cardiovascular events, renal impairment, neurological and ophthalmological complications are also at the epidemic levels in developing countries, having deterrent effects on the quality of life and the lifespan overall. An 'Asian phenotype' is seen in Indians, which is a risk factor for early cardiovascular events, which is characterised by higher insulin resistance, high waist circumference despite low BMI, high inflammatory markers like C reactive protein and lower adiponectin levels.^[15] Early diagnosis and management are crucial in the prognosis of the disease and in prevention of these complications

Depression

Depression is a common mental disorder that affects children, adolescents, adults and the geriatric population. It is a leading cause of disability and as per WHO, 3.8% of the population (an approximate 280 million people) have depression. It is different from the usual mood fluctuations and is a serious health condition, which can result in suicide. Yearly, about 7 lakh people die due to suicide and depression

contributes to a major share of these deaths, with suicide being the 4th most common cause of death among adolescents ^[18]

History-

Ancient Romans and Greeks have coined the terms Melancholia and Mania and have given a temperamental basis for these disorders. Hippocrates in 460 BC has described melancholia as a state which causes aversion to food, dejection, insomnia, irritability and restlessness^[19]

In 19th century, the French and German have worked on mood disorders extensively, which influences the current understanding of mood disorders.

Galen (131 AD to 201 AD) has described melancholia as ‘fear, depression, hatred towards people and discontent’. A few hundred years later, Aurelianus, citing the works of Soranus of Ephesus has highlighted the role of suicide/aggression in melancholia^[19]

In the modern era, Robert Burton’s Anatomy of Melancholy, 1621 has focused on somatoform disorders, hypochondriasis along with melancholia. ^[20]

In the later years, 18th and 19th centuries have introduced human medical and hospital care for the mentally ill and have looked into psychopathology, prognosis and the outcomes of mood disorders^[21]

Emil Kraepelin was the scientist who focused on pathology of depression and had described that it consists of low mood and slowing down of mental and physical processes. He gave the term ‘Involutional melancholia’ which included older patients with severe anxiety, delusions and agitation that later turned out to be the manic-depressive group^[22]

Although the classification of mood disorders according to various diagnostic manuals is still evolving, these were broadly classified into depressive disorders without manic/hypomanic episodes and depressive episodes with manic/hypomanic episodes by Carlo Perris, Jules Angst, George Winokur, Paula Clayton, Karl Leonhard and Theodore Reich, independently in the late 19th century and have also said that the manic-depressive group had higher genetic loading ^[23]

Emil Kraepelin has described mood disorders as dualistic, which is having either a somatic or psychological origin. Adolf Meyer later has attempted to differentiate between soma and psyche. He has further given the term 'Depression' instead of melancholia ^[24]

Contemporary models of depression

- 1) Aggression-Turned-Inward Model- According to this model, given by Sigmund Freud and Karl Abraham, depression is secondary to aggressive impulses against an ambivalently loved object that is internalised. Because of this aggression towards a loved object, guilt can develop, which can cause suicide. This model is used nowadays in clinical conceptualization however there is little significance in terms of therapeutic importance^[25]
- 2) Object Loss and Depression Model- Object loss refers to losing attachment from a significant figure that can be traumatic. This object loss can be ego-psychological object loss model or id-psychological model. John Bowlby was the scientist who focused upon attachment styles, bonds established by a child with the mother, substitutes of attachment figures and has given a two-step hypothesis, which is a) early disturbances in attachment, that causes vulnerability to depression and b) trauma in adult life, that revives the childhood trauma and predisposes to

depression. This theory is more realistic to clinical depression, but can be an etiological factor for depression rather than a theory ^[26]

- 3) Loss of Self-esteem and Depression- Self-esteem is an important part of the personality structure and is the core of the person. Those with both high and low self-esteem can develop depression, which can be due to instable self-esteem, predisposing to the same. It is also said that depression is caused due to the inability of 'ego', a component of structural theory of mind, given by Sigmund Freud, in giving up goals like power, identity and status, that are unattainable ^[27]
- 4) Cognitive Model- Given by Aaron Beck at the University of Pennsylvania, elaborates that depression is due to negative thinking. Beck's triad, that is the presence of 3 symptoms- Helplessness, Hopelessness and Worthlessness is the hallmark for depression. These symptoms occur due to cognitive bias and negative attributions that are global, internal and stable. This model gives a link between ego-psychological model and behavioural models of depression ^[28]
- 5) Learned Helplessness Model- This model says that depression occurs due to learning that happens from the past events, where the person wasn't able to terminate the unwanted incidents of an event. This is believed to be the experimental analogue of the cognitive model. Learned helplessness is a broader disposition that plays role in illnesses other than depression e.g.: Post traumatic stress disorder ^[29]
- 6) Depression and Reinforcement- Psychologist Peter Lewinsohn has given that depression is caused due to improper reinforcements. When there is lack of rewards, it can predispose to depression. Another explanation is that the person's self-esteem is lowered by providing rewards that are considered to be undeserving (rewards that aren't given in response to person's actions) which can reduce the person's response to rewarding contingencies. ^[30]

7) Biogenic amine imbalance- After the neurobiological techniques have developed, scientists have studied the complexity of limbic-diencephalic structures and emotional behaviour. Neurons acting via the norepinephrinergic system were found to be involved in regulating mood, rewards, arousal, drives and appetite, as given by Joseph Schildkraut at Harvard University, William Bunney and John Davis at National Institute of Mental Health. Other important amines apart from norepinephrine are a) Dopamine that is involved in motivation, pleasure, and psychomotor activity b) Serotonin that is involved in mood, aggression and biological function c) Cholinergic neurons that have opposite effects to the actions of catecholamines. This theory was further strengthened by substantiation from the pharmacological actions on neurotransmitters. ^[31]

With the development of Imaging studies, it was found that in untreated patients with severe depression, there was blunted response to serotonin in temporo-parietal areas and prefrontal regions. ^[32] Serotonin was found to have a greater role in suicide and other disorders like OCD, Eating disorders, Alcoholism, Impulsivity and Panic disorders. Novel treatment options that have concurrent action on serotonin and norepinephrine suggest that depression is more complex than the hypothesis of single neurotransmitter involvement. Newer explorations are now being focused upon molecular perturbations like second messenger systems, signal transduction, DNA and RNA messenger systems, transcription and translation and phosphorylation of G protein system ^[33]

Biological stressors like physical diseases precede the onset of depression in a patient with a personal and family history of depressive disorders ^[34]

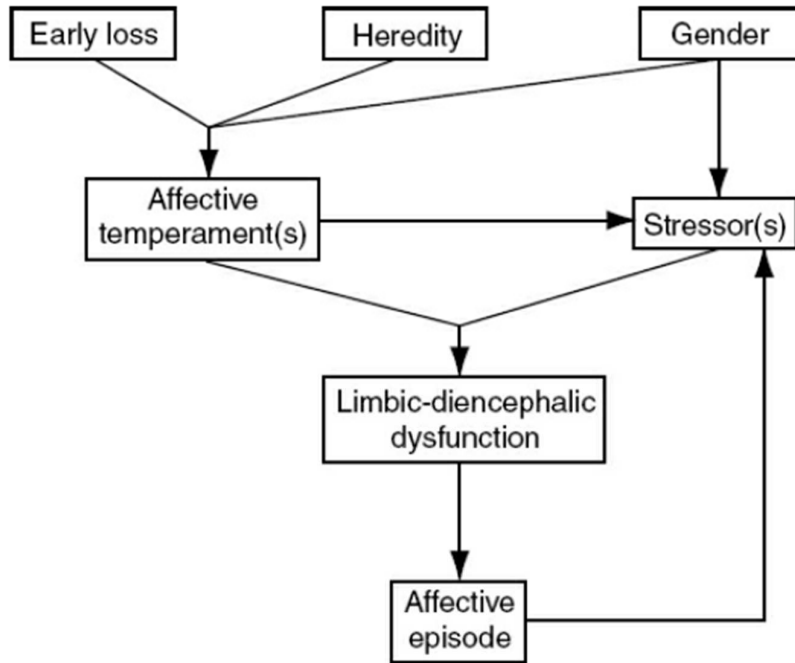


Figure 1 showing integrative pathogenic model of depression^[35]

Early studies on depression that studied the natural course of depression like the Zurich study ^[36] and Collaborative Depression Study ^[37] has showed that depression can be severely impairing for the individual. Risk factors that are predisposing for depression were found to be female, unmarried, low income^[5], family history of depression, certain behavioural traits and patterns ^[5,38] and chronic medical illnesses like hypertension and diabetes. Cognitive risk factors, as described to Aaron Beck were found to be that viewing the world, self and future in negative outlook results in cognitive bias, causing impairment in domains of mood, behaviours, biological functions, emotion and cognition^[28]. These predisposing factors of unstable cognitive and neural vulnerabilities during a period of stress trigger depressive reactions. Studies have found that cognitive deficits are specifically consistent with negative cognitive bias, difficulty in disengaging from negative material and cognitive control ^[39] Along with these, executive functioning was also found to be impaired in depressed patients ^[40]

Structural imaging studies in depression have showed that in adults with depression had significant increase in cortical thickness in orbitofrontal cortex, temporal lobes, Insula, anterior and posterior cingulate cortices. There were also subcortical changes, mainly the hippocampal volume which was found to be lower in the depressed group as compared to controls.^[41,42]

Gender variations were seen to be present in depression. Women were found to have higher likelihood of having severe depression, which peaks at adolescence^[43] underlying factors being female reproductive system, with a different hormonal profile from males such as and phases of women's reproductive life starting from puberty, premenstrual dysphoric syndrome, postpartum depression and perimenopausal mood disturbances. Due to complex associations between neuroendocrine mechanisms, neurotransmitter systems, along with contributions from genetic, environmental, developmental effects.^[38] According to social construct theory, larger gender differences are observed in nations with larger gender inequality, which was a risk factor for depression^[44]

Diagnosing depression

As per ICD 11^[45],

Depressive disorders are described as a state of mood which is sad, irritable or empty, with loss of pleasure in activities, along with other cognitive, behavioural and neurovegetative symptoms, that affect the functioning of the person, for a period of at least 2 weeks. It can be classified into single/ recurrent episodes, mild/ moderate/ severe based on the number of the symptoms and with/without psychotic symptoms. It can also occur as dysthymia which is a persistent depressive mood lasting at least 2 years. Depression can co-exist with anxiety, can be a component of bipolar disorders,

adjustment disorders, bodily distress disorders and can occur secondary to other mental illnesses like psychosis, OCD, dementia and substance use.

General criteria-

A)

- G1) The episode of depression should last for at least 2 week
- G2) There should be no manic or hypomanic symptoms that are sufficient to meet criteria for manic or hypomanic episode at any point of time in life
- G3) The depressive episode is not due to the use of any organic mental disorder or psychoactive substance use

B)

- A depressive mood, that is at an abnormal degree for the patient, that is present almost every day, for most part of the day, uninfluenced by the circumstances and persists for a minimum of 2 weeks.
- Loss of interest or pleasurable activities that were normally pleasurable
- 3)Increased fatiguability or reduced energy

Additional criteria-

- 1) Loss of self-esteem or confidence
- 2) Unreasonable self-reproach and severe, inappropriate guilt
- 3) Recurrent thoughts of death and suicidal behaviour
- 4)Reduced ability to concentrate, having indecisiveness and vacillation
- 5) Either increased or decreased psychomotor activity
- 6) Sleep disturbances
- 7) Change in appetite and weight alterations

DSM V[46] describes depressive disorders as a group of disorders which include disruptive mood regulation disorder, major depressive disorder, premenstrual dysphoric

disorder, persistent depressive disorder, medication/substance induced disorders, depressive disorder due to medical conditions and other/unspecified depressive disorder. These disorders have varied aetiologies and durations but commonly have the presence of sad/empty/irritable mood, that affect the functioning of the person.

DSM V criteria for depressive disorder^[46].

- A. A two-week period of at least one of the symptoms being a) depressed mood or
b) Reduced interest or pleasure
- 1) Depressed mood that is present almost every day for most part of the day, that is either subjective or objective.
 - 2) Reduced interest in activities or pleasure in almost all activities, every day for most part of the day
 - 3) Significant weight changes in the form of weight loss or gain (5% change from baseline) or changes in the appetite
 - 4) Hypersomnia or insomnia
 - 5) Psychomotor retardation or agitation almost every day
 - 6) Loss of energy or fatiguability almost everyday
 - 7) Excessive guilt feelings or of worthlessness almost everyday
 - 8) Reduced thinking ability or being indecisive nearly everyday
 - 9) Frequent thoughts about death and suicide, with planned suicidal ideations or attempts
- B) The symptoms should cause severe distress that causes significant impairment in occupational, social or other areas of functioning
- C) The episode is not because of a medical condition or physiological effects of any substance.

Diabetes and Depression

Historically, Thoman Willis, more than 300 years ago has described that diabetes is due to prolonged grief or sorrow, with minimal scientific basis. Further, 'Depression interview and structured Hamilton (DISH)' scale was developed by Freedland et al (2002) ^[47] to diagnose depression in those with a medical illness, which gave an insight into interactions between diabetes and depression. Patients with diabetes had higher prevalence of psychiatric disorders overall as compared to healthy controls and depression contributed to the highest prevalent psychiatric disorder^[48]

Various studies have found depression and diabetes to exist in a bidirectional linkage. Depression was found to be more prevalent in diabetic patients as compared to general population and not only depression increases the risk for development of diabetes and its complications like insulin resistance and vascular complications, but is also an independent predictor of the same ^[49-51] . This linkage is due to a shared aetiology, which includes autonomic dysregulation, neurohormonal imbalances, inflammation, obesity, and hippocampal alterations. Patients with Type 2 diabetes were found to be having about 24% higher risk of developing depression as compared to healthy controls^[52] and depression was found to be twice as prevalent in diabetic patients as compared to general population^[53] Due to these interactions between the two disorders, diabetic patients were seen not only to have an increased prevalence of depression but also have an increased risk of worsening of the course of depression and depression adversely affecting the course of diabetes like poorer quality of life, poor glycaemic control and poor selfcare behaviours. ^[5]

Similar biological mechanisms in Type 2 Diabetes and depression-

Studies done on mice showed that exposure to social defeat/stress has caused increased ghrelin levels in mice, a hormone that increases visceral and intracapsular accumulation of brown fat deposition, and also an increased appetite resulting in dysfunction of the endocrine system like hyperinsulinemia, altogether contributing to the development of diabetes^[54]. The abnormal functioning of HPA axis, which causes increased cortisol levels also is a common mechanism seen in diabetes and depression ^[55,56]. High cortisol levels were found to cause signal disruption, that happens when insulin binds with its receptor, causing Insulin resistance ^[56]

Impaired neurological systems also contribute to both diabetes and depression. The structures involved are hippocampus and limbic system, which play a major role in memory and emotion. HPA axis and hippocampus have anatomical links, causing both depression and diabetes. Along with this, the process of neurogenesis in hippocampus and hippocampal atrophy was found to cause diabetes ^[57,58]

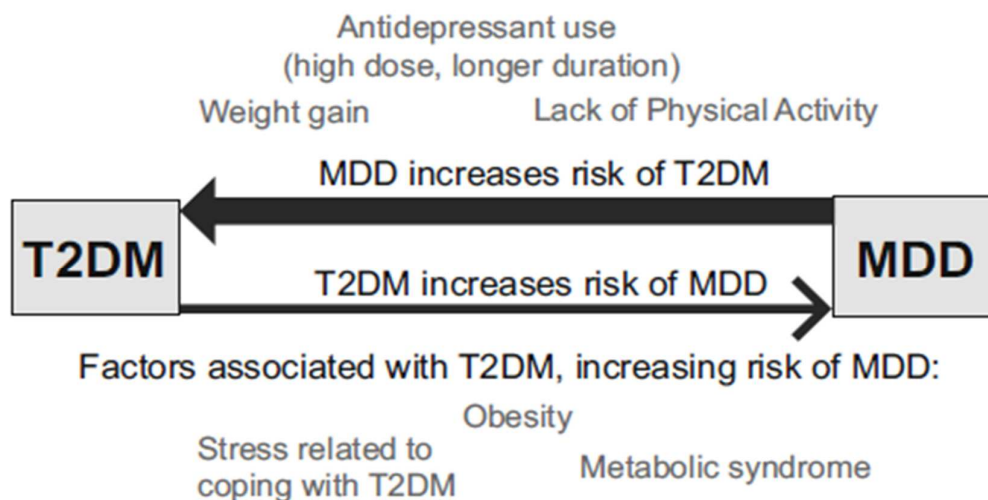


Figure 2 showing the bidirectionality between diabetes and depression ^[5]

Other factors that were associated with higher incidence of depression in diabetic patients were high body mass index, low educational level^[2,59] lack of job^[9], smoking, positive family history, shorter duration of diabetes^[2], major life events and the presence of complications of diabetes

Globally, various studies have found that around 28% of patients with T2DM were have depression of various degrees^[60] with 14.5% of them having major depressive disorder^[61] and more so in developing countries, where the prevalence varied between 34 to 54 %^[62-64]

Patients with newly diagnosed diabetes were 30% more likely to have a depressive episode in past 3 years before the onset of diabetes^[5] and the risk of developing diabetes in these patients was found to be higher as compared to general population^[65]. Subthreshold depression, the presence of depressive symptoms that do not fulfil the entire criteria for a depressive episode, is the single most important predictor for developing major depression^[66] and 40% of diabetic patients with subthreshold depression were said to develop severe depression within 2 years^[3], causing loss of productivity and health care utilization. Hence it is crucial to screen and treat the depressive symptoms that are not evident in diabetic patients and prevent the progression to a major episode.

