

**PREVALENCE AND ASSOCIATED FACTORS OF
DEPRESSION AMONG DIABETIC PATIENTS -
A MULTI-INSTITUTIONAL STUDY IN
THIRUVANANTHAPURAM CORPORATION**

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DECLARATION

I hereby declare that this dissertation titled — “Prevalence and associated factors of depression among diabetic patients- A multi-institutional study in Thiruvananthapuram corporation” is the result of my original research. It has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

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CERTIFICATE

Certified that the dissertation titled — “Prevalence and associated factors of depression among diabetic patients- A multi-institutional study in Thiruvananthapuram corporation” is a record of the research work undertaken by Dr Catherine Suresh Emmanuel, in partial fulfilment of the requirements for the award of the degree of — Masters of Public Health under my guidance and supervision.



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LIST OF ABBREVIATIONS

PHQ-9	Nine Item Patient Health Questionnaire
UPHC	Urban Primary Health Centre
FHC	Family Health Centre
NMHP	National Mental Health Program
DMHP	District Mental Health Program
JHI	Junior Health Inspector
JPHN	Junior Public Health Nurse
ASHA	Accredited Social Health Activist
MPW	Multipurpose Worker
WHO	World Health Organization
IDF	International Diabetes Federation
MHCA	Mental Health Care Act
NCD	Non-Communicable Diseases
DALY	Disability Adjusted Life Years
APL	Above Poverty Line
BPL	Below Poverty Line

ABSTRACT

Prevalence and associated factors of depression among diabetic patients- A multi-institutional cross-sectional study in Thiruvananthapuram Corporation.

Background:

Depression as a co-morbid condition in Type 2 diabetes mellitus patients is linked to high morbidity, death, and increasing health-related costs. Understanding the incidence of depression related with the chronic condition is crucial given that the Indian healthcare system is gravely strained by it. It has been considered a modifiable risk factor for diabetes control and management. Diabetic patients should undergo depression screening as part of an organised strategy to case management and follow-up due to the negative effects of co-morbid depression on patient self-care and treatment results.

Objective:

The primary objective was to estimate the pooled prevalence of depression among Type 2 diabetes mellitus patients, and the secondary goal was to assess the prevalence based on socio demographic, lifestyle factors, physiological and physical variables.

Methodology:

A multi-institution based cross sectional study with a total of 334 participants. All the consecutive diabetic patients attending the health centres were administered a structured interview schedule to assess the various factors and screened for depression with the nine-item patient health questionnaire. Univariate, bivariate and multiple logistic regression analyses were done using SPSS version 25.

Results:

The prevalence of depression among the diabetic patients in the study was found to be 41.9% CI (32.71-51.69). In bivariate analyses the following risk factors were identified: sex, socioeconomic status, spousal support, family support, family history of diabetes, advice from physician regarding physical activity and diet, Insulin usage, diabetic expenses, presence of comorbidities and presence of cardiovascular diseases. However, multivariate analysis indicated that sex [OR=8.72; 95% CI (4.22-17.99)], spousal support [OR=2.91;

95% CI (1.52-5.57)], presence of comorbidities [OR=4.65; 95% CI (1.86-11.63)] and CVD [OR=6.21; 95% CI (2.96-13.06)] are significant predictors of depression.

Conclusion:

Depression was significantly associated with socio-behavioural and clinical factors. A holistic approach for identification and rectification of these associated factors is necessary to tackle the double burden.

CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Depression and Type 2 diabetes mellitus are both chronic conditions that may advance for years before being identified. Depression is one of the most frequent mental health disorders accompanying chronic diseases. Its existence in type 2 diabetic patients may impair therapy adherence and efficacy. Most research on depression in diabetes patients are hospital-based, indicating the need for a community-based study to investigate the correlates of depression in diabetes patients (Aminu, n.d.).

Mental depression most often co-occurs with chronic diseases like Type 2 diabetes mellitus and can lay a very negative impact on an individual's wellbeing (Johnson et al., R2021). In accordance with studies, having diabetes elevates one's risk of developing depression (Rajput et al., 2016). In India and around the world, depression is a widespread mental illness that can affect anyone, regardless of age, gender, or socioeconomic level. Daily activities can be challenging for those who are depressed, and this load is made even more onerous by the presence of Type 2 diabetes mellitus (Arvind et al., 2019).

The probability of developing a mental health condition in life is around 50%, which leads to a decrease in employment, productivity, and income.(OECD: Making mental health count: the social and... - Google Scholar, n.d.). Depression and anxiety are the fourth and eighth leading causes of disability adjusted life years (DALYs) in industrialized nations, respectively (Blue Marble Health and the Global Burden of Disease Study 2013 | PLOS Neglected Tropical Diseases, n.d.). There is evidence that the prevalence of depression is modestly higher in prediabetic patients and undiagnosed diabetic patients, and significantly higher in previously diagnosed diabetic patients compared to persons with normal glucose metabolism (Chen et al., 2016). The prevalence of depression and anxiety in diabetic patients worsens the diabetes prognosis, increases noncompliance with medical therapy (Gonzalez et al., 2008), reduces quality of life (Baumeister et al., 2011), and increases death (Egede et al., 2005).

Depression, on the contrary, may raise one's risk of developing type 2 diabetes by 60% (Mezuk et al., 2008; Rubin et al., 2008). Thus, there exists a bidirectional complex relationship between the two disorders. Also suggested is that patients with better mood follow their diabetic treatment plan better. Such a disease that can take quite a toll on human life can be tackled with the least of complex solutions. Increased physical activity or exercise, dietary modification, enough rest, sleep, and social interaction, the use of mindfulness-based meditation techniques, and the reduction of recreational drugs like nicotine, alcohol, and drugs, have all been linked to improvements in diabetes and depression (Sarris et al., 2014).

1.2 Review of Literature

1.2.1 Definition of depression: In contrast to stress and anxiety:

Depression is a common mental condition characterized by sadness, lack of interest or pleasure, feelings of guilt or low self-worth, disrupted sleep or food, fatigue, and impaired concentration (Depressive disorder (depression), n.d.). A depressive episode lasts at least two weeks and is characterized by a person's low mood (sad, irritated, or empty feelings) or a loss of enjoyment or interest in activities. It is more than just a lousy mood or a terrible day. One may be depressed if having an extended period of sadness that interferes with regular, everyday functioning (*Centers for Disease Control and Prevention, 2023*). They also exhibit poor concentration, feelings of guilt or low self-worth and are at an increased risk of suicide (Depressive disorder (depression), n.d.).

“Stress can be defined as a state of worry or mental tension caused by a difficult situation. Stress is a natural human response that prompts us to address challenges and threats in our lives. Everyone experiences stress to some degree. The way we respond to stress, however, makes a big difference to our overall well-being. Stress makes it hard for us to relax and can come with a range of emotions, including anxiety and irritability also accompanied with lack of concentration reduced or loss of appetite. Stressful situations can also cause or exacerbate mental health conditions, most commonly anxiety and depression, which require access to health care. When we suffer from a mental health condition, it may be because our symptoms of stress have become persistent and have started affecting our daily functioning” (Stress, n.d.).

On the other hand, excessive dread, concern, and behavioural abnormalities are hallmarks of anxiety disorders. The symptoms are strong enough to cause substantial anguish or functional impairment. Excessive fear or worry, panic attacks etc are ways in which anxiety manifests (What is the difference between Depression, Stress and Anxiety?, n.d.)

1.2.2 Symptoms and characteristics of depression:

During a depressive episode, a person experiences a depressed mood characterized by unpleasant emotions, poor humour, agonies, panic attacks, worsening of psychic and cognitive abilities, a propensity for isolation, demotivation, apathy, abulia, difficulty enjoying life, desperation, motor inhibition, hypotonia, and negative thoughts, also including delusional behaviour in cases of severe severity (Rondón, 2018). Other symptoms may also present as inability to concentrate feelings of overwhelming guilt or poor self-worth hopelessness about the future thoughts about death or suicide disrupted sleep changes in appetite or weight feeling very weary or low in energy. The severity of a depressive episode is determined by the frequency and intensity of symptoms, as well as the influence on the individual's functioning. (Depressive disorder (depression), n.d.). Depression can affect people differently, depending on their age (*National Institute of Mental Health (NIMH)*, n.d.).

1.2.3 Contributing factors of depression:

Demographic factors such as age, sex, and ethnicity contribute to developing depression. Gender differences in depression are marked, important and of complex causation (Angst et al., 2002). The majority of clinical and epidemiological investigations on depression using various tools have revealed that females had a greater prevalence rate as evidenced by studies both nationally (Chaudhry et al., 2010) and internationally (Bebbington et al., 1998). Depressive symptoms may be brought on by a diagnosis of diabetes or the stress of managing its consequences (Talbot and Nouwen, 2000). Sex dynamics are crucial to investigate since women have inferior quality of care for diabetes (Bird et al., 2003).