Older age group with T2DM have a higher risk of developing depression, with an increased risk of chronicity of the episodes^[67] and recurrent depressive episodes^[68]. In patients over the age 55, when presented with depression at index evaluation, the risk of diabetes was up by 65%^[69]. The management of diabetes and late life depression is tricky as compared to younger population as caregiver burden is high, with frequent occurrence of loss and grief in this age group^[70], limited social support^[71], family

conflicts^[72,73] and symptoms like easy fatiguability, impaired sleep and appetite, that are often ignored as they can be present in diabetes as well.^[74] The risk of suicidal ideations was also found to be higher in this age group ^[75-77]

With diabetes and depression independently contributing to cognitive impairment and memory, recent studies have also shown that older adults with depression and diabetes can have an increased risk of dementia ^[78]which could be due to malfunctional hypothalamic pituitary adrenal axis ^[79,80]

Other contributing factors for the higher prevalence of type 2 diabetes in depression was linked with the usage of antidepressant medications that resulted in weight gain and hyperglycaemia, with longer treatment duration and higher doses having pronounced effects on the diabetic profile^[81], the augmentation of antidepressants with second generation antipsychotics, the use of which has increased from 4.6% in year 2000 to 12.5% by year 2010, which are notorious for causing metabolic syndrome ^[82,83] directly predisposing the patients to diabetes.

A systematic review done on depression and diabetes by Mendenhall et al (2018)^[84] has found that the rates of depression were higher in diabetic patients of those residing in low- and middle-income countries as compared to high income countries. ^[85] In the review carried out in India, few centres have shown that 25% to 33% diabetic patients were found to have depression and other centres have shown 19.7% to 23.4% of patients having depression ^[85]

Treatment compliance in diabetic patients

Patients are said to be compliant with the treatment when along with compliance to medications, other forms of management like lifestyle changes, dietary modifications and physical activity suggested by the health professional are also followed for the advised amount of duration ^[86,87]

Most of the studies done on adherence to diabetic medications have shown that noncompliance for medications was between 17%-86%, 62%-71% for dietary changes and 47%-80% for physical activity ^[86] and adherence to all 3 were found in only 26.1% of patients ^[88] however there is a need for quantifying each of these variables as diabetes is a long term, multifactorial disease with regional and ethnic variations that requires more than one form of management

Measures for medication compliance can be done by various objective procedures like pill count assessment, refill records ^[87] or subjective patient reported assessments like Morisky scores, dichotomous indicators etc ^[89]

Comprehensive empirical studies on treatment adherence, done have found that 57% of studies showed to have better glycaemic indices with better adherence to medication. ^[87] The ability to draw such conclusions were frequent in the group where prescription refills were the means to measure adherence as compared to subjective report by patients ^[87]

Various reasons for non-compliance can be forgetfulness, uncertainty about treatment, poor knowledge regarding consequences, ease of availability, financial barriers, social support, psychiatric illnesses, substance use, complex treatment plans,

tolerability, drug-drug interactions and adverse effects being the most common cause of poor compliance^[88,90]

Family and social support, especially for geriatric population, where diabetes is a common disorder plays a key role in maintaining treatment compliance as they rely on families for nutrition, physical activity, transportation and consultations^[88]

A study done on diabetic patients by Kuo et al (2003) for adherence and incidence of diabetic complications and have found that amongst patients with poor adherence, 59% had more renal complications, 66% of them more likely to die of diabetes related complications and 43% were more likely to die of any cause.^[91]

Poor adherence also leads to increased hospitalisations, with about 10% increase in adherence leading to a mean decrease of 6.6% ($P < 0.05$) in hospitalizations^[92]

Treatment compliance in patients with diabetes and depression

Patients with the comorbidity of diabetes and depression are less likely to adhere to lifestyle modifications like diet and exercise, poor monitoring of blood glucose, have poor adherence to medications that they miss double the doses of medication as compared to those with only diabetes.^[93,94] For those patients who received intervention with antidepressant medication, glycaemic control was achieved twice as higher compared to those not receiving the intervention.^[95] Apart from pharmacological interventions, psychotherapy, group therapy and collaborative care were shown having significant effect on controlling the blood glucose, that reflected in HBA1C levels, which was the highest when the baseline HBA1C levels were on the higher side. Clinical trials have shown that interventions like knowledge regarding adhering to

medications, teaching healthy dietary modifications and problem-solving therapy have shown to reduce the incidence of severe depression in older age group ^[95]

The mortality in those with this double diagnosis was found to be high^[96], with major depression causing 2.3 times and minor depression causing 1.7 times higher mortality as compared with those with only T2DM^[97]. This risk is additive and these patients can have an increased risk of mortality than the mortality associated with depression or diabetes alone.^[5] Active intervention in older population was found to reduce the all-cause mortality by 24% ^[98] as compared to depressed older individuals without t 2 DM.

As compared to patients who have had low-severity depression tertile, patients in medium and high severity tertiles, were found to have higher percentage of days of non-adherence to the prescribed oral hypoglycaemic regimen, and also were less adherent to dietary recommendations, and had higher functional impairment. ^[99]

Amongst patients who had diabetes and comorbid depression, intervention with anti-depressants was seen to improve compliance to diabetic medications and achieved lower HBA1C levels as compared to groups without intervention.^[100,101]

A multicentre study done in China on 2538 diabetic patients, associations were made between depression, treatment adherence, hyperglycaemia, and hypoglycaemia by rating patients on PHQ-9 scale for depression and MGLS scale for medication adherence. A PHQ-9 score of more than 10 was considered to be positive for depression and found 6.1%, 8.9% and 5.3% to be the prevalence rate in different centres of china. The medication adherence rates were found to be lower in depressed group as compared to non-depressed group, as tabulated in table 2 ^[101]

In a population-based cohort study done in Canada, which included patients who has received at least one antidiabetic drug in a 6-year period from 2001-2006 were studied for depression based on ICD-9 and ICD-10. Non-adherence was taken as computed data of proportion of days covered by less than 90% of anti-diabetic medications. Adherence was studied before and after diagnosis of depression and have found that 53.32% were adherent before the onset of depression which was reduced to 48.04% one year after the diagnosis of depression.^[102]

A cross-sectional study done in Tehran where diabetic patients with affective temperaments like depressive, cyclothymic, hyperthymic, cyclothymic, anxious, and irritable temperaments were rated on Beck depression inventory and found 13.5% patients had mild depression, 19.3% had moderate and 8.2% had severe depression. Compliance was studied on a Likert scale and found that depressed patients had poor compliance to anti diabetic medication, as tabulated below^[103]

In a retrospective study done in Germany between 2013-2015 where association between already diagnosed depression and the oral antidiabetic drugs in patients with type 2 diabetes mellitus were compared to controls, i.e., diabetic patients without depression. Drug persistence was measured by recording prescription supply, number of days of drug supply, quantity and the dosage information. At 12 months of follow up, drug persistence was found to be higher in patients without depression as compared to depressed patients^[104]

In a descriptive, cross-sectional study by done on 110 diabetic patients in Turkey, to study depression coping strategies, glycaemic control, and patient compliance, 30.9% of patients were found to have moderate to severe depression with positive correlation between depression scores and duration of illness and have found that compliance to pharmacological treatment was seen only in 44% of patients and

also found that compliance to diet and exercise was higher in non-depressed patients as compared to depressed patients. [105]

An analytical cross-sectional study conducted in Mexico, over one year, where 179 diabetic patients were studied for anxiety, depression and anxious depression and its relation to treatment medication adherence. Patients were rated on Goldberg Anxiety and Depression Scale and MGLS scale and found that compliance rates were 43.7%, 80%, 75.7% in patients with anxious depression, anxiety and depression respectively. The rates of compliance were 77% in patients who had neither anxiety nor depression. [106]

In a study done in Seattle, USA, 4,463 diabetic patients were rated on questionnaires for self-care, diabetes monitoring, depression and medication adherence. Depression was rated on PHQ scale and pharmacy data base was considered to check for medication adherence and have found that 19.5% of patients were nonadherent to oral hypoglycaemic medicines [94]

Sr.no.	Authors	Population size	Percentage of patients with Poor compliance
1.	Y. ZHANG et al. (2015) ¹⁰¹	n=2538	61.3%
2.	C. LUNghi et al. (2017) ¹⁰²	n=3106	52%
3.	SHAMSI et al. (2014) ¹⁰³	n=207	24.6%
4.	KAREL KOSTEV et al. (2017) ¹⁰⁴	n=6449	32.5%
5.	HULYA PARLIDAR et al. (2014) ¹⁰⁵	n=100	44%
6.	T. GONZALEZ HEREDIA et al. (2021) ¹⁰⁶	n=179	24.3%
7.	LIN and associates (2004) ⁹⁴	n= 4463	19.5%

Table 2: Showing previous studies done on treatment compliance in type 2 diabetes patients with depression

Quality of life

Quality of life, that includes mental, physical and social well-being is poor in diabetic patients, more so in those with diabetic complications. Complications of diabetes are the most important disease-specific determinant of quality of life.^[107] There is causal relationship between quality of life and adherence with diabetes treatment ^[108]

Quality of life was found to be poor in patients with MDD and T2 DM than in diabetes alone.^[109-111] Studies done on diabetic patients with subthreshold depression were found to be having 3 times poorer quality of life as compared to those with no depression.^[112] On studies done on patients with Type 2 Diabetes with depression, Quality of life was found to be having negative correlation with depression rating scores ^[113]

MATERIALS AND METHODS

This study was designed as a cross-sectional descriptive study, involving type II diabetes patients attending the Department of Endocrinology at KLE's Dr Prabhakar Kore Charitable Hospital, Nehru Nagar, Belagavi. Patients were recruited using purposive sampling

Data collection took place between 1st January 2021- 31st December 2021.

Source of sample: Type II Diabetic patients attending Endocrinology OPD

Sample size: 270

Sampling procedure: Assuming a small effect size of depression on compliance, minimum sample size in each group (depressed and non-depressed) would be 120 (with alpha error of 5% and power 20%)

So, the sample size in both the groups would be 240.

Considering 10% additional sample to make up for any incomplete or lost data, sample size is determined to be 264 which is rounded to 270

Inclusion Criteria:

1. All adults over the age of 18 years diagnosed with Type II Diabetes Mellitus
2. Patients willing to give informed consent.

Exclusion Criteria:

1. Patients with Independent mood disorders or psychotic disorders.
2. Patients with substance dependence except Nicotine.
3. Patients with other chronic illnesses except hypertension.

Ethical clearance: Prior to commencement, ethical clearance was obtained from Institutional Ethics Committee, Jawaharlal Nehru Medical College, Belagavi.

Ethical clearance number- MDC/DOME/42

TOOLS:

PHQ-9: Patient Health Questionnaire- 9. The PHQ-9 is the depression module, which scores each of the nine DSM-IV criteria as "0" (not at all) to "3" (nearly every day). It is one of the most widely used scale to screen for depression and was developed by Dr Robert L. Spitzer, Dr Janet B.W. Williams, Dr Kurt Kroenke and colleagues from Columbia University in 1999. It takes about 3minutes to apply and can be self-rated/applied by the clinician. This scale has a reliability of 0.84 and the validity is 0.73. It gives 5 depression severity levels as following

PHQ-9 Score	Depression severity
1-4	None/Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

TABLE 3 showing PHQ-9 score and corresponding depression severity

MGLS: Morisky Green Levine Scale is a self-rated 4-item scale designed by Dr. Morisky and colleagues initially as a measure of treatment adherence in hypertensive patients. It includes 4 questions with yes/no answers that takes less than a minute to apply. It gives levels of treatment compliance and also the reason for poor compliance. A score of 0 indicates high compliance, a score of 1-2 indicates medium compliance and a score of 3-4 indicates low compliance. The scale has a reliability of 0.18 and the validity is 0.6.

WHOQOL BREF: WHO Quality of life scale is a 26-item self-rated/interviewer administered scale developed by the World Health Organisation. It takes 10-15minutes to apply and gives scores in 4 domains- Physical, Psychological, Social and Environmental health. It is a shorter version of WHOQOL-100, and is a widely used scale to assess the quality of life. The BREF scale gives raw scores of each domain that are to be converted into transformed scores, comparable with the WHOQOL-100. The overall reliability of the scale is 0.68 and the overall validity is 0.57 in depression

DATA ANALYSIS: The data obtained is tabulated.

The socio-demographic and clinical details of the patients are described using percentages (for categorical variables) and as mean and standard deviation (for continuous variables). To Test for Significant Association, Chi Square or Fischer Exact tests are applied for Categorical variables. Unpaired Student t test is applied for Continuous variables. Correlation coefficient between two groups is calculated using Spearman Correlation coefficient. All tests are two tailed. P value of less than 0.05 is considered significant.

RESULTS

TABLE 4: SOCIO-DEMOGRAPHIC PROFILE OF STUDY SAMPLE

S.no	Variables		Non-depressed group (n=178)	Depressed group (n=92)	Total (n=270)	P value
1	Age (Mean \pm SD) (In years)		47.01 \pm 9.61	57.2 \pm 12.95	50.5 \pm 11.88	<0.0001
2	Sex	Males	109 (61.20%)	51 (56.66%)	160 (59.2%)	0.363
		Females	69 (38.76%)	41 (44.56%)	110 (40.7%)	
3	Place of residence	Rural	125 (70.22%)	74 (80.40%)	199 (73.7%)	0.08
		Urban	53 (29.77%)	18 (19.56%)	71 (26.29%)	
4	Education	Primary school/Uneducated	19 (10.67%)	32 (34.78%)	51 (18.88%)	<0.0001
		Middle school	36(20.22%)	27 (29.34%)	63 (23.33%)	
		High school	38 (21.30%)	16 (17.30%)	54 (20%)	
		PUC/12 TH	34 (19.10%)	9 (9.78%)	43 (15.92%)	
		Graduate	39 (21.90%)	8 (8.6%)	47 (17.40%)	
		Post graduate	12 (6.74%)	0 (0%)	12 (4.44%)	
5	Per-capita income (Mean \pm SD) (In Rupees)		Rs 21014 \pm 20186	Rs12456 \pm 17536	Rs18098 \pm 19715	0.0007
6	Employment	Unemployed	53 (29.70%)	52 (56.5%)	105 (55.55%)	<0.0001
		Semi-skilled	54 (30.3%)	25(27.17%)	79 (29.25%)	
		Skilled	46 (25.8%)	11 (11.95%)	57 (21.11%)	

		Professional	25 (14.04)	4 (4.3%)	29 (10.74%)	
7	Marital status	Married	155 (87.07%)	73(79.34%)	228 (84.44%)	0.02
		Single	7 (3.93%)	0 (0%)	7 (2.59%)	
		Divorced	3(1.6%)	3(3.2%)	7 (2.59%)	
		Widowed	10(5.61%)	14(15.2%)	24 (8.88%)	
		Separated	3(1.6%)	1(1.08%)	4 (1.48%)	

Table 4 shows the demographic profile of the study sample. Patients in depressed group were older [Mean age being 57.2 ± 12.95 years, significantly higher than 47.01 ± 9.61 years, the mean age of non-depressed group] Both groups had higher number of females than males. Both the groups also had higher number patients residing in rural residence Depressed group had significantly lower education levels than non-depressed group. 34.78% of depressed patients have studied only up to primary school and only 8.6% of depressed patients have graduated. In the non-depressed group, 21.90 % have graduated. 56.50% of depressed patients were unemployed and the depressed group had a significantly lower per- capita income as compared to non-depressed group. Marital status had significant correlation with depression (P value=0.02). There are higher number of married patients in non-depressed group. 15.2% of patients in depressed group were widowed as compared to 5.61% in non-depressed group.