Behavioural factors like smoking and obesity were linked to an increased risk of satisfying major and minor depression criteria (Katon et al., 2004). Depression has also been linked to a number of diabetes complications like diabetic retinopathy, nephropathy, neuropathy, macrovascular issues etc.(de Groot et al., 2001) (Raval et al., 2010). Poor income, unemployment, income disparity, poor education, and limited social support are examples of one's socioeconomic position predisposing to depression. Natural catastrophes, war, conflict, climate change, and migration are examples of environmental factors. Social change brought on by wealth shifts, urbanization, and environmental damage can lead to depression (Patel et al., 2016).

Studies also showed that severe hypoglycaemia was linked with the intensity of depressed symptoms in patients with type 2 diabetes mellitus who did not receive anti-depressant medication, regardless of glycaemic control, insulin therapy, lifestyle variables, or diabetes complications (Kikuchi et al., 2015). Depression has a synergistic impact on individuals with both type 1 and type 2 diabetes mellitus, raising the risk of micro- and macrovascular problems, hyperglycaemia, and predicting a more severe death. This comorbidity also predicts an earlier occurrence of problems in older persons (Black et al., 2003).

As mentioned, several times, diabetes and depression both diminish an individual's quality of life, but they have a greater detrimental impact when combined. However, depression in diabetes patients is underdiagnosed and undertreated (Li et al., 2009). A simple tool for screening depression that's used on routine diabetic follow-ups would be the first step in raising awareness of depression in diabetes and perhaps improving the results.

1.2.4 Consequences of depression:

Untreated clinical depression is a serious problem. In addition to impairing performance, depression raises the sense of ill health, medical service utilization, and health-care expenses (Cole and Dendukuri, 2003). Depressed people cannot just "pull themselves together" and be cured. Untreated clinical depression can linger for weeks, months, or years if not treated with antidepressants and/or psychotherapy. Appropriate therapy, on the other hand, can benefit the majority of persons suffering from depression (Angst et al., 2002). With regard to the stigma, discrimination, and bigotry against those who have mental illnesses, patients are reluctant to voice up or disclose their issues. Stigmatizing depression can decrease hope, decrease medication compliance, make it more difficult to maintain social connections, and prevent the self- and social support necessary for treatment. Understanding how to handle and battle this issue might be

beneficial because patients with mental illness are frequently marginalized and are vulnerable to various sorts of discrimination.

1.2.5 Global burden of depression:

Global burden of disease 2010 identified depression as a leading cause of burden majorly contributing to suicide and ischemic heart disease (Ferrari et al., 2013). Depression is the major cause of mental health-related illness burden worldwide, impacting an estimated 300 million people listed by the World Health Organization (WHO). Depression prohibits people from attaining their full potential, reduces human capital, and is linked to early death from suicide and other disorders (Herrman et al., 2019). It is an obstacle to sustained development in every country (Lund et al., 2018). Globally, the number of incident cases of depression grew by 49.86% from 172 million in 1990 to 25.8 million in 2017 (Liu et al., 2020).

1.2.6 Global burden of diabetes mellitus:

The global adult diabetes population was expected to increase from 135 million (4.0%) in 1995 to 300 million (5.4%) by 2025 (King et al., 1998). According to the International Diabetes Federation (IDF), 642 million persons worldwide will have diabetes by the year 2040, up from an estimated 415 million in 2015 which means the estimate predicted to reach by 2025 has already crossed by over a 100.0 million affected by the year 2015. In 2015, it was predicted that \$673 billion was spent globally on treating diabetes and its complications, and by 2040, that amount is expected to rise to \$802 billion. According to the IDF, most nations spend 5% to 20% of their overall healthcare budgets on diabetes (Herman, 2017). The relative costs and benefits of prevention and treatment of type 2 diabetes, and managing long-term consequences and comorbidities has to be evaluated at the international, national, and local levels.

As of 2019 study shows that diabetes affects over half a billion people globally, and the number is expected to rise by 25% by 2030 and 51% by 2045 (Saeedi et al., 2019). Between 2000 and 2030, the urban population in emerging nations is expected to double and is a major predisposing factor for this diabetic epidemic. The most significant demographic shift in diabetes prevalence appears to be an increase in the number of adults over the age of 65 (Wild et al., 2004).

1.2.7 Bidirectional relationship:

Diabetes has been associated with depression as both a cause and a consequence. According to studies, people with diabetes who are not depressed are more likely to subsequently experience depressive symptoms, while people who are depressed are more bound to have pre-diabetes or undiagnosed diabetes. Attention needs to be paid to this relationship given that depression is physiologically linked to hyperglycaemia, and can raise the risk of complications from diabetes and, as a result, increase mortality (Mendenhall et al., 2012). If the patient's mood was worse than usual on the previous day, it has been discovered that there would be a subsequent increase in fasting blood sugar (Skaff et al., 2009).

When compared to other chronic disorders, depression alone can cause significant health deterioration (Moussavi et al., 2007). When diabetes and depression exist together it can be challenging for a person to live an economically and socially rewarding life. Patients who have combined diabetes and depression take poorer care of themselves, follow diet and exercise regimens less religiously, quit smoking less consistently, and take prescriptions less persistently. All of these factors contribute to a bigger burden of medical symptoms, a greater degree of functional impairment, a higher risk of complications and mortality, and unquestionably a much greater financial load on patients, their loved ones, and their providers. Therefore, it is not surprising that comorbid depression has caused an up to 50% increase in the expense of healthcare for diabetics. This financial strain more seriously impairs the mental health of diabetic patients, which in turn results in poorer self-care, generating a vicious cycle. Studies have shown that addressing depression will dramatically improve a person's diabetic condition and disease burden.

1.2.8 Double burden: Depression as a comorbid condition of diabetes:

Diabetes and mental disease have long been linked, according to research (Holt: Undoing Descartes: integrating diabetes care... - Google Scholar, n.d.). With diabetes and depression affecting 8.3% (Whiting et al., 2011) and 10% (*Bulletin of the World Health Organization*, 2000) of the global population, respectively, comorbidity between diabetes and depression is to be expected. Depression and diabetes are two of the top 15 causes of DALYs worldwide (Murray and Lopez, 2013). According to epidemiological data, at least one-third of diabetics experience clinically significant depression problems (Anderson et al., 2001). According to a recent meta-analysis of 11 trials with approximately

50,000 participants who had type 2 diabetes but no history of depression at baseline, the prevalence of depression was 24% greater in adults with diabetes (Nouwen et al., 2010). People with depression additionally face a higher risk of developing diabetes, and people with diabetes likewise have a higher risk of developing depressive symptoms (Lloyd et al., 2010).

The processes underlying depression and Type 2 diabetes mellitus co-morbidity may interact reciprocally, causing one to exacerbate and worsen the other (Renn et al., 2011). There have been proposed five explanations for the correlation between diabetes and depression. Therapy causing physical and mental side effects, organic psychological effects, psychosocial response to physical disease, mental physical illness and behavioural disruption producing physical sickness are the factors that link both diseases. The latter two of these categories focus on disorder caused by depression, whereas the first three relate to how depression may be caused by a disorder or how it is treated (*Journal of Gerontology*, 1984).

Accordingly, we could assert that there exists a bidirectional relationship between the two disorders. Many researchers have argued that diabetes precedes depression and causes it, either directly through hyperglycaemia, which may result in altered glucose transport, or indirectly through psychological stress brought on by learning of the diagnosis of diabetes or the demands of treatment, including pharmacological and lifestyle changes (Renn et al., 2011). However, a number of recent cohort studies have questioned this presumption showing depression could be a risk factor for diabetes (Engum, 2007).

In addition to its effects on one's physical, emotional, and social well-being, co-morbid depression also raises the expenses of medical care due to decreased quality of life, poor self-care, and non-compliance with prescribed treatments. High levels of self-care are necessary for people with diabetes, including regular blood glucose checks, medication administration, and tight dietary restrictions. Because the illness is persistent, individuals must learn ways to adapt as it may lead to medical issues and diminished mobility. An increased risk of depression in people with diabetes may be caused by biochemical changes related to the disease, such as neural system arousal. In furthermore, individuals who suffer from depression are more likely to engage in poor self-care practises, which might lead to worsening glucose control and greater difficulties ultimately on (Knol et al., 2007).