TABLE 5: CLINICAL FACTORS IN NON-DEPRESSED AND DEPRESSED GROUPS

Sr. no	Variables		Non-depressed group (n=178)	Depressed group (n=92)	P value
1.	BMI	<18.5	34 (19.10%)	18 (19.56%)	0.0010
		18.5-24.9	79 (44.38%)	23 (25%)	
		25-29.9	36 (20.22%)	24 (26.08%)	
		30-34.9	28 (15.73%)	20 (21.73%)	
		>=35	1 (0.56%)	7 (7.60%)	
2.	Family History of Depression	Present	24 (13.4%)	17 (18.4%)	0.2
		Absent	154 (86.51%)	75 (81.5%)	
3.	Hypertension	Present	67 (37.64%)	58 (63.04%)	0.03
		Absent	111 (62.35%)	34 (36.95%)	
4.	Nicotine Dependence	Present	69 (38.76%)	42 (45.65%)	0.29
		Absent	109 (61.21%)	50 (54.34%)	

FIGURE 3: BMI IN DEPRESSED VS NON-DEPRESSED PATIENTS CORRESPONDING TO TABLE 5

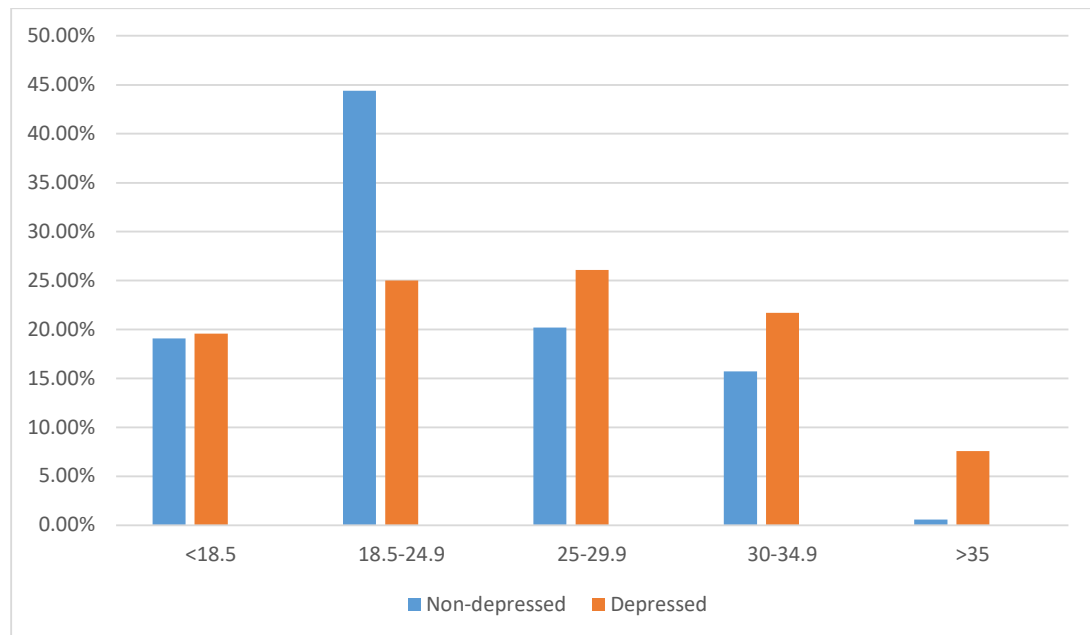


Table 5 and Figure 3 shows the association between BMI and depression. Depressed group had significantly higher BMI as compared to non-depressed group. 44.3% of non-depressed patients were in the range of normal BMI while only 25% of depressed patients were in normal BMI range. 7.60% of depressed patients had class 2 obesity while only 0.56% of non-depressed patients had class 2 obesity.

Table 5 shows that Hypertension has a significant correlation with depression. 63.04% of patients were seen to have hypertension in depressed group as compared to 37.64% in non-depressed group.

No correlation was seen with family history of depression and nicotine dependence

TABLE 6: DIABETIC COMPLICATIONS IN NON- DEPRESSED AND DEPRESSED GROUPS*

Sr. no	Variables		Non depressed group (n=178)	Depressed group (n=92)	P value
1.	Diabetic complications	Total	63 (35.39%)	69 (75%)	0.11
		Cardiovascular	22 (34.92%)	17 (24.63%)	
		Ophthalmological	11 (17.46%)	25 (36.23%)	
		Nephrological	16 (25.39%)	14 (20.28%)	
		Neurological	21 (33.33%)	17 (24.63%)	

*Table 6 shows diabetic complications that are not mutually exclusive as each patient can have multiple complications

FIGURE 4: DIABETIC COMPLICATIONS IN NON-DEPRESSED VS DEPRESSED GROUPS CORRESPONDING TO TABLE 6

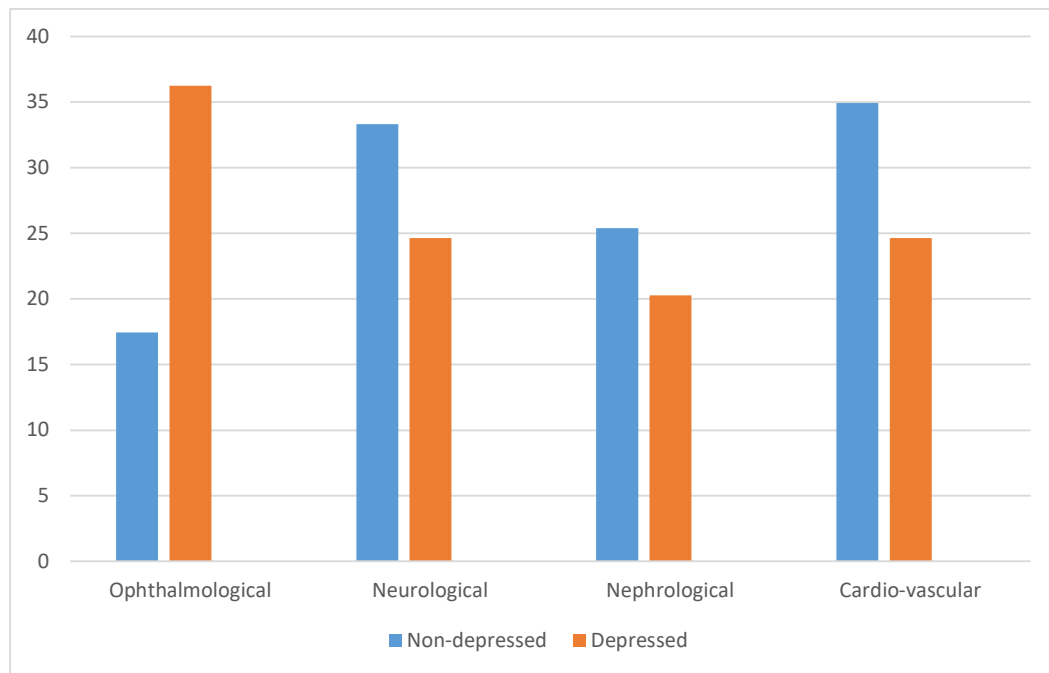


Table 6 and Figure 4 show that 75% of depressed patients had a diabetic complication and only 35.39% of non-depressed patients had a diabetic complication. 36.23% of the patients with complications in depressed group had an ophthalmological complication and 34.92% of patients with complications in non-depressed patients had a cardiovascular complication however these differences were not statistically significant

TABLE 7: COMPARISON OF FASTING BLOOD SUGAR (FBS) AND GLYCATED HEMOGLOBIN (HBA1C) IN NON-DEPRESSED AND DEPRESSED GROUPS

S.no	Variables	Non depressed group (n=178)	Depressed group (n=92)	P value
1.	Fasting blood sugar (Mean \pm SD)	137.4 \pm 35.45	184.6 \pm 58.52	<0.0001
2.	Glycated Haemoglobin (HBA1C) (Mean \pm SD)	6.66 \pm 1.22	8.46 \pm 2.31	<0.0001

FIGURE 5: COMPARISON OF FASTING BLOOD SUGAR IN NON-DEPRESSED VS DEPRESSED PATIENTS CORRESPONDING TO TABLE 7

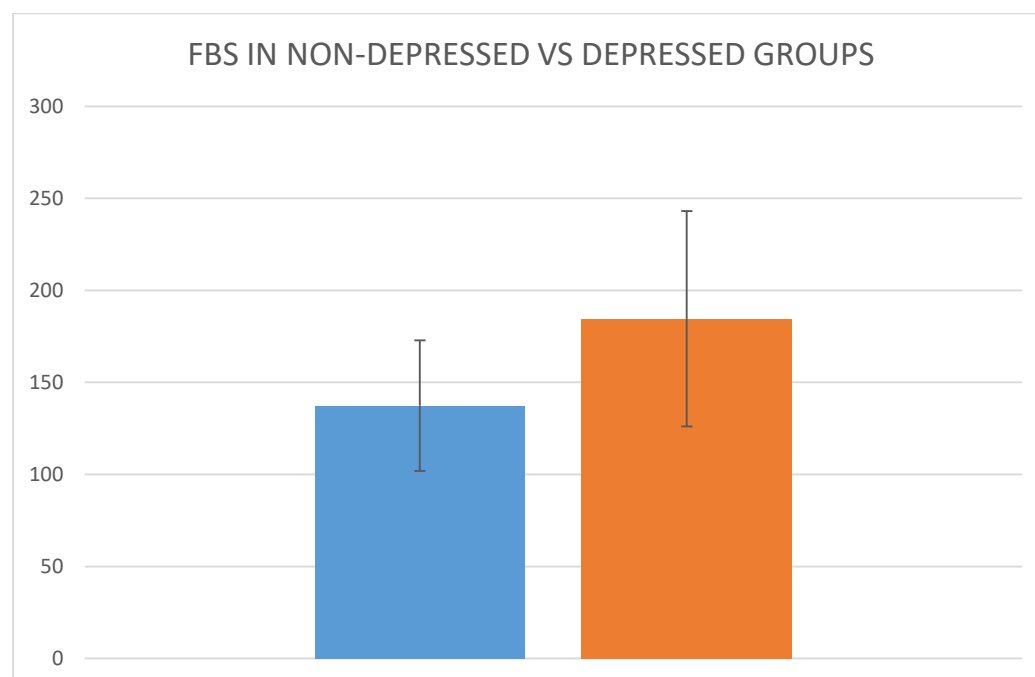


FIGURE 6: MEAN HBA1C IN NON-DEPRESSED VS DEPRESSED PATIENTS CORRESPONDING TO TABLE 7

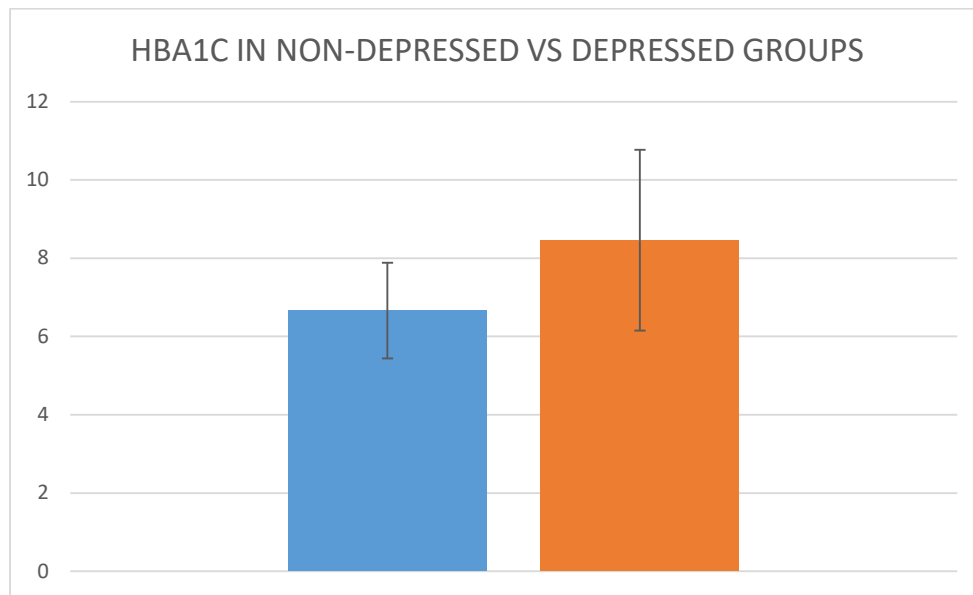


Table 7, Figure 5 and 6 show the mean FBS and HBA1C of depressed and non-depressed patients. Depressed patients had a significantly higher blood sugar level, FBS and HBA1C being 184.6 ± 58.52 and 8.46 ± 2.31 respectively. FBS and HBA1C were 137.4 ± 35.45 and 6.66 ± 1.22 respectively in the non-depressed group

TABLE 8: PREVALENCE OF DEPRESSION IN TYPE 2 DIABETIC PATIENTS

Sr. no.	Diagnosis of depression	Study population
1.	Present	92 (34.07%)
2.	Absent	178 (65.92%)

FIGURE 7: PREVALENCE OF DEPRESSION IN TYPE II DIABETIC PATIENTS

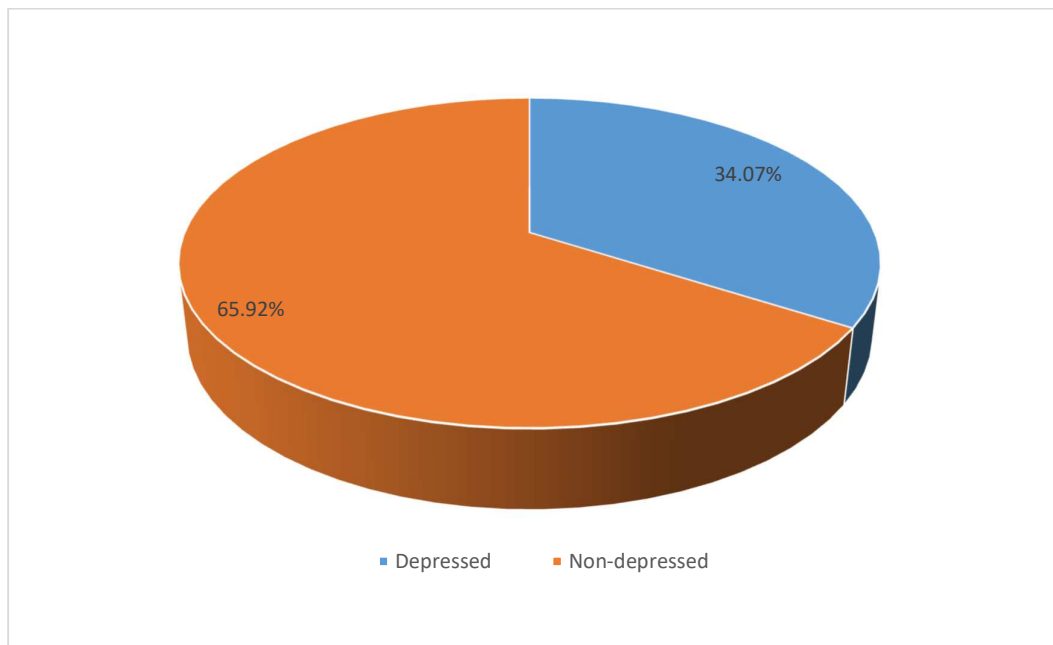


Table 8 and Figure 7 shows the prevalence of depression in diabetic patients, with 34.07% diagnosed to have depression (PHQ-9 score ≥ 5)

TABLE 9: COMPARISON OF LEVEL OF COMPLIANCE (MEAN MGLS SCORE) BETWEEN NON- DEPRESSED AND DEPRESSED GROUPS

Sr. no	Variable	Non depressed (n=178)	Depressed (n=92)	P value
1.	MGLS Score	0.3 ± 0.54	1.84 ± 0.97	<0.0001

FIGURE 8: COMPARISON OF LEVEL OF COMPLIANCE (MEAN MGLS SCORE) BETWEEN NON- DEPRESSED AND DEPRESSED GROUPS CORRESPONDING TO TABLE 9

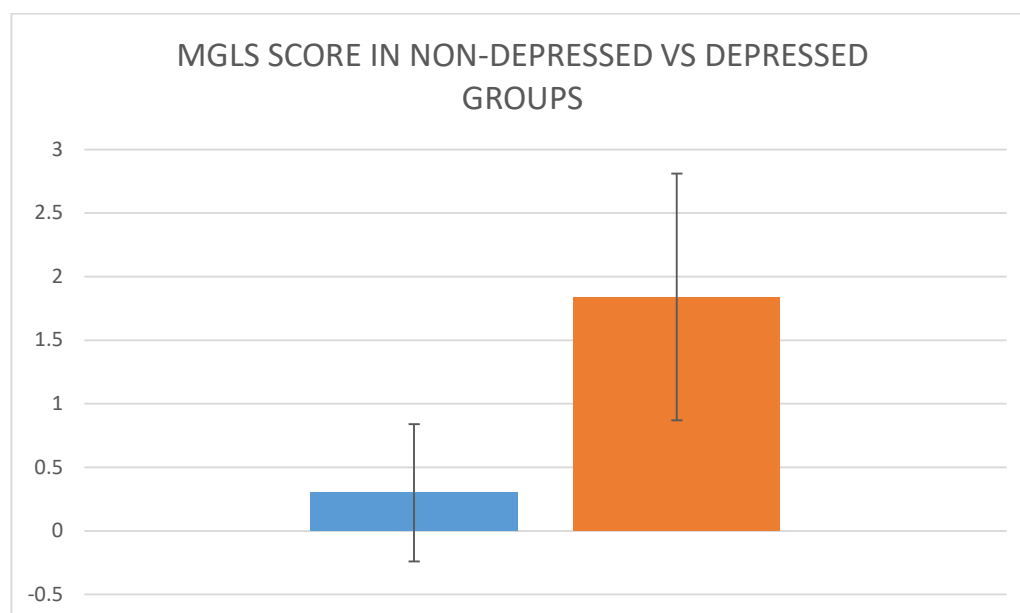


Table 9 And figure 8 show the mean MGLS score of depressed and non-depressed groups. Higher MGLS score indicate poor compliance. The mean MGLS score is 1.84 ± 0.97 in depressed group, which means a significantly lower compliance than the non-depressed group, who had a mean MGLS score of 0.3 ± 0.54