Despite the significant negative effects of co-morbid depression and diabetes on the individual and the significance of this issue for public health, the precise mechanisms by which these two chronic illnesses interact are unclear, and there are few integrated treatments available (Roy and Lloyd, 2012). Another explanation is that additional risk factors make people more susceptible to both depression and diabetes (Pan et al., 2010). However, early detection and treatment of depression in diabetics improves quality of life, can avoid or postpone problems, and has a positive influence on glycaemic control (Chapman et al., 2015). Understanding the frequency and distribution of depression across the country is critical for improving the health outcomes of patients with diabetes who have co-morbid depression (Hussain et al., 2018).

1.2.9 Estimate of double burden in India:

Based to the International Diabetes Federation (IDF), 72 million people in India alone suffer from diabetes. Despite the fact that one in every two persons living with diabetes is undiagnosed, it is worth noting that the population living in poor and middle-income nations accounts for three-quarters of the worldwide diabetic population (Hussain et al., 2018).. The pooled prevalence of depression in type 2 diabetes mellitus patients was found to be 38%. Overall, the study found a high prevalence of depression among type 2 diabetes mellitus patients in India. Diabetes management programs in India may consider early screening of depression in type 2 diabetes mellitus patients (Hussain et al., 2018). Treatment and support services for depression are frequently absent or insufficient in low- and middle-income nations. The precise disease burden of the country is still unknown due to variations in diabetes and depression incidence rates across different regions of India (Siu et al., 2016).

Comparing the prevalence of depression in India to that of communicable diseases like HIV/AIDS (India HIV Estimates 2021, n.d.) and Tuberculosis (Tb India 2017) ,the prevalence of depression is many times higher. It has been established that 49% of diabetic patients in Kerala suffer from depression (Madhu et al., 2013), which implies that depression is likely to affect every second person. Approximately 50% of patients with depressive illness do not have depression diagnosed in general practice or primary care, despite its high incidence and substantial comorbidities, and the situation has not much improved over time (Dowrick and Buchan, 1995). Although not much has been done to specifically screen for depression in primary centre diabetes clinics, there have been some

confined efforts made. Therefore, it is safe to say that, regrettably, there are still few or no psychological therapies available to diabetic patients in most primary care settings (Peyrot et al., 2006). Depression screening is thus recommended as the very first phase in intervention (Siu et al., 2016).

1.2.10 District mental health program:

By offering readily available, economically viable, superior medical services, India's National Mental Health Policy and National Mental Health Program (NMHP) hopes to lessen the burden of mental health conditions, including depression (Gupta and Sagar, 2022). Despite their best intentions, the high increasing prevalence of depression is a clarion call for all stakeholders to scale up mental health services at all levels of the health care delivery system, particularly primary care. The National Mental Health Programme (NMHP) was established to decentralize mental health services and offer mental health services at the grassroots level by integrating mental health with the general healthcare delivery system. India was one of the first developing nations to implement this programme in 1982. Bellary model was the pilot project implemented to achieve this objective of the program and it demonstrated that primary health care workers including doctors could be trained to identify most types of mental disorders. Following its success this program was launched in 4 districts and now currently running successfully in almost 125 districts (Singh, 2018).

Study conducted by Indian Council for Market Research discovered that the majority of patients' initial encounter hospital is still a district hospital or a psychiatric institution (68%-98%) (IMHO 2021). To rectify this situation, the National Institute of Mental Health and Neurosciences (NIMHANS) has been educating medical officers for three months in order to equip them to treat mental problems at the basic level. Despite the fact that evidence-based therapies and cost-effective treatment choices exist to lessen the burden of depression, the failure to implement them has had a significant socioeconomic impact on individuals, communities, and the nation (Seth, n.d.). Without the assistance of publicly-funded or privately-financed insurance, the combination of depression and diabetes will plunge impoverished households into economic disaster, creating an endless spiral of unemployment and depressive disorders (Patel et al., 2010).

Under each District Mental Health Program which forms the implementation arm of the NMHP, 25000-35000 adults would need care for depression, and roughly 40% of them would have severe depression (the typical population of an Indian district is 1.5-2 million) (Arvind et al., 2019). This

requires collaborating jointly on depression treatment with other national health programs in order to address the burden and advance towards the 2030 Sustainable Development Goals. Studies suggest that combining therapy for patients with both disorders led to a diminution in depressed symptoms and an improvement in diabetic status (Ali et al., 2020). The Mental Healthcare Act (MHCA), 2017 allows only emergency treatment for 72 hours by a physician before referral to higher centre, and there is no provision for treatment by a nonmental health professional during follow-up. This act was formed in view to treat mental health patients with dignity and not to be harassed in any form. It also projects to form adequate legal framework to safeguard the patients seeking care against misdiagnosis or discrimination.