TABLE 10: CORRELATION BETWEEN SEVERITY OF DEPRESSION (PHQ9 SCORE) AND TREATMENT COMPLIANCE (MGLS SCORE) IN DEPRESSED GROUP

Sr. no.	Spearman r value	P value
1.	0.61	<0.0001

FIGURE 9: CORRELATION BETWEEN MGLS AND PHQ- 9 SCORES IN DEPRESSED GROUP CORRESPONDING TO TABLE 10

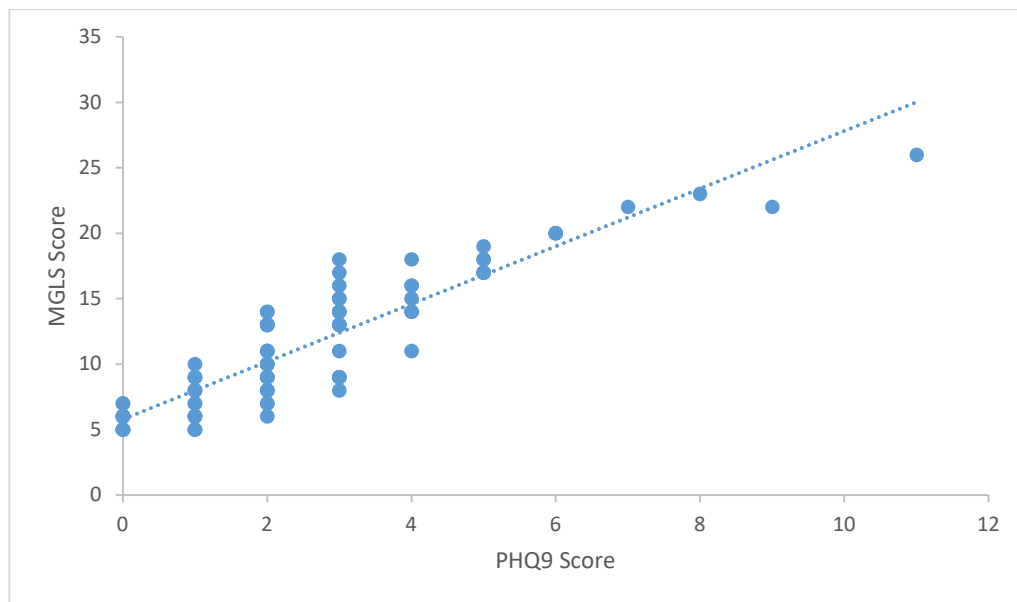


Table 10 and Figure 9 shows the correlation between mean PHQ-9 score and mean MGLS score of the depressed group (treatment compliance). There was a strong positive relationship ($r=0.61$, $P<0.0001$). As PHQ-9 score increased, MGLS score increased which means that treatment compliance is poorer as PHQ-9 score (depression severity) increased

TABLE 11: WHOQOL BREF DOMAIN SCORES IN NON-DEPRESSED AND DEPRESSED GROUPS

S.no.	DOMAIN	Non-depressed group (n=178) (Mean \pm SD)	Depressed group (n=92) (Mean \pm SD)	P value
1	Domain 1 (Physical health)	52.98 \pm 6.94	43.67 \pm 6.22	<0.0001
2	Domain 2 (Psychological health)	55.96 \pm 7.73	50.13 \pm 7.26	<0.0001
3	Domain 3 (Social relationships)	58.0 \pm 12.12	42.57 \pm 13.83	<0.0001
4	Domain 4 (Environment)	60.0 \pm 8.54	48.23 \pm 8.04	<0.0001

FIGURE 10: WHOQOL BREF DOMAIN SCORES IN NON-DEPRESSED AND DEPRESSED GROUPS CORRESPONDING TO TABLE 11

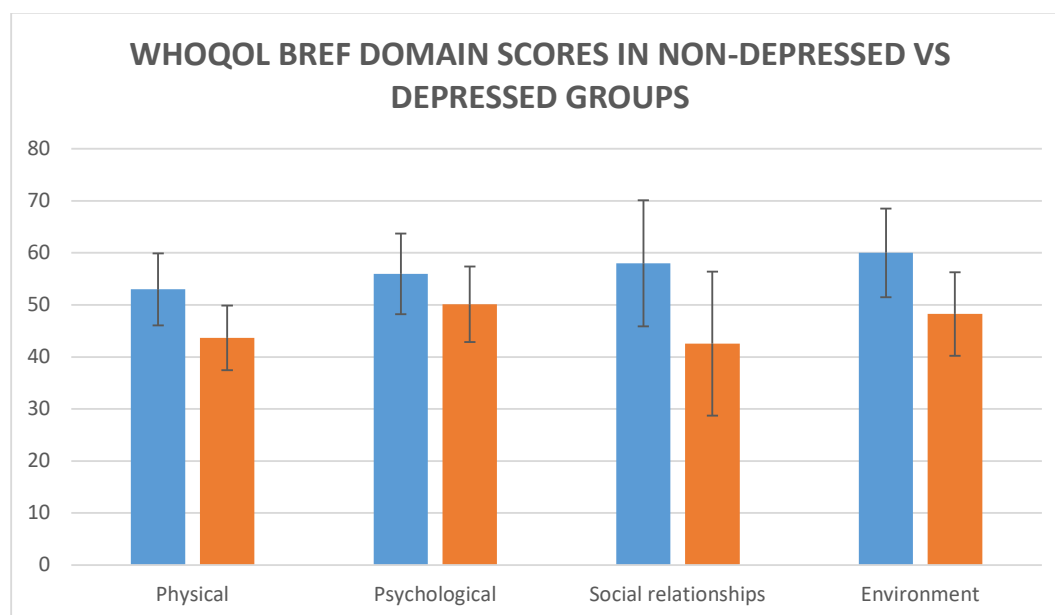


Table 11 and figure 9 show the WHOQOL BREF domain scores between depressed and non-depressed groups. The physical domain score was lower in depressed group as compared to non-depressed group [43.67 \pm 6.22 vs 52.98 \pm 6.94 (P value=<0.0001)]. The psychological domain score was also lower in depressed group as compared to non-

depressed group [50.13 ± 7.26 vs 55.96 ± 7.73 (P value= <0.0001)]. Depressed group scored less in domain of social relationships as compared to non-depressed group [42.57 ± 13.83 vs 58.0 ± 12.12 (P value= <0.0001)]. In environmental domain, depressed group scored lower than the depressed group [48.23 ± 8.04 vs 60.0 ± 8.54 P value= <0.0001]. Higher scores indicate a better quality of life. Depressed group scored significantly less than non-depressed in all domains of quality of life, hence have poorer quality of life.

DISCUSSION

Patients with diabetes suffer from higher risk of having depression and the consequences of it. Many studies done previously have established the same. Our study has assessed not only the prevalence of depression in diabetic patients but also the impact of depression on treatment compliance, the glycaemic index in depressed patients and quality of life.

DEMOGRAPHIC FACTORS AFFECTING DEPRESSION IN PATIENTS WITH DIABETES

In this study, we have compared the baseline characteristics between the diabetic patients with and without depression.

The mean age of those in depression group was higher as compared to the non-depressed group, indicating that depression is more prevalent in those in higher age group (Refer to Table 4 in results)

In a study done by Zuberi et al (2011)^[8] on 286 patients with Type 2 diabetes and the association of depression with treatment outcomes have found similar results that depressed subjects were older as compared to the non-depressed group. They found that there are higher number of patients in the age group of 57-60 years in the depression group compared to non-depressed group [33.6% vs 32.2%]

In a study done by Campayo, de jonge, roy et al.^[69] where depressive disorder and incident diabetes was studied, have found that depressed subjects had a higher age group compared to non-depressed subjects [73.6 ± 9.6 years vs 71.8 ± 9.2 years]

In a study done by Hashim et al (2016)^[4] on 204 patients with Type 2 diabetes mellitus, where they have studied- comorbid depression and associated factors have

found that the mean age of depressed patients was lower than non-depressed group [57.8 ± 15.1 years vs 62.9 ± 9 years]

There exists a discord between studies. Some studies have found that the average age of those with depression is lower as compared to the non-depressed group. However, the risk of geriatric depression is said to be higher in the context of chronic medical disorders, by up to 50%, as compared to elderly, medically healthy adults.^[114] The late-life cumulative depression prevalence was found to be as high as 11.19%.^[115] Our study has found similar results to most of the other studies that the mean age of depressed patients is higher than the non-depressed patients

Our study has found that there are a greater number of males as compared to females in both depressed and non-depressed groups- 56.66% males and 44.56% females in the depressed group and 61.20% of males and 38.76% of females in the non-depressed group. However, higher percentage of females (44.56%) were in depressed group as compared to the non-depressed group (38.76%) (Refer to Table 4 in results)

As per a study done by Arshad et al (2016)^[2], the male: female ratio in depressed and non-depressed groups were 13:38 and 42:40, indicating that there were higher number of females in the depressed group as compared to males

In a study done by Zuberi et al (2011)^[8], 286 patients with diabetes have been studied for association of depression with the treatment outcomes and found that 60.8% of patients in depressed group were females and 39.2% were males

These differences between the studies mentioned and our study is because our total study population consists of higher males than females i.e., 59.2% of patients were males and 40.8% were females. This could be because of lower treatment seeking behaviour of the female patients from a rural background, which formed higher proportion of patients in our study

Most of the population were seen to be rural habitants in both groups- 80.40% in depressed group and 70.22% in non-depressed group, as our study is carried out in a 2-tier city, with higher number of patients from rural catchment area. (Refer to Table 4 in results)

These results were similar to study conducted by Edah et al (2020) [9] on 252 diabetic patients for depression where they found that only 10% of depressed group had urban residence

Education is found to be having significant correlation with depression. Only 10.67% of patients in the non-depressed group of our study are educated up to primary school in as compared to 34.78% patients in the depressed group, which included the highest number of patients in a single category of education in the depressed group. The single highest number of patients in non-depressed group, 21.90%, were educated up to graduate level while only 8.6% of patients in depressed group have graduated (Refer to Table 4 in results)

Our results were in line with previous studies done by Arshad et al (2016) [2] where they found lower education level to be significantly associated with depression in diabetic patients

A study conducted by Hashim et al (2016) [4] on depression and associated factors on 204 diabetic patients have found that patients without major depression were higher in number in each educational level as compared to those with major depression

As per a study done by Bjelland et al (2008) [116], ‘The Hunt Study’, significant associations were found to be present between low educational level and the development of depression and that higher level of education is a protective factor in the development of depression. These results were similar to the results obtained in our study

Employment and per-capita income were found to be significantly associated with depression, with unemployed group contributing to the highest number in the depressed patient group i.e., 56.50%, compared to 29.7% in the non-depressed group (P value <0.0001). As depression can affect employment, with patients having symptoms like reduced concentration and anhedonia could lead to more absenteeism at work and hence higher unemployment and a lower per-capita income. Our study found depressed patients to have a significantly lower per-capita income as compared to non-depressed group [Rs 12456 ± 17536 vs Rs 21014 ± 20186 (P value = 0.0007)] (Refer to Table 4 in results)

In a study done by Dirmaier J (2010) ^[7] on diabetes and its association between depression, non-adherence and glycaemic control have found similar results that there was a significant association between employment and depression. 89.1% of depressed patients and 90.4% patients with subthreshold depression in their study were unemployed in comparison to 82.9% of patients without depression

Lower levels of education seen in depressed patients could be one of the reasons for unemployment and lower per-capita income, both seen in our study, having similar results as the other studies mentioned

Marital status is seen to have correlation with depression. Depressed group had lower number of married patients as compared to non-depressed group [79.34% vs 87.07%]. Depressed group had 15.2% widowed patients while 5.61% of patients were widowed in the non-depressed group. (Refer to table 4 in results)

In a similar study by Hashim et al (2016) [4], similar results were found as our study that 86.3% of non-depressed patients were married in comparison to only 13.7% in the depressed group

Dirmaier et al (2010) ^[7] have found similar results that 66.3% of depressed diabetic patients were married in comparison to 69.6% in the non-depressed diabetic group

Marital status and the relationship with depression is said to be complex in that unmarried individuals are at greater risk for depression but being unmarried can also be a result of adverse life events due to depression.^[117] Hence depression is seen more commonly in divorced/separated/widowed patients, which is in line with the results of our study

BMI was seen to be significantly associated with depression (P value= 0.0010). 26.08% of patients, highest single category in the depressed group were overweight and 44.38% of patients, highest single category in the non-depressed group were seen to have normal BMI. 7.60% of depressed patients have class 2 obesity and only 0.56% of patients in the non-depressed group had class 2 obesity (Refer to Table 5 in results)

In the study done by Arshad et al (2016) ^[2] high BMI was found to be significantly associated with depression. Their study has found similar results as ours that the mean BMI in depressed group was higher than non-depressed group [28.01 ± 5.39 vs 25.51 ± 3.60 (P = 0.002)]

Another study carried out by Dirmaier et al (2010) ^[7] have found similar results to our study that BMI in depressed diabetic patients is higher than non-depressed diabetic patients [30.5 ± 5.8 vs 29.4 ± 4.7]

The reason for higher BMI among depressed patients could be due to appetite alterations, anhedonia and easy fatiguability that restricts patients from adhering to the advised dietary modifications or physical exercise

Hypertension was found to have significant correlation with depression. 63.04% of depressed patients in our study had hypertension and 37.64% of non-depressed patients had hypertension (Refer to table 5 in results)

In a similar study done by Arshad et al (2016) ^[2], similar results were found as our study that higher proportion of depressed patients had comorbid hypertension in comparison to the non-depressed group [56.86% vs 43.90%] but was not a statistically significant finding

A study conducted by Axon et al (2016) ^[118] where comorbid depression was studied in diabetic patients have found that hypertension was present in higher number of depressed patients as compared to the non-depressed group [80.19% vs 75.59%]. This finding is in line with our study that hypertension is more prevalent in depressed diabetic patients than the non-depressed counterparts

This finding could be because of the underlying mechanisms of stress, impaired HPA axis and overactive sympathetic nervous system ^[119] which makes it a rule rather than an exception for the disorders to coexist

Our study has found no significant correlation between depression and the presence of family history or comorbid nicotine use

PREVALENCE OF DEPRESSION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

To assess the prevalence of depression, Patient health questionnaire- 9 was used, which is a self-reported scale, screens for the presence or absence of depression over last 2 weeks, as well as gives various severity levels.

In this study it was seen that 34.07% of patients scored above the cut off (≥ 5), indicating the presence of at-least mild level of depression. 65.92% have scored <5 on the PHQ-9 scale, which indicates no diagnosable depression. (Refer to table 8 in results)

Study done by Arshad A et al (2016) [2] to study the frequency of depression in 133 patients with type 2 diabetic patients have found that 38.35% of patients were depressed

Another study done by Mariska et al (2010)[3] on incident major depression in 114 diabetic outpatients have found that 42% of diabetic patients had comorbid major depression at the end of a 2 year follow up.

Study done by Zhang et al (2015)[101], on 2538 patients with type 2 diabetes mellitus, prevalence of depression was found to be 13.0%. The lower prevalence of depression found in this study could be because of a higher cut-off value of 7 on PHQ-9 scale this study has used to diagnose depression, whereas our study uses a cut off value of 5.

Our study has found similar results as compared to most of the studies mentioned above. These findings also support the hypothesis of depression being more common in diabetic patients as compared to general population (5% as per WHO) [18],

which could be due to similar underlying biological mechanisms of diabetes and depression involving the HPA dysfunction contributing to the higher prevalence rates in diabetic patients.

IMPACT OF DEPRESSION ON TREATMENT COMPLIANCE IN PATIENTS WITH DIABETES MELLITUS

We have used Morisky green levine scale to check for treatment compliance. This scale gives a score of 0-4, which gives three levels of adherence. A score of 0 indicates high compliance and a score of ≥ 1 indicates some amount of non-compliance. A score of 1-2 indicates medium compliance and 3-4 indicates low compliance.

The mean MGLS score in depressed group was significantly higher as compared to non-depressed group [1.84 ± 0.97 vs 0.3 ± 0.54 (P value of <0.0001)] which shows that non-depressed diabetic patients had a better compliance (Refer to table 9 in results)

There is a significant correlation between severity of depression and treatment compliance in depressed group with a P value of <0.0001 and Spearman r value of 0.61, indicating that there is a strong positive correlation between the depression severity and the MGLS score. Hence the patients with higher severity of depression were found to have higher MGLS score, which means that more severe the depression is, poorer the compliance to treatment

In a study carried out by Zhang et al (2015) ^[101], 2538 diabetic patients in China were studied for hyperglycaemia, hypoglycaemia, and treatment adherence. Patients were rated on same scales as our study, PHQ-9 for depression and MGLS for treatment adherence. Assuming a similar phenotype between Chinese and Indian population,

results were found to be similar to our study. There was significant association between depression and treatment adherence. Only 38.7% of depressed patients had high adherence to medications in comparison to 60.3% in the non-depressed group.