1.2.11 ASWAAS:

NMHP focuses on treating the mentally ill, enabling rehabilitation and promoting positive mental health but in practice, little does it emphasize on early and timely screening of depression so that the condition can be tackled at sprout level. ASWAAS is the mental health program taken up by the Kerala state government and is laboriously carried out by health care service providers and field staffs of Family Health Centres (FHCs). There exists a system in the FHCS where, a population survey is conducted by the field level health workers (JPHNs and JHIs) using Malayalam version of PHQ9 questionnaire who are initially identified by the ASHAs. Confirmation of this diagnosis is made by the trained multi-purpose workers (MPW) or DMHP teams that arrive at each FHC on their fixed mental health clinic day. Follow up care is taken up by either the FHC or the subcentres.

Aside from FHCs, there is a total of 18 Urban Primary Health Centres (UPHCs) in Thiruvananthapuram Corporation, that actively participates in providing primary health care to the average twelve lakh population residing in this Corporation area. Unlike the FHC, UPHC does not involve in any screening programs nor do they have a fixed day allotted for mental health clinic. Given the large number of NCD patients they serve and the way of life that city inhabitants lead, it is only logical to think that one should frequently engage in screening of depression and in its prompt diagnosis. Unlike the ASWAAS program, priority should be given to diabetic patients in this clinic-based screening, given all the studies that points to occurrence of depression in the long run of diabetes.

As mentioned above, the prevalence of depression in India is several folds higher when compared to communicable diseases like HIV or Tb. An important health policy question is that when there exists

a systematic process to diagnose and treat the said communicable diseases in UPHCs, the absence of a prompt screening procedure and treatment protocol for depression seems irrational.

1.2.12 Urbanization and depression:

A meta-analysis of papers from India (Reddy and Chandrashekar, 1998) and around the world (Sundquist et al., 2004) reveals a link between depression and urbanisation. Numerous variables, including alterations in family structure, social isolation, an imbalance between work and personal life, economic stress, substance abuse, etc. are connected to urban living patterns, which could set up the conditions for a higher prevalence of depression in urban environments (Srivastava, 2009). The main challenges to obtaining care among people with depressive disorders globally include low perceived need, attitude barriers, and stigma associated with mental illness (Andrade et al., 2014).

In a state like Kerala, where the tertiary medical facilities are advanced and prompt, seldom attention is given to primary care. Kerala's primary care reforms have improved facilities, but they are still in early stages as seen by the resemblance in coverage and outcome measures (Negi and Nambiar, 2020). Diabetic patients could be routinely screened for depression to help narrow the treatment gap for their condition. Using community health professionals to provide care, expanding the quantity and calibre of mental health-related personnel, and integrating therapy for depression among diabetics into primary healthcare can all help bridge the treatment gap for depression (Patel et al., 2010). Both pharmacological and non-pharmacological means of treatment that are affordable and accessible should be made available to all, emphasizing on the urban and rural primary health care centres.

1.2.13 Depression in primary care:

Except for hypertension, depression is the most common disease seen by primary care physicians, and its management offers a challenge to busy primary care practices (Dejesus et al., 2007). As per to research, depressive disorders are a fairly widespread illness that affects both patients and the broader adult population, and they are closely linked to functional limits. Despite the fact that the primary care sector is perceived to be the sole mode of contact for around 50% of people with mental problems, as shown by studies, depression in this sector frequently goes undiagnosed and untreated. There is also insufficient data on how depression treatment efficacy varies for patients in various health care delivery systems or whose care is paid for through upfront or fee-for-service contracts (Wells and Burnam, 1991).

It's only reasonable to treat depression and diabetes together when a patient presents with both. However, treating depression should be considered as improvements in glycaemic control and levels of HbA1c take many months to stabilize whereas responses to antidepressants are often observed in 2-4 weeks (Petрак et al., 2015).