Our study results were similar to study done by Gonzalez et al (2007) ^[93], where 879 diabetic patients were studied for depression, self-care and medication adherence, have also found significant correlation between depression severity & treatment compliance as measured by HANDS (Harvard department of psychiatry/National depression screening scale) that every 1-point increase on this scale increased the odds of missing at least one dose of treatment by 1.12-fold.

Similar results were found in another study carried out by Lin and associates (2004) [94] where 4463 diabetic patients with diabetes were studied for relationship of depression, diabetes self-care, medication adherence, has found that depressed patients were non-adherent for an average of 24.5% days in a year, significantly higher than in non-depressed patients, i.e., 18.8% of days in a year

The significant impact of depression on treatment compliance in diabetic patients could be due to the symptoms of depression like ideas of hopelessness, helplessness and worthlessness of depressed patients which prevents them from active treatment adherence behaviours. The symptoms of impaired attention and concentration of depression can present as pseudo-dementia, often making patients non-adherent to the long course of treatment in diabetic patients

Hence it is important to screen diabetic patients for depression due to its higher prevalence and intervene when necessary. This can potentially improve the treatment compliance in diabetic patients and prevent various diabetes related complications

IMPACT OF DEPRESSION ON QUALITY OF LIFE

We have studied the quality of life in depressed and non-depressed diabetic patients.

The physical domain score was lower in depressed group as compared to non-depressed group [43.67 ± 6.22 vs 52.98 ± 6.94 (P value= <0.0001)]. The psychological domain score was also lower in depressed group as compared to non-depressed group [50.13 ± 7.26 vs 55.96 ± 7.73 (P value= <0.0001)]. Depressed group scored less in domain of social relationships as compared to non-depressed group [42.57 ± 13.83 vs 58.0 ± 12.12 (P value= <0.0001)]. In environmental domain, depressed group scored lower than the depressed group [48.23 ± 8.04 vs 60.0 ± 8.54 P value= <0.0001]

Depressed group were found to have a lower quality of life as compared to non-depressed in all domains of quality of life

Most of the studies previously done have assessed the quality of life in diabetic patients or depressed patients. Only few studies have studied the quality of life in depressed diabetic patients.

A study carried out by Goldney R et al (2004) ^[121] on diabetes, depression and quality of life have found that depressed diabetic patients scored significantly low in all domains of quality of life as measured by SF-36 scale and have also found that depression impacted the quality of life more than diabetes and that the risk is additive when the comorbidity is present

A study done by Grandy S et al (2008) [122] have found that health related quality of life as measured by SF-12 has shown lower quality of life among diabetic

patients as compared to those at lower risk of developing diabetes. Physical component was affected more than the Mental component i.e., a SF-12 score of 39.5 and 49.01 respectively in the diabetic group and 50.6 and 49.52 respective score in the low-risk group.

IMPACT OF DEPRESSION ON BLOOD GLYCEMIC LEVELS

We have also assessed the derangement of blood sugar in depressed and the non-depressed group. This was done by measuring FBS and HBA1C levels in all the patients. We have found that in the depressed group, the mean FBS was higher as compared to the non-depressed group [184.6 ± 58.52 vs 137.4 ± 35.45 ($P < 0.0001$)] (Refer to table 7)

The mean HBA1C levels in depressed group was higher than the non-depressed group [8.46 ± 2.31 vs 6.66 ± 1.2 ($P < 0.0001$)] (Refer to table 7)

Both the values (FBS and HBA1C) were shown to be significantly higher in the depressed group as compared to the non-depressed group, indicating poor sugar control in patients with depression.

As per the study done by Zhang et al (2015) ^[101], on diabetic patients with and without depression has yielded similar results as our study. Significant association was found between the severity of depression and HBA1C level. Only 36.2% of the patients in the study with PHQ-9 score of >10 were found to achieve a target HBA1C level of $<7.0\%$ as compared to 45.6% of patients with a PHQ-9 score of <10

As per a study done by Echeverry et al (2009) ^[120], a randomized double-blind trial on 75 diabetic patients with depression have found that treatment with anti-depressant sertraline has resulted in significant reduction of HBA1C levels of these diabetic patients, which indicates that depression and its treatment has a correlation with the glycaemic levels, similar to the findings as our study

CONCLUSION

The study shows that one-third of diabetic patients have depression (34.07%)

Treatment compliance is found to be significantly lower in depressed diabetic group. Treatment compliance is seen to have a negative correlation with depression. As depression worsened, treatment compliance has worsened

Quality of life is found to be lower in depressed diabetic group as compared to non-depressed diabetic group in physical, psychological, social relationships and environmental domains of life

Depression had significant association with socio-demographic profile of age, education, employment, per-capita income, and marital status. BMI and hypertension were also seen to have significant association with depression

Depressed diabetic patients had higher glycaemic index as measured by FBS and HBA1C values, compared to the non-depressed counterparts

STRENGTHS OF THE STUDY:

1. The sample size of our study is higher than most studies performed on diabetic patients
2. Our study has used structured tool for assessing compliance

LIMITATIONS OF THE STUDY:

1. Our study groups are not comparable in baseline characteristics. The depressed group had a higher age group, higher number of unemployed patients with a lower per-capita income
2. The confounding factors like higher mean age, higher levels of unemployment, being poorer and rural residence in depressed group were not considered

SUMMARY

Depression is more common in diabetic patients than the general population. They often co-exist and it is found that the two disorders have a bidirectional relationship. Depression and diabetes affect the course and various factors of each disorder independently.

The present study is a one-year descriptive cross-sectional study, which was conducted in The Department of Endocrinology, KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi from 1st January 2021 to 31st December 2021. A total of 270 cases with a diagnosis of Type II Diabetic mellitus were taken up for the study after due consent. Patients were screened with Patient Health Questionnaire-9 for depression, Morisky Green Levine Scale for Treatment compliance and WHO-QOL BREF for quality of life.

34.07% of diabetic patients had PHQ-9 score ≥ 5 (diagnosable depression), who had a significantly higher FBS and HBA1C level as compared to the non-depressed group. The treatment compliance was significantly lower in the depressed group, with a mean MGLS score of 1.84 ± 0.97 as compared to 0.3 ± 0.54 in the non-depressed group. The MGLS score increased as PHQ-9 score increased, indicating that treatment compliance was poorer as depression got severe. The depressed group also had lower quality of life as compared to the non-depressed group, in all domains of WHOQOL-BREF.

BIBLIOGRAPHY

1. Pradeepa R, Mohan V. Epidemiology of type 2 diabetes in India. *Indian J Ophthalmol*. 2021 Nov;69(11):2932–8.
2. Arshad AR, Alvi KY. Frequency of depression in type 2 diabetes mellitus and an analysis of predictive factors. *J Pak Med Assoc [Internet]*. 2016 Apr;66(4):425–9.
3. Bot M, Pouwer F, Ormel J, Slaets JPJ, de Jonge P. Predictors of incident major depression in diabetic outpatients with subthreshold depression. *Diabetic Medicine [Internet]*. 2010 Nov;27(11):1295–301.
4. Hashim N, Ariaratnam S, Salleh M, Said M, Sulaiman A, Azreen Hashim N, et al. Depression and Associated Factors in Patients with Type 2 Diabetes Mellitus. PhD; 2016.
5. Semenkovich K, Brown ME, Svrakic DM, Lustman PJ. Depression in type 2 diabetes mellitus: Prevalence, impact, and treatment. *Drugs*. 2015 Apr 1;75(6):577–87.
6. Gonzalez JS, Safren SA, Cagliero E, Wexler DJ, Delahanty L, Wittenberg E, et al. Depression, Self-Care, and Medication Adherence in Type 2 Diabetes. *Diabetes Care*. 2007 Sep 1;30(9):2222–7.
7. Dirmaier J, Watzke B, Koch U, Schulz H, Lehnert H, Pieper L, et al. Diabetes in primary care: Prospective associations between depression, nonadherence and glycemic control. *Psychother Psychosom*. 2010 Apr;79(3):172–8.

8. Zuberi SI, Syed EU, Bhatti JA. Association of depression with treatment outcomes in Type 2 Diabetes Mellitus: A cross-sectional study from Karachi, Pakistan. *BMC Psychiatry*. 2011 Feb 15;11.
9. Edah J, Goar S, Odoh G, Lawal B, Dayom P, Sunday Z, et al. Undiagnosed depression among adults with diabetes mellitus in Jos. *Niger J Clin Pract* [Internet]. 2020;23(10):1431.
10. ADEGHATE E, SCHATTNER P, DUNN E. An Update on the Etiology and Epidemiology of Diabetes Mellitus. *Ann N Y Acad Sci*. 2006 Nov 1;1084(1): 1–29.
11. Sun H, Saeedi P, Karuranga S, Pinkepank M, Ogurtsova K, Duncan BB, et al. IDF Diabetes Atlas: Global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045. *Diabetes Res Clin Pract*. 2022 Jan;183:109119.
12. The Emerging Risk Factors Collaboration. Diabetes mellitus, fasting blood glucose concentration, and risk of vascular disease: a collaborative meta-analysis of 102 prospective studies. *The Lancet*. 2010 Jun;375(9733):2215–22.
13. Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. *Nat Rev Endocrinol*. 2018 Feb 8;14(2):88–98.
14. Lovic D, Piperidou A, Zografou I, Grassos H, Pittaras A, Manolis A. The Growing Epidemic of Diabetes Mellitus. *Curr Vasc Pharmacol*. 2020;18(2): 104–9.

15. Mohan V, Sandeep S, Deepa R, Shah B, Varghese C. Epidemiology of type 2 diabetes: Indian scenario. *Indian J Med Res.* 2007 Mar;125(3):217–30.
16. Egede LE, Ellis C. Diabetes and depression: Global perspectives. Vol. 87, *Diabetes Research and Clinical Practice.* 2010. p. 302–12.
17. 2. Classification and Diagnosis of Diabetes: *Standards of Medical Care in Diabetes—2021.* *Diabetes Care.* 2021 Jan 1;44(Supplement_1):S15–33.
18. World health organization. depression. 2021.
19. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry.* 10th ed. Vol. 1. 2017. 4106 p.
20. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry.* 10th ed. Vol. 1. 2017. 4109 p.
21. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry.* 10th ed. Vol. 1. 2017. 4111 p.
22. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry.* 10th ed. Vol. 1. 2017. 4112–4113 p.
23. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry.* 10th ed. Vol. 1. 2017. 4113 p.
24. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry.* 10th ed. Vol. 1. 2017. 4114 p.
25. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry.* 10th ed. Vol. 1. 2017. 4115 p.

26. Sadock BSV 'Ruiz, P. Comprehensive textbook of psychiatry. 10th ed. Vol. 1. 2017. 4116 p.
27. Sadock BSV 'Ruiz, P. Comprehensive textbook of psychiatry. 10th ed. Vol. 1. 2017. 4117–4118 p.
28. Sadock BSV 'Ruiz, P. Comprehensive textbook of psychiatry. 10th ed. Vol. 1. 2017. 4118–4119 p.
29. Duman CH. Models of Depression. In 2010. p. 1–21.
30. Sadock BSV 'Ruiz, P. Comprehensive textbook of psychiatry. 10th ed. Vol. 1. 2017. 4120–4121 p.
31. Sadock BSV 'Ruiz, P. Comprehensive textbook of psychiatry. 10th ed. Vol. 1. 2017. 4121–4122 p.
32. Sadock BSV 'Ruiz, P. Comprehensive textbook of psychiatry. 10th ed. Vol. 1. 2017. 4123 p.
33. Sadock BSV 'Ruiz, P. Comprehensive textbook of psychiatry. 10th ed. Vol. 1. 2017. 4124 p.
34. Sadock BSV 'Ruiz, P. Comprehensive textbook of psychiatry. 10th ed. Vol. 1. 2017. 4132 p.
35. Sadock BSV 'Ruiz, P. Comprehensive textbook of psychiatry. 10th ed. Vol. 1. 2017. 4133 p.

36. Angst J, Dobler-Mikola A, Binder J. The Zurich study ?A prospective epidemiological study of depressive, neurotic and psychosomatic syndromes. *Eur Arch Psychiatry Neurol Sci.* 1984 Apr;234(1):13–20.
37. Bebbington PE, Brugha T, MacCarthy B, Potter J, Sturt E, Wykes T, et al. The Camberwell Collaborative Depression Study I. Depressed Probands: Adversity and the Form of Depression. *British Journal of Psychiatry.* 1988 Jun 2;152(6):754–65.
38. Hammen C. Risk Factors for Depression: An Autobiographical Review. *Annu Rev Clin Psychol.* 2018 May 7;14(1):1–28.
39. Foland-Ross LC, Hardin MG, Gotlib IH. Neurobiological Markers of Familial Risk for Depression. In 2012. p. 181–206.
40. Snyder HR. Major depressive disorder is associated with broad impairments on neuropsychological measures of executive function: A meta-analysis and review. *Psychol Bull.* 2013;139(1):81–132.
41. Lorenzetti V, Allen NB, Fornito A, Yücel M. Structural brain abnormalities in major depressive disorder: A selective review of recent MRI studies. *J Affect Disord.* 2009 Sep;117(1–2):1–17.
42. Mannie ZN, Filippini N, Williams C, Near J, Mackay CE, Cowen PJ. Structural and functional imaging of the hippocampus in young people at familial risk of depression. *Psychol Med.* 2014 Oct 7;44(14):2939–48.

43. Salk RH, Hyde JS, Abramson LY. Gender differences in depression in representative national samples: Meta-analyses of diagnoses and symptoms. *Psychol Bull.* 2017 Aug 1;143(8):783–822.
44. Eagly AH, Wood W. Social Role Theory. In: *Handbook of Theories of Social Psychology*. 1 Oliver's Yard, 55 City Road, London EC1Y 1SP United Kingdom: SAGE Publications Ltd; p. 458–76.
45. International Classification of Diseases Eleventh Revision (ICD-11). Geneva: World Health Organization; 2022. 11th ed. 2018. 33 p.
46. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. American Psychiatric Association; 2013.
47. Freedland KE. The Depression Interview and Structured Hamilton (DISH): Rationale, Development, Characteristics, and Clinical Validity. *Psychosom Med.* 2002 Nov 1;64(6):897–905.
48. Weyerer S, Hewer W, Pfeifer-Kurda M, Dilling H. Psychiatric disorders and diabetes— results from a community study. *J Psychosom Res.* 1989 Jan;33(5):633–40.
49. Clouse RE, Lustman PJ, Freedland KE, Griffith LS, McGill JB, Carney RM. Depression and Coronary Heart Disease in Women With Diabetes. *Psychosom Med.* 2003 May;65(3):376–83.
50. de Groot M, Anderson R, Freedland KE, Clouse RE, Lustman PJ. Association of Depression and Diabetes Complications: A Meta-Analysis. *Psychosom Med.* 2001 Jul;63(4):619–30.

51. Lustman PJ, Anderson RJ, Freedland KE, de Groot M, Carney RM, Clouse RE. Depression and poor glycemic control: a meta-analytic review of the literature. *Diabetes Care*. 2000 Jul 1;23(7):934–42.
52. Nouwen A, Winkley K, Twisk J, Lloyd CE, Peyrot M, Ismail K, et al. Type 2 diabetes mellitus as a risk factor for the onset of depression: a systematic review and meta-analysis. *Diabetologia*. 2010 Dec 14;53(12):2480–6.
53. Anderson RJ, Freedland KE, Clouse RE, Lustman PJ. The Prevalence of Comorbid Depression in Adults With Diabetes. *Diabetes Care*. 2001 Jun 1;24(6):1069–78.
54. Patterson ZR, Khazall R, MacKay H, Anisman H, Abizaid A. Central Ghrelin Signaling Mediates the Metabolic Response of C57BL/6 Male Mice to Chronic Social Defeat Stress. *Endocrinology*. 2013 Mar 1;154(3):1080–91.
55. Axelson DA, Doraiswamy PM, McDonald WM, Boyko OB, Tupler LA, Patterson LJ, et al. Hypercortisolemia and hippocampal changes in depression. *Psychiatry Res*. 1993 May;47(2):163–73.
56. Weber B, Schweiger U, Deuschle M, Heuser I. Major depression and impaired glucose tolerance. *Experimental and Clinical Endocrinology & Diabetes*. 2000 Dec 31;108(03):187–90.
57. Bruehl H, Wolf OT, Convit A. A blunted cortisol awakening response and hippocampal atrophy in type 2 diabetes mellitus. *Psychoneuroendocrinology*. 2009 Jul;34(6):815–21.

58. Ho N, Sommers MS, Lucki I. Effects of diabetes on hippocampal neurogenesis: Links to cognition and depression. *Neurosci Biobehav Rev*. 2013 Sep;37(8):1346–62.
59. Sweileh WM, Abu-Hadeed HM, Al-Jabi SW, Zyoud SH. Prevalence of depression among people with type 2 diabetes mellitus: a cross sectional study in Palestine. *BMC Public Health*. 2014 Dec 13;14(1):163.
60. Khaledi M, Haghighatdoost F, Feizi A, Aminorroaya A. The prevalence of comorbid depression in patients with type 2 diabetes: an updated systematic review and meta-analysis on huge number of observational studies. *Acta Diabetol [Internet]*. 2019 Jun 22;56(6):631–50.
61. Wang F, Wang S, Zong Q -Q., Zhang Q, Ng CH, Ungvari GS, et al. Prevalence of comorbid major depressive disorder in Type 2 diabetes: a meta-analysis of comparative and epidemiological studies. *Diabetic Medicine*. 2019 Aug;36(8):961–9.
62. Hussain S, Habib A, Singh A, Akhtar M, Najmi AK. Prevalence of depression among type 2 diabetes mellitus patients in India: A meta-analysis. *Psychiatry Res [Internet]*. 2018 Dec 1 [cited 2022 Aug 23];270:264–73.
63. Pashaki MS, Mezel JA, Mokhtari Z, Gheshlagh RG, Hesabi PS, Nematifard T, et al. The prevalence of comorbid depression in patients with diabetes: A meta-analysis of observational studies. *Diabetes & Metabolic Syndrome: Clinical Research & Reviews [Internet]*. 2019 Nov 1 [cited 2022 Aug 23];13(6):3113–9.

64. Roy T, Lloyd CE, Parvin M, Mohiuddin KGB, Rahman M. Prevalence of comorbid depression in out-patients with type 2 diabetes mellitus in Bangladesh. *BMC Psychiatry* [Internet]. 2012 Dec 22;12(1):123.
65. Everson-Rose SA, Meyer PM, Powell LH, Pandey D, Torr ns JI, Kravitz HM, et al. Depressive Symptoms, Insulin Resistance, and Risk of Diabetes in Women at Midlife. *Diabetes Care*. 2004 Dec 1;27(12):2856–62.
66. Meeks TW, Vahia I v., Lavretsky H, Kulkarni G, Jeste D v. A tune in “a minor” can “b major”: A review of epidemiology, illness course, and public health implications of subthreshold depression in older adults. *J Affect Disord*. 2011 Mar;129(1–3):126–42.
67. Iosifescu D v, Nierenberg AA, Alpert JE, Papakostas GI, Perlis RH, Sonawalla S, et al. Comorbid medical illness and relapse of major depressive disorder in the continuation phase of treatment. *Psychosomatics*. 45(5):419–25.
68. Klein DN, Shankman SA, Rose S. Ten-year prospective follow-up study of the naturalistic course of dysthymic disorder and double depression. *Am J Psychiatry*. 2006 May;163(5):872–80.
69. Campayo A, de Jonge P, Roy JF, Saz P, de la C mara C, Quintanilla MA, et al. Depressive Disorder and Incident Diabetes Mellitus: The Effect of Characteristics of Depression. *American Journal of Psychiatry* [Internet]. 2010 May;167(5):580–8.
70. Stroebe M, Schut H, Stroebe W. Health outcomes of bereavement. *The Lancet*. 2007 Dec;370(9603):1960–73.

71. Pinquart M, Sörensen S. Influences of socioeconomic status, social network, and competence on subjective well-being in later life: a meta-analysis. *Psychol Aging*. 2000 Jun;15(2):187–224.
72. Thompson A, Fan MY, Unützer J, Katon W. One extra month of depression: the effects of caregiving on depression outcomes in the IMPACT trial. *Int J Geriatr Psychiatry*. 2008 May;23(5):511–6.
73. Yanni EA, Naoum M, Odeh N, Han P, Coleman M, Burke H. The health profile and chronic diseases comorbidities of US-bound Iraqi refugees screened by the International Organization for Migration in Jordan: 2007-2009. *J Immigr Minor Health*. 2013 Feb;15(1):1–9.
74. Park M, Reynolds CF. Depression among older adults with diabetes mellitus. Vol. 31, *Clinics in Geriatric Medicine*. W.B. Saunders; 2015. p. 117–37.
75. Unützer J. Clinical practice. Late-life depression. *N Engl J Med*. 2007 Nov 29;357(22):2269–76.
76. Lyness JM, Yu Q, Tang W, Tu X, Conwell Y. Risks for depression onset in primary care elderly patients: potential targets for preventive interventions. *Am J Psychiatry*. 2009 Dec;166(12):1375–83.
77. Remick RA. Diagnosis and management of depression in primary care: a clinical update and review. *CMAJ*. 2002 Nov 26;167(11):1253–60.
78. Katon W, Lyles CR, Parker MM, Karter AJ, Huang ES, Whitmer RA. Association of depression with increased risk of dementia in patients with type

- 2 diabetes: the Diabetes and Aging Study. *Arch Gen Psychiatry*. 2012 Apr;69(4):410–7.
79. Lok A, Mocking RJT, Ruhé HG, Visser I, Koeter MWJ, Assies J, et al. Longitudinal hypothalamic-pituitary-adrenal axis trait and state effects in recurrent depression. *Psychoneuroendocrinology*. 2012 Jul;37(7):892–902.
80. Stetler C, Miller GE. Depression and hypothalamic-pituitary-adrenal activation: a quantitative summary of four decades of research. *Psychosom Med*. 73(2):114–26.
81. Andersohn F, Schade R, Suissa S, Garbe E. Long-Term Use of Antidepressants for Depressive Disorders and the Risk of Diabetes Mellitus. *American Journal of Psychiatry*. 2009 May;166(5):591–8.
82. Pan A, Lucas M, Sun Q, van Dam RM, Franco OH, Manson JE, et al. Bidirectional Association Between Depression and Type 2 Diabetes Mellitus in Women. *Arch Intern Med*. 2010 Nov 22;170(21).
83. Gerhard T, Akincigil A, Correll CU, Foglio NJ, Crystal S, Olfson M. National Trends in Second-Generation Antipsychotic Augmentation for Nonpsychotic Depression. *J Clin Psychiatry*. 2014 May 15;75(05):490–7.
84. Udedi M, Pence B, Kauye F, Muula AS. The effect of depression management on diabetes and hypertension outcomes in low- and middle-income countries: a systematic review protocol. *Syst Rev [Internet]*. 2018 Dec 5;7(1):223.

85. Mendenhall E, Norris SA, Shidhaye R, Prabhakaran D. Depression and type 2 diabetes in low- and middle-income countries: A systematic review. Vol. 103, Diabetes Research and Clinical Practice. Elsevier Ireland Ltd; 2014. p. 276–85.
86. Arrelias CCA, Faria HTG, Teixeira CR de S, Santos MA dos, Zanetti ML. Adesão ao tratamento do diabetes mellitus e variáveis sociodemográficas, clínicas e de controle metabólico. Acta Paulista de Enfermagem. 2015 Aug;28(4):315–22.
87. Asche C, LaFleur J, Conner C. A Review of Diabetes Treatment Adherence and the Association with Clinical and Economic Outcomes. Clin Ther. 2011 Jan;33(1):74–109.
88. Lerman I. Adherence to Treatment: The Key for Avoiding Long-Term Complications of Diabetes. Arch Med Res. 2005 May;36(3):300–6.
89. Sharma, Taruna & Kalra, Juhi & Dhasmana, Dilipchander & Basera, H.. (2014). Poor adherence to treatment: A major challenge in diabetes. Journal, Indian Academy of Clinical Medicine. 15. .
90. Rubin RR. Adherence to pharmacologic therapy in patients with type 2 diabetes mellitus. Am J Med. 2005 May;118(5):27–34.
91. Kuo YF, Raji MA, Markides KS, Ray LA, Espino D v., Goodwin JS. Inconsistent Use of Diabetes Medications, Diabetes Complications, and Mortality in Older Mexican Americans Over a 7-Year Period. Diabetes Care. 2003 Nov 1;26(11):3054–60.

92. Balkrishnan R, Rajagopalan R, Camacho FT, Huston SA, Murray FT, Anderson RT. Predictors of medication adherence and associated health care costs in an older population with type 2 diabetes mellitus: A longitudinal cohort study. *Clin Ther.* 2003 Nov;25(11):2958–71.
93. Gonzalez JS, Safren SA, Cagliero E, Wexler DJ, Delahanty L, Wittenberg E, et al. Depression, Self-Care, and Medication Adherence in Type 2 Diabetes. *Diabetes Care.* 2007 Sep 1;30(9):2222–7.
94. Lin EHB, Katon W, von Korff M, Rutter C, Simon GE, Oliver M, et al. Relationship of Depression and Diabetes Self-Care, Medication Adherence, and Preventive Care. *Diabetes Care* [Internet]. 2004 Sep 1;27(9):2154–60. Available from:
95. Brieler JA, Lustman PJ, Scherrer JF, Salas J, David Schneider F. Antidepressant medication use and glycaemic control in co-morbid type 2 diabetes and depression. *Fam Pract.* 2016 Feb 1;33(1):30–6.
96. Egede LE, Nietert PJ, Zheng D. Depression and All-Cause and Coronary Heart Disease Mortality Among Adults With and Without Diabetes. *Diabetes Care.* 2005 Jun 1;28(6):1339–45.
97. Zhang X. Depressive Symptoms and Mortality among Persons with and without Diabetes. *Am J Epidemiol.* 2005 Apr 1;161(7):652–60.
98. Gallo JJ, Morales KH, Bogner HR, Raue PJ, Zee J, Bruce ML, et al. Long term effect of depression care management on mortality in older adults: follow-up of cluster randomized clinical trial in primary care. *BMJ.* 2013 Jun 5;346:f2570.

99. Ciechanowski PS, Katon WJ, Russo JE. Depression and Diabetes. *Arch Intern Med.* 2000 Nov 27;160(21):3278.
100. Gonzalez JS, Safren SA, Cagliero E, Wexler DJ, Delahanty L, Wittenberg E, et al. Depression, self-care, and medication adherence in type 2 diabetes: Relationships across the full range of symptom severity. *Diabetes Care.* 2007 Sep;30(9):2222–7.
101. Zhang Y, Ting RZ, Yang W, Jia W, Li W, Ji L, et al. Depression in Chinese patients with type 2 diabetes: Associations with hyperglycemia, hypoglycemia, and poor treatment adherence. *J Diabetes.* 2015 Nov 1;7(6):800–8.
102. Lunghi C, Zongo A, Moisan J, Grégoire JP, Guénette L. Factors associated with antidiabetic medication non-adherence in patients with incident comorbid depression. *J Diabetes Complications.* 2017 Jul 1;31(7):1200–6.
103. Shamsi A, Khodaifar F, Arzaghi SM, Sarvghadi F, Ghazi A. Is there any relationship between medication compliance and affective temperaments in patients with type 2 diabetes? *J Diabetes Metab Disord.* 2014 Sep 27;13(1).
104. Kostev K, Jacob L. Association between depression and persistence with oral antihyperglycemic drugs in type 2 diabetes mellitus patients in Germany. *Psychiatry Res.* 2018 Mar 1;261:90–3.
105. Parildar H, Cigerli O, Demirag NG. Depression, coping strategies, glycemic control and patient compliance in Type 2 diabetic patients in an endocrine outpatient clinic. *Pak J Med Sci.* 2014;31(1):1–6.

106. Gonzalez Heredia T, González-Ramírez LP, Hernández-Corona DM, Maciel-Hernández EA. Anxious depression in patients with Type 2 Diabetes Mellitus and its relationship with medication adherence and glycemic control. *Glob Public Health*. 2021;16(3):460–8.
107. Rubin RR, Peyrot M. Quality of life and diabetes. *Diabetes Metab Res Rev*. 15(3):205–18.
108. Rodríguez-Almagro J, García-Manzanares Á, Lucendo AJ, Hernández-Martínez A. Health-related quality of life in diabetes mellitus and its social, demographic and clinical determinants: A nationwide cross-sectional survey. *J Clin Nurs*. 2018 Nov;27(21–22):4212–23.
109. Anderson BJ, Edelstein S, Abramson NW, Katz LEL, Yasuda PM, Laviertes SJ, et al. Depressive Symptoms and Quality of Life in Adolescents With Type 2 Diabetes. *Diabetes Care* [Internet]. 2011 Oct 1;34(10):2205–7.
110. Egede LE, Hernández-Tejada MA. Effect of comorbid depression on quality of life in adults with Type 2 diabetes. *Expert Rev Pharmacoecon Outcomes Res* [Internet]. 2013 Feb 9;13(1):83–91.
111. Wexler DJ, Grant RW, Wittenberg E, Bosch JL, Cagliero E, Delahanty L, et al. Correlates of health-related quality of life in type 2 diabetes. *Diabetologia*. 2006 Jul 29;49(7):1489–97.
112. Polonsky WH, Fisher L, Earles J, Dudl RJ, Lees J, Mullan J, et al. Assessing Psychosocial Distress in Diabetes. *Diabetes Care*. 2005 Mar 1;28(3):626–31.

113. Babenko AY, Mosikian AA, Lebedev DL, Khrabrova EA, Shlyakhto E v. Mental state, psychoemotional status, quality of life and treatment compliance in patients with Type 2 diabetes mellitus. *J Comp Eff Res*. 2019 Jan 1;8(2):113–20.
114. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry*. 10th ed. Vol. 2. 2017. 4783 p.
115. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry*. 10th ed. Vol. 2. 2017. 4782 p.
116. Bjelland I, Krokstad S, Mykletun A, Dahl AA, Tell GS, Tambs K. Does a higher educational level protect against anxiety and depression? The HUNT study. *Soc Sci Med*. 2008 Mar;66(6):1334–45.
117. Sadock BSV 'Ruiz, P. *Comprehensive textbook of psychiatry*. 10th ed. Vol. 1. 2017. 4144 p.
118. Axon RN, Gebregziabher M, Hunt KJ, Lynch CP, Payne E, Walker RJ, et al. Comorbid depression is differentially associated with longitudinal medication nonadherence by race/ethnicity in patients with type 2 diabetes. *Medicine (United States)*. 2016 Jun 1;95(25).
119. Scalco AZ, Scalco MZ, Azul JBS, Lotufo Neto F. Hypertension and depression. *Clinics (Sao Paulo)*. 2005 Jun;60(3):241–50.
120. Echeverry D, Duran P, Bonds C, Lee M, Davidson MB. Effect of Pharmacological Treatment of Depression on A1C and Quality of Life in Low-Income Hispanics and African Americans With Diabetes. *Diabetes Care*. 2009 Dec 1;32(12):2156–60.

121. Goldney RD, Phillips PJ, Fisher LJ, Wilson DH. Diabetes, Depression, and Quality of Life. *Diabetes Care*. 2004 May 1;27(5):1066–70.

122. Grandy S, Chapman RH, Fox KM, SHIELD Study Group. Quality of life and depression of people living with type 2 diabetes mellitus and those at low and high risk for type 2 diabetes: findings from the Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes (SHIELD). *Int J Clin Pract*. 2008 Apr;62(4):562–8.

ANNEXURE I: CONSENT FROMS

INFORMED CONSENT

**CONSENT FOR PARTICIPATION IN RESEARCH ‘THE IMPACT OF
DEPRESSION ON TREATMENT COMPLIANCE IN PATIENTS WITH TYPE II
DIABETES MELLITUS: A CROSS-SECTIONAL STUDY’**

Investigator: Reg no BQ0120002

Post Graduate Student,

Department Of Psychiatry,

KLE Academy of Higher Education & Research,

Jawaharlal Nehru Medical College

Guide: Dr _____

Associate Professor,

Department Of Psychiatry,

KLE Academy of Higher Education & Research,

Jawaharlal Nehru Medical College,

Belagavi-590010

You are hereby requested to participate in the above said research to be conducted at KLE’S Dr. Prabhakar Kore’s Hospital and Medical Research Centre, Belagavi from January 2021 to December 2021 by me.

INTRODUCTION

PURPOSE OF THE STUDY

The study aims to know the impact of depression on treatment compliance in patients with Type II Diabetes Mellitus.

PROCEDURE:

After taking informed consent, you will be subjected to semi-structured questionnaires to document socio-demographic and clinical details. Patient Health Questionnaire (PHQ9) will be applied to diagnose depressive disorder. Morisky Green Levine Medication Adherence Scale will be used to test for Treatment Adherence.

WHO Quality of Life (WHOQOL-BREF) will be used to measure the impact of depression on Quality of Life in Type II diabetes mellitus patients

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM THE STUDY:

Taking part in the study is voluntary. You may choose not to en-roll yourself in this study and may choose to leave the study anytime in between.

ALTERNATIVES:

You are free to discontinue the participation in the study at any time for any reasons and you will not be paid any reimbursement for participation in the research.

PRIVACY AND CONFIDENTIALITY

All data collected or disclosed by you during the course of participation of study will be kept fully confidential. However, during the course if it becomes necessary for the progress of the course to disclose the identity, it would be done so only after your informed & written consent.

The only people to know that you are a research subject are members of the research team. No information about you will be disclosed to other without your written permission except:

- In emergency to protect your rights and welfare.
- If required by law.

INSTITUTIONAL/SPONSERS POLICY:

Not applicable to this research.

FINANCIAL INCENTIVES FOR PARTICIPATION: No additional costs shall be incurred upon you for the purpose of this study. It is purely being done with the idea of research and all the cost of study will be borne by the investigator. There will be not be any remuneration, reimbursement, compensation or free medical care.

AUTHORIZATION TO PUBLISH RESULT:

The results of the study may be used to publish an article. When the results of research published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information obtained in connection with this study and that can be identified with you will remain confidential.

QUESTIONS/CONTACT DETAILS:

You shall be free to contact the below mentioned name & addresses anytime during the study period for any clarification or help as you may desire for.

RISKS AND BENEFITS

There are no major risks involved.

Benefits: With the help of this study the coexistence of depression in patients with diabetes will be known and it can help for further treatment if the patient wishes to do so. It will also help in improving the adherence to the diabetic treatment and an overall improvement in quality of life.

NO SPONSORS/FINANCIAL INCENTIVES

In case of any queries, you can contact

Reg No BQ0120002

Post Graduate student

Department of Psychiatry

JNMC, Belagavi-590010

DR _____

Associate Professor,

Department of Psychiatry,

KLE academy of higher education & research,

Jawaharlal Nehru Medical College,

Belagavi-590010

If you have any questions about your rights or research participation, you may contact Chairman ethical committee:

DR. HARSHA HEGDE

Chairperson,

Jawaharlal Nehru Medical College

ICE & Scientist D,

ICMR,

National Institute of Traditional Medicine

Belagavi

Participant's name:

Sign/thumb print:

Experimenters' name& sign:

Witness's name and sign:

STATEMENT OF CONSENT

I have read and have completely understood the entire information given in the consent form, which explains all the details of the study, i.e, the purpose, procedure involved, risks & benefits, privacy & confidentiality, incentives and the authorization to publish the results of the study. My signature in the space provided for signature below indicates that I have voluntarily agreed to participate in the study. I may withdraw my participation for any reason or may be withdrawn by the investigator from the study for any reason at any time. I am giving up any of my legal rights by signing this consent form.

Signature of the participant with date: _____

Name of the participant: _____

Signature of the Investigator with date: _____

Name of the investigator: _____

ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಸಲಹೆ

1. ನಾನು ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುತ್ತಿದ್ದೇನೆ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.
2. ರೋಗಿಯ ಮಾಹಿತಿಹಾಳೆಯಲ್ಲಿ ನಮಾಹಿತಿಯನ್ನು ನಾನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ. ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವ ಅನುಕೂಲಗಳು ಮತ್ತು ಅನಾನುಕೂಲತೆಗಳ ಬಗ್ಗೆ ಮಾಹಿತಿಯೊಂದಿಗೆ ಕಾರ್ಯವಿಧಾನವನ್ನು ನನಗೆ ವಿವರವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ. ಪ್ರಯೋಗದ ಎಲ್ಲಾ ಅಂಶಗಳನ್ನು ಚರ್ಚಿಸಲು ನನಗೆ ಅವಕಾಶ ನೀಡಲಾಗಿದೆ, ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳು ಮತ್ತು ಅದರ ಮೇಲೆ ಈ ಕೆಳಗಿನವುಗಳನ್ನು ವಿವರಿಸಿರುವ ವಿಚಾರಣೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಸಮ್ಮತಿಸಿ ನೀಡಲಾಗಿದೆ.
3. ಈ ಅಧ್ಯಯನದ ಪಾಲ್ಗೊಳ್ಳುವ ನಿರ್ಧಾರ ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ ಮತ್ತು ನಾನು ಆಯ್ಕೆ ಮಾಡಬಹುದು ಎಂದು ನನಗೆ ತಿಳಿದಿದೆ. ಸಮಯದ ಹಂತದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹೊರಬರಲು.
4. ವೈದ್ಯಕೀಯ, ವೈಜ್ಞಾನಿಕ ಅಥವಾ ಶೈಕ್ಷಣಿಕ ಉದ್ದೇಶಗಳಿಗಾಗಿ ನನ್ನ ದೇಹದ ಸೂಕ್ತವಾದ ಭಾಗಗಳನ್ನು ಒಳಗೊಂಡ ಕಾರ್ಯವಿಧಾನದ ಛಾಯಾಚಿತ್ರ ಅಥವಾ ರೆಕಾರ್ಡಿಂಗ್‌ನನ್ನು ಒಪ್ಪಿಗೆಯನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗಿಲ್ಲ ಅಥವಾ ಚಿತ್ರಗಳನ್ನು ಒಳಗೊಂಡಿರುವ ವಿವರಣಾತ್ಮಕ ಪಠ್ಯಗಳ ಮೂಲಕ ಬಹಿರಂಗ ಪಡಿಸುವುದಿಲ್ಲ.
5. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಮಾಡಿದ ಪರೀಕ್ಷೆಯಲ್ಲಿ ಯಾವುದೇ ಮಹತ್ವದ ಅಪಾಯವಿಲ್ಲ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.
6. ಪಡೆಯಬಹುದಾದ ಫಲಿತಾಂಶಗಳಿಗೆ ಯಾರಿಗೂ ಖಾತರಿ ಅಥವಾ ಭರವಸೆ ನೀಡಲಾಗಿಲ್ಲ.
7. ಮೇಲಿನ ರೂಪವನ್ನು ಅರ್ಥಮಾಡಿಕೊಂಡ ನಂತರ ನಾನು ಭಾಗವಹಿಸಲು ಸ್ವಇಚ್ಛೆಯಿಂದ ನಿರ್ಧರಿಸಿದ್ದೇನೆ ಎಂದು ಈ ರೂಪದಲ್ಲಿ ನನ್ನ ಸಹಿಸೂಚಿಸುತ್ತದೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು / ಕಾನೂನುಬದ್ಧವಾಗಿ ಅಧಿಕೃತ ಪ್ರತಿನಿಧಿ
ಪ್ರತಿನಿಧಿಸಹಿ

ಸಂದರ್ಶಕರ ಹೆಸರು ಮತ್ತು ಸಂದರ್ಶಕರ ಸಹಿ

ದಿನಾಂಕ:

ಸ್ಥಳ :

अनुसंधान अध्ययन में भाग लेना क्यलए सहमति

1. मैं समझता हूँ कि मैं अध्ययन में भाग लरहा हूँ ।
2. मैं पुष्टि करता हूँ कि मैंने प्रीज सूचना शीट में जानकारी पढ़ली हूँ और समझली हूँ। अध्ययन में समझाया गया हूँ कि अध्ययन में भाग लेना फायदा और नुकसान कबारा में जानकारी कसाथ मुझविस्तार सँ बताया गया हूँ। मुझपरीक्षण कसभी पहलुओं पर चर्चा करना क्वा अवसर दिया गया हूँ। प्रश्न पूछें और इस तरह सँकपर दिए गए मुकदमों में सहभागिता की सहमति हूँ।
3. यह समझें कि इस अध्ययन में भाग लेना क्वा निर्णय पूरी तरह सँस्वच्छिक हूँ और मुझपता हूँ कि मैं चुन सकता हूँ एक समय पर अध्ययन सँबा पस लेना क्यलए।
4. मडिकल, वज्ञानिक या शक्षिक उद्देश्यों क्यलए मँशरीर कउपयुक्तभाग सहित कार्य करना क्यलए प्रक्रिया की तस्वीर या रिकॉर्डिंग क्यलए सहमति दी गई हूँ। बशर्ते मँशी पहचान चित्रों में या उनकसाथ आनँ वाली वर्णनात्मक ग्रंथों में प्रकट नहीं हुई हूँ।
5. मैं समझता हूँ कि इस अध्ययन में किए गए किसी भी महत्वपूर्ण जोखिम को शामिल नहीं किया गया हूँ।
6. कोई गारंटी या आश्वासन किसी भी व्यक्ति द्वारा दिए गए परिणाम क्वरूप में नहीं दिया गया हूँ।
7. इस फार्म पर मँश हस्ताक्षर दर्शाता हूँ कि मैंने ऊपर की जानकारी समझना क्वा बाद खुशी-खुशी भाग लेना का फसला किया हूँ।

प्रतिभागी कनाम / कानूनी तौर पर अधिकृत प्रतिनिधि

हस्ताक्षर नाम

गवाह क्यहस्ताक्षर

साक्षात्कारकर्ता का नाम और हस्ताक्षर

दिनांक:

स्थान :

संशोधन अभ्यासक्रमात सहभागी होण्या साठी संमती

1. मला समजताऱ्की मी या अभ्यासात भाग घेत आहे।
2. मी पुष्टी करतो की मी रुग्णमाहिती पत्रकात माहितीवा चली आहेआणि समजून घेतली आहे।अभ्यासात भागघेण्याच्या फायदाआणि तोट्या विषयीमाहिती सहप्रक्रियात पशीलान।मला समजावून सांगितला।आहे।
. मला चाचणीच्या सर्व पलूवर चर्चा करण्याची, प्रश्न विचारण्याद्वाराआणि उपरोक्त दिलेल्याचाचणीत सहभागी होण्या संसंमती देण्याची संधी दिली गेली आहे।
3. समजून घ्या कीया अभ्यासात भाग घेण्याचा निर्णय पूर्णपणेस्वयं सखी आहेआणि मला याची जाणीव आहे।की मीनि वडूशक तोए कावळस अभ्यासातून बाहस पडण्यासाठी
4. वलकीय, वल्लानिक किंवा शल्लणिक हतू साठी माझ्या शरीराच्या योग्यभागां सहित कार्या साठी छायाचित्र काढणकिं वा रळॉर्डिंग करण्या संसंमती देणाहणजसाझी ओळखचित्रां मध्यकिंवा त्यांच्या सोबत असला। ल्यावर्णनात्मक ग्रंथां मध्यलघड झाली नाही.
5. मला हसमजताऱ्की या अभ्यासात कलल्याचा चणी मध्यकोणतही लक्षणीय धोका समाविष्ट नाही.
6. कोणतीही हमी किंवा आश्वासन कोणी ही मिळ वूशकतील अस।परिणाम म्हणून दत नाही.
7. या फॉर्म वर माझस्वाक्षरी असादर्शवताऱ्की मी उपरोक्त माहिती समजल्यानंतर सहभागी होण्या चानिर्णय घेतला आहे।

सहभागी चलाव / कायदक्षीर पणअधिकृत प्रतिनिधी
स्वाक्षरी चलाव

साक्षीदारांची सही नाव:

मुला खतकाराचलाव वस्वाक्षरी

दिनांक:

ANNEXURE II: PROFORMA

- Case no:
- Name:
- Age:
- OP/IP No:
- Gender: M/F
- Marital status

Unmarried	Married	Divorced	Widowed	Separated
-----------	---------	----------	---------	-----------

- Address:

Urban	Rural
-------	-------

- Education Level:

Primary School	Middle School	High School
Intermediate/PUC/12th	Graduate	Post Graduate

- Occupation:

Unemployed	Semi-Skilled	Skilled	Professional
------------	--------------	---------	--------------

- Per-Capita Income:

- BMI:

<18.5	18.5-24.9	25-29.9	>30-34.9	>35
-------	-----------	---------	----------	-----

- Duration since diagnosis with Diabetes:

- Number of oral anti-diabetic medications:

0	1	2	3	>3
---	---	---	---	----

- No. Of Injectables:

0	1	2	>2
---	---	---	----

- No. of Dosing's:

0	1	2	3	>3
---	---	---	---	----

- No. of units of Insulin:

- Investigations:

- 1.HBAlc
- 2.FBS

- Any Diabetic Complications:

Ophthalmological	Neurological	Nephrological	Cardiology	Others
------------------	--------------	---------------	------------	--------

- Previous Hospital admissions for Diabetes:

- If yes, how many?

- History of Diabetic Keto-Acidosis:

Yes	No
-----	----

- Hypertension:

Yes	No
-----	----

- Nicotine use in dependence

Yes	No
-----	----

pattern:

- Any other medications:

ANNEXURE III: TOOLS**PATIENT HEALTH QUESTIONNAIRE (PHQ-9)**

ID #: _____ DATE: _____

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

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

add columns + +

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

10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	_____
	Somewhat difficult	_____
	Very difficult	_____
	Extremely difficult	_____

MORISKY GREEN LEVINE SCALE

1. Do you ever forget to take your medicine?	Yes/No
2. Are you careless at times about taking your medicine?	Yes/No
3. When you feel better, do you sometimes stop taking your medicine?	Yes/No
4. Sometimes if you feel worse when you take the medicine, do you stop taking it?	Yes/No

WHOQOL BREF SCALE

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the last two weeks. For example, thinking about the last two weeks, a question might ask: ..

	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5
Do you get the kind of support from others that you need?					

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5
Do you get the kind of support from others that you need?				4	

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

WHOQOL-BREF
Page 3

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
		1	2	3	4	5
1(G1)	How would you rate your quality of life?					

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2 (G4)	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life?	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how good or satisfied you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last two weeks.

		Never	Seldom	Quite often	Very often	Always
26 (F8.1)	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5

Case no.	Age	Address	Gender	BMI	Education Level	Occupation	Marital status	Per-Capita Income	Duration since diagnosis with diabetes	Type of diabetes	Number of oral anti-diabetic medications	No. of Injectables	No. of dosings	No. of units of Insulin	Hba1c	Fbs	Diabetic Complications	Previous hospital admissions for Diabetes	Past History of Diabetes Keto-Acidosis	Previous Diagnosis of Depression	Family history of depression	Hypertension	Nicotine/tobacco usage	Nicotine use in dependent pattern	Ever forget to take medicines	Ever careless about taking medicines	Stop taking medicines when feeling better	Stop taking medicines if you feel worse	Over the last 2 weeks, have you had little interest in doing things?	Over the last 2 weeks, have you been feeling down, depressed, or hopeless?	Over the last 2 weeks, have you been having trouble falling or staying asleep, or sleeping too much?	Over the last 2 weeks, have you been feeling tired or having little energy?	Over the last 2 weeks, have you been having poor appetite or been overeating?	Over the last 2 weeks, have you been feeling bad about yourself or that you are a failure or have let yourself or your family down?	Over the last 2 weeks, have you been having trouble concentrating on things, remembering or watching television?	Over the last 2 weeks, have you been having thoughts that you would be better off dead, or of hurting yourself in some way?	If you had checked off any problems, how difficult has it been to make it for you to do your work, take care of things at home, or get along with other people?	Q1	Q2	Q3	Q4	Q5	Q21	Q22	Q23	Q24	Q25	Q26	
1	46	Rural	Female	30-35	Primary School	Semi-skilled	Married	24000	1-5years	Type 2 Diabetes Mellitus	3	0	0	6.6	136		No	No	No	No	No	No	No	No	1	1	0	1	1	1	1	1	1	1	0	0	Somewhat difficult	3	2	3	4	2	3	3	4	2	3		
2	42	Urban	Female	30-35	High School	Skilled	Married	40000	1-5years	Type 2 Diabetes Mellitus	2	0	0	6.5	132		Yes	No	No	No	No	No	No	No	0	1	0	0	1	2	1	1	1	1	1	0	1	Very difficult	3	2	3	4	2	3	3	4	3	2	
3	38	Rural	Male	25-30	Graduate	Skilled	Married	50000	6m-1year	Type 2 Diabetes Mellitus	2	0	0	6.5	119		No	No	No	Yes	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
4	60	Rural	Female	30-35	Primary School	Unemployed	Widowed	0	>10years	Type 2 Diabetes Mellitus	2	1	2	15-20	6.9	145	Ophthalmological	Yes	No	No	yes	Yes	No	No	1	1	1	0	2	3	2	2	2	1	1	0	1	Very difficult	3	2	2	3	2	3	4	4	4	3	2
5	55	Urban	Female	20-25	Middle School	Skilled	Married	60000	5-10 years	Type 2 Diabetes Mellitus	3	1	2	15-20	6.4	138	Neurological	Yes	Yes	No	No	Yes	No	No	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
6	43	Rural	Male	30-35	High School	Skilled	Married	30000	1-5years	Type 2 Diabetes Mellitus	3	0	0	6.9	142	Cardiological	Yes	Yes	No	No	Yes	Yes	Yes	Yes	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
7	27	Urban	Female	20-25	Graduate	Professional	Married	50000	1-5years	Type 1 Diabetes Mellitus	0	2	2	15-20	6.5	114		Yes	No	No	Yes	No	No	No	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
8	42	Rural	Male	15-20	High School	Semi-skilled	Married	11000	6m-1year	Type 2 Diabetes Mellitus	2	0	0	5.3	114		No	No	No	No	Yes	Yes	Yes	Yes	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
9	53	Rural	Male	30-35	Middle School	Semi-skilled	Married	34000	1-5 years	Type 2 Diabetes Mellitus	3	0	0	6.9	151	Ophthalmological	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
10	48	Rural	Female	30-35	Primary School	Unemployed	Married	0	5-10 years	Type 2 Diabetes Mellitus	2	1	2	15-20	6.5	145	Cardiological	Yes	No	No	No	Yes	Yes	Yes	1	0	0	1	3	3	2	2	3	1	2	0	2	0	2	0	2	0	2	0	2	2			
11	41	Rural	Female	25-30	Middle School	Unemployed	Single	0	1-5years	Type 2 Diabetes Mellitus	3	1	2	0-10	10.7	258		Yes	Yes	No	Yes	No	Yes	Yes	1	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
12	76	Rural	Male	15-20	Middle School	Semi-skilled	Married	27000	>10years	Type 2 Diabetes Mellitus	2	2	2	15-20	6.6	129	Ophthalmological	Yes	Yes	No	No	Yes	Yes	Yes	1	1	0	1	3	3	3	3	2	1	3	0	2	0	2	0	2	0	2	0	2	3	1		
13	46	Rural	Male	15-20	High School	Semi-skilled	Married	30000	1-5years	Type 2 Diabetes Mellitus	2	1	2	15-20	7.9	180	Neurological	Yes	Yes	No	No	Yes	Yes	Yes	1	0	0	0	2	3	1	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
14	53	Rural	Male	30-35	Graduate	Skilled	Widowed	42000	>10years	Type 2 Diabetes Mellitus	2	2	3	>25	11.3	258	Cardiological	Yes	No	No	No	Yes	Yes	Yes	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
15	39	Rural	Male	15-20	High School	Semi-skilled	Married	20000	1-5years	Type 2 Diabetes Mellitus	3	1	2	15-20	11.6	243		Yes	No	Yes	No	Yes	Yes	Yes	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
16	47	Rural	Female	25-30	Primary School	Unemployed	Married	0	>10years	Type 2 Diabetes Mellitus	2	1	2	10-15	6.8	128	Ophthalmological	No	No	No	No	No	Yes	No	1	0	0	1	2	3	3	3	3	3	2	2	1	1	0	1	0	1	0	1	0	1	0	1	
17	38	Urban	Female	20-25	Middle School	Unemployed	Married	0	5-10 years	Type 2 Diabetes Mellitus	3	0	0	6.1	104		No	No	No	No	No	No	No	No	1	0	0	0	1	1	2	1	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0		
18	50	Rural	Male	30-35	PUC/12th	Skilled	Married	42000	5-10 years	Type 2 Diabetes Mellitus	1	2	2	15-20	6	122	Cardiological	No	No	No	Yes	Yes	Yes	Yes	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
19	77	Rural	Male	30-35	Middle School	Semi-skilled	Married	15000	>10years	Type 2 Diabetes Mellitus	2	2	3	20-25	6.3	139	Ophthalmological	Yes	Yes	No	No	Yes	Yes	Yes	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
20	45	Rural	Female	25-30	Middle School	Unemployed	Married	0	1-5years	Type 2 Diabetes Mellitus	3	0	0	6.4	138		No	No	No	No	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
21	60	Urban	Female	25-30	Primary School	Unemployed	Divorced	0	>10years	Type 2 Diabetes Mellitus	2	1	2	10-15	6.3	130	Neurological	Yes	No	No	No	No	No	No	1	1	0	0	3	3	3	3	3	0	1	1	1	1	0	1	0	1	0	1	0	1	0		
22	53	Rural	Female	20-25	Primary School	Semi-skilled	Married	5000	5-10 years	Type 2 Diabetes Mellitus	3	0	0	5.8	99	Nephrological	No	No	No	No	No	No	No	No	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
23	72	Rural	Male	25-30	High School	Semi-skilled	Married	7600	>10years	Type 2 Diabetes Mellitus	0	2	3	20-25	6.4	135	Nephrological	Yes	No	No	No	Yes	Yes	Yes	1	0	0	0	0	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
24	47	Rural	Male	30-35	Graduate	Skilled	Married	50000	5-10 years	Type 2 Diabetes Mellitus	2	0	0	6.4	128	Cardiological	No	No	No	No	Yes	Yes	Yes	Yes	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
25	38	Rural	Male	25-30	High School	Semi-skilled	Single	18000	1-5 years	Type 2 Diabetes Mellitus	3	0	0	6.4	130		No	No	No	Yes	No	No	No	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
26	34	Rural	Male	25-30	Graduate	Skilled	Married	22000	1-5years	Type 2 Diabetes Mellitus	2	0	0	6.3	111		No	No	No	No	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
27	46	Rural	Female	25-30	Primary School	Semi-skilled	Married	8000	1-5years	Type 2 Diabetes Mellitus	2	0	0	6.6	130	Cardiological	No	No	No	No	No	Yes	Yes	Yes	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
28	46	Rural	Male	30-35	Primary School	Semi-skilled	Married	12500	1-5years	Type 2 Diabetes Mellitus	2	0	0	7	175		No	No	No	No	Yes	Yes	Yes	Yes	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
28	43	Rural	Female	20-25	Primary School	Unemployed	Divorced	0	1-5years	Type 2 Diabetes Mellitus	2	2	2	20-25	6.7	138	Nephrological	Yes	No	No	Yes	Yes	Yes	Yes	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
28	37	Rural	Male	15-20	High School	Semi-skilled	Married	26000	1-5years	Type 2 Diabetes Mellitus	2	0	0	6.9	135		Yes	No	No	Yes	No	Yes	Yes	Yes	1	0	0	1	0	2	1	2	1	1	1	0	1	0	1	0	1	0	1	0	1	0			
28	39	Urban	Female	30-35	Middle School	Unemployed	Married	0	1-5years	Type 2 Diabetes Mellitus	0	2	3	20-25	11.7	278	Cardiological	Yes	Yes	No	No	Yes	No	No	1	0	0	0	0	2	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
32	44	Rural	Male	20-25	Post graduate	Professional	Married	56000	1-5years	Type 2 Diabetes Mellitus	3	0	0	6.6	141		No	No	No	No	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
33	34	Urban	Female	15-20	Middle School	Semi-skilled	Married	13000	<6months																																								

115	53	Rural	Male	20-25	High School	Semi-skilled	Married	32000	5-10 years	Type 2 Diabetes Mellitus	2	2	>3	15-20	12.6	243	Neurological	Yes	Yes	No	Yes	Yes	Yes	Yes	1	1	0	0	1	3	2	3	2	1	1	0	1	Very difficult	3	3	2	3	3	3	3	3	4	4	4	2			
116	43	Rural	Female	30-35	PUC/12th	Unemployed	Married	0	5-10 years	Type 2 Diabetes Mellitus	2	2	3	20-25	11.8	256	Neurological	Yes	No	No	No	No	No	No	0	0	0	1	2	3	2	2	1	1	0	1	1	Very difficult	3	3	3	2	2	3	2	3	3	3	3	3			
117	46	Rural	Male	20-25	Graduate	Skilled	Married	55000	1-5years	Type 2 Diabetes Mellitus	1	0	0		5.9	125		No	No	No	No	Yes	Yes	Yes	0	0	0	1	0	0	0	0	0	0	0	0	0	0	Somewhat difficult	3	4	4	3	4	4	3	3	3	4	5			
118	50	Rural	Male	15-20	Middle School	Semi-skilled	Married	7000	1-5years	Type 2 Diabetes Mellitus	>3	0	0		NA	113	Ophthalmological	Yes	No	No	No	Yes	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	3	4	3	4	4	2	3	3	4	5			
119	37	Rural	Male	20-25	PUC/12th	Skilled	Married	15000	6m-1year	Type 2 Diabetes Mellitus	2	0	0		5.8	132	Cardiological	No	No	No	No	No	Yes	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	4	5	3	4	4	2	3	3	3	5	
120	42	Rural	Male	30-35	PUC/12th	Semi-skilled	Married	18000	1-5years	Type 2 Diabetes Mellitus	2	1	2	10-15	6.3	129		No	No	No	No	No	Yes	Yes	0	0	0	1	2	3	0	2	2	1	0	0	1	Not difficult at all	3	3	4	3	3	3	2	3	3	3	4				
121	51	Rural	Male	25-30	High School	Skilled	Divorced	58000	1-5years	Type 2 Diabetes Mellitus	2	1	1	0-10	NA	100	Ophthalmological	No	No	No	No	Yes	No	No	1	0	0	1	2	3	1	2	2	1	1	0	2	Somewhat difficult	2	3	3	4	1	2	3	2	3	3	2				
122	66	Rural	Male	15-20	Primary School	Unemployed	Married	0	5-10 years	Type 2 Diabetes Mellitus	1	0	0		10.3	246	Ophthalmological	Yes	Yes	No	No	No	Yes	Yes	1	1	1	1	3	3	2	3	2	0	1	0	2	Somewhat difficult	2	3	4	3	3	3	3	3	3	4	3	2			
123	38	Rural	Male	20-25	Graduate	Skilled	Married	40000	6m-1year	Type 2 Diabetes Mellitus	2	0	0		5.9	108		No	No	No	No	No	Yes	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Somewhat difficult	4	4	2	3	4	4	3	4	3	3	5			
124	55	Rural	Female	30-35	Graduate	Skilled	Married	28000	5-10 years	Type 2 Diabetes Mellitus	0	2	3	20-25	7	147	Cardiological	Yes	No	No	No	No	Yes	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Somewhat difficult	4	4	4	3	4	3	3	4	3	4	4	
125	48	Rural	Male	>35	Middle School	Semi-skilled	Married	18000	6m-1year	Type 2 Diabetes Mellitus	3	0	0		5.7	127		No	No	No	No	Yes	No	No	0	0	0	1	1	2	1	1	1	0	0	1	1	Not difficult at all	3	2	3	2	4	3	2	4	3	3	3				
126	40	Rural	Male	20-25	Middle School	Unemployed	Married	0	<6months	Type 2 Diabetes Mellitus	2	0	0		5.8	118	Neurological	No	No	No	No	No	Yes	Yes	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	4	3	4	3	4	2	4	3	3	5	
127	67	Rural	Male	25-30	Primary School	Unemployed	Married	0	5-10 years	Type 2 Diabetes Mellitus	2	2	3	20-25	12.1	278	Nephrological	Yes	No	No	No	Yes	No	No	1	0	0	1	1	3	1	2	1	1	1	0	1	Somewhat difficult	3	2	3	3	3	2	3	2	3	3	2				
128	41	Rural	Female	20-25	Graduate	Skilled	Married	32000	1-5years	Type 2 Diabetes Mellitus	>3	0	0		6	103	Cardiological	No	No	No	No	Yes	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Somewhat difficult	4	4	3	3	3	4	2	4	3	4	5		
129	52	Rural	Male	30-35	PUC/12th	Skilled	Married	42000	<6months	Type 2 Diabetes Mellitus	2	0	0		6.3	134	Neurological	No	No	No	No	No	No	No	1	0	0	1	1	2	2	1	2	0	1	0	1	Not difficult at all	3	2	4	3	3	2	2	3	2	3	2				
130	45	Rural	Female	15-20	Primary School	Unemployed	Married	0	1-5years	Type 2 Diabetes Mellitus	2	0	0	0	6.4	119		No	No	No	No	Yes	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Somewhat difficult	4	3	3	3	3	3	2	4	3	4	5		
131	34	Rural	Male	20-25	Graduate	Skilled	Married	40000	1-5years	Type 2 Diabetes Mellitus	3	0	0		7	172		No	No	No	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	5	4	5	4	3	3	4	5	5	4	5	
132	52	Rural	Male	15-20	Middle School	Skilled	Married	20000	1-5years	Type 2 Diabetes Mellitus	2	1	2	15-20	8.3	170	Neurological	No	No	No	No	Yes	Yes	Yes	0	0	1	0	0	1	1	2	2	0	0	0	0	0	0	Very difficult	3	3	4	3	3	3	3	4	3	4	3		
133	67	Rural	Male	20-25	Primary School	Semi-skilled	Married	16000	>10years	Type 2 Diabetes Mellitus	0	>2	3	>25	10.2	257	Ophthalmological	Yes	No	No	No	Yes	Yes	Yes	1	1	0	0	0	3	3	3	2	1	1	0	1	Extremely difficult	3	2	3	4	3	2	3	3	2	1	1				
134	70	Rural	Male	20-25	Middle School	Unemployed	Widowed	0	>10years	Type 2 Diabetes Mellitus	0	2	2	15-20	11	278	Neurological	Yes	No	No	No	Yes	No	No	1	0	0	0	1	2	1	2	1	0	1	0	0	Somewhat difficult	4	4	4	3	4	2	3	4	3	3	3				
135	48	Rural	Female	25-30	High School	Unemployed	Married	0	1-5years	Type 2 Diabetes Mellitus	2	0	0		6.9	150		No	No	No	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	4	4	4	4	4	4	4	4	4	3	5
136	43	Rural	Male	25-30	PUC/12th	Skilled	Married	35000	1-5years	Type 2 Diabetes Mellitus	>3	0	0		5.9	135		No	No	No	No	No	Yes	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	4	4	4	4	4	4	4	4	3	5
137	41	Rural	Male	25-30	Graduate	Skilled	Married	50000	1-5years	Type 2 Diabetes Mellitus	2	1	1	0-10	6.6	140		No	No	No	No	No	Yes	Yes	0	1	0	0	1	3	2	3	2	0	1	0	1	Somewhat difficult	3	3	3	3	3	2	3	4	5	3	2				
138	53	Rural	Female	15-20	Middle School	Unemployed	Married	0	<6months	Type 2 Diabetes Mellitus	2	0	0		5.8	118		No	No	No	No	Yes	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Somewhat difficult	4	2	4	2	3	4	3	4	4	3	5	
139	37	Rural	Male	30-35	PUC/12th	Skilled	Married	23000	6m-1year	Type 2 Diabetes Mellitus	3	0	0		7	178		No	No	No	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	5	4	5	3	4	4	3	4	4	3	5
140	33	Rural	Female	20-25	PUC/12th	Unemployed	Widowed	0	1-5years	Type 2 Diabetes Mellitus	3	0	0		6	115		No	No	No	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	3	4	3	4	1	3	3	3	3	5
141	53	Rural	Male	20-25	High School	Semi-skilled	Married	20000	<6months	Type 2 Diabetes Mellitus	>3	0	0		6.3	NA	Neurological	No	No	No	No	Yes	Yes	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	3	3	4	3	3	2	4	3	3	5	
142	44	Rural	Female	15-20	Post graduate	Skilled	Married	37000	5-10 years	Type 2 Diabetes Mellitus	2	0	0		7.8	180	Cardiological	No	No	No	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	4	3	3	4	3	3	4	4	4	5
143	49	Rural	Male	30-35	Middle School	Semi-skilled	Married	28000	5-10 years	Type 2 Diabetes Mellitus	>3	0	0		6.3	NA		No	No	No	No	Yes	No	No	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	3	3	4	3	3	3	2	4	3	3	4		
144	82	Rural	Male	20-25	Primary School	Unemployed	Married	0	>10years	Type 2 Diabetes Mellitus	2	2	2	15-20	12.2	NA	Ophthalmological	No	No	No	No	Yes	No	No	0	0	0	0	0	0	1	2	1	1	0	1	0	0	Not difficult at all	3	3	3	3	4	2	3	4	4	3	4			
145	45	Rural	Male	25-30	High School	Semi-skilled	Married	17000	6m-1year	Type 2 Diabetes Mellitus	2	0	0		6.3	111		No	No	No	No	No	Yes	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	3	5	3	4	4	4	5	5	3	5
145	54	Rural	Male	>35	Middle School	Semi-skilled	Seperated	40000	5-10 years	Type 2 Diabetes Mellitus	>3	0	0		8.4	164	Neurological	Yes	No	No	Yes	Yes	Yes	No	0	1	0	0	0	0	2	1	2	0	0	0	0	0	0	Not difficult at all	4	2	3	4	3	1	3	4	3	4	3		
147	40	Rural	Male	25-30	Post graduate	Professional	Married	40000	6m-1year	Type 2 Diabetes Mellitus	2	0	0		6.1	116		Yes	No	No	No	No	No	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	3	3	4	3	4	4	3	4	4	4	5
148	57	Rural	Male	30-35	Graduate	Skilled	Married	45000	<6months	Type 2 Diabetes Mellitus	1	0	0		6.1	112		No	No	No	No	Yes	No	No	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	Not difficult at all	4	3	4	4	4	4	4	5	5	4	5
149	48	Rural	Female	30-35	Middle School	Unemployed	Married	0	5-10 years	Type 2 Diabetes Mellitus	2	1	2	15-20	8.3	NA	Nephrological	Yes	No	No	No	Yes	No	No	0	1	0	0	0	0	1	2	1	1	0	0	0	0	Somewhat difficult	3	3	4	3	3	4	3	4	4	2	4			
150	67	Rural	Male	20-25	Middle School	Semi-skilled	Married	9000	>10years	Type 2 Diabetes Mellitus	0	2	3	20-25	7	160	Ophthalmological	No	No	No	No	No	No	No	1	0	0	0	2	3	2	1	0	0	0	0	1	Not difficult at all	2	2	4	3	2	3	2	2	4	3	4				
151	52	Rural	Male	15-20	High School	Semi-skilled	Married	25000	5-10 years	Type 2 Diabetes Mellitus	3	0	0		8.2	162	Neurological	No	No	No																																	