1.3 Nine item patient health questionnaire (PHQ-9) tool

Developed by Kroenke et al., the Patient Health Questionnaire-9 is a free resource with an educational grant from Pfizer Inc. It is a simple self-administered measure with demonstrated validity and reliability, and it is a regularly used depression screening instrument in primary care practice (Dejesus et al., 2007). The instrument defines minimal (or no depression), mild, moderate, and severe depression, respectively, as total values of 0-4, 5-9, 10-14, and 15 or above (Kroenke et al., 2001). Based on organized psychiatric interviews, the PHQ-9 diagnosis of major depression was found to have high sensitivity (73%) and specificity (98%) to the diagnosis of major depression (Spitzer et al., 1999). The instrument has been previously validated in the Indian population (Ganguly et al., 2013; Raval et al., 2010). It can be easily administered by health workers and with a cut off value of 10, it displays good validity to diagnose depression in patients attending primary care. A study for the validation of the PHQ-9 suggested that increasing the cut-off for major depression at 12 points (instead of 10 points) in diabetic patients may improve the discrimination between diabetes-related symptoms and depressive symptoms as a screening tool for depression in diabetes patients (van Steenbergen-Weijenburg et al., 2010).

1.4 Background of the study

According to projections, unipolar depression is expected to contribute the second-highest amount to the global burden of disease by the year 2030 (Mathers and Loncar, 2006). In accordance to current estimations, the number of those with diabetes in developing nations would rise by 69% by 2030, compared to a 20% rise in affluent nations, with India having the highest number of diabetic adults worldwide (Shaw et al., 2010). Low- and middle-income nations should improve their health systems since there is a large treatment gap and a lack of resources for mental health. This can be achieved by enhancing the treatment provided to diabetics with depression and enhancing the services and coverage offered. Currently, diabetic patients should be screened for depression, in accordance to international clinical guidelines (*Diabetes Care*, 2009).

A fated harsh reality about depression is the stigma that comes with it. This setting is insufficient unless the harsh reality of discrimination against people with mental disorders is addressed. Many people fail to seek medical attention for their problem because they are terrified of being treated differently or of being categorized as a mental patient. Despite all endeavours of awareness raising and educational efforts, many people remain to have a poor perception of those who suffer from mental illness. This situation calls for consistent efforts from the public health sector to strive at straightening out the facts and halt the misconceptions that comes with this disease.

1.5 Rationale for the study

Depression is a common and very serious medical disease with a lifetime prevalence ranging from approximately 11% in low-income countries to 15% in high-income countries (Bromet et al., 2011). The World Health Organization cautions us that there is a significant gap between the burden imposed by mental diseases and the resources available to prevent and cure them. According to estimates, four out of five individuals with significant mental illnesses who reside in low- and middle-income nations do not obtain the necessary mental health care (Mental Health Atlas 2011, n.d.).

Depression in diabetes patients is still underdiagnosed, thus it's crucial for diabetic specialists to be aware of this widespread co-morbidity. A multidisciplinary approach to treating diabetes patients would help them experience better health, have fewer DALYs, and even experience lower mortality and hence the importance of diagnosing depression in them. Prevention, timely detection, and prompt treatment of health disorders are crucial for a healthy society.

The comorbid condition of depression and diabetes has a major impact on life expectancy and can alter the quality of life. Hardly few numbers of studies exist scouting the risk factors for depression among diabetic patients in similar study settings. Although the combined effect has been deemed a global health problem, clinicians and policy makers seldom consider this a priority.

1.6 Objectives of the study

Major objective: To determine the prevalence of depression among diabetic patients attending the UPHCs of Thiruvananthapuram Corporation.

Minor objective: To identify the risk factors associated with depression among diabetic patients.

CHAPTER 2

METHODOLOGY

2.1 Study Design

This is a multi-institutional cross-sectional study.

2.2 Study Setting

The study was conducted in the Urban Primary Health Centres of Thiruvananthapuram Corporation. This setting caters to the urban population from the district of Thiruvananthapuram and are dedicated institutions for primary care.

2.3 Sample Size Estimation

Sample size was estimated using OpenEpi version 3.01. A prevalence of 30% was expected based on previously available literature for sample size calculation. Assuming an alpha level 0.05 and 95% confidence interval (CI), the sample size required was calculated using the formula $[(1.96)^2 pq/d^2] * \text{design effect}$, where p is the expected prevalence, q is 1-p and d is the precision which was taken as 5%. The calculated sample size was 323 but in total, 334 was collected.

2.4 Sampling Procedure

There is a total of 18 UPHCs in Thiruvananthapuram corporation out of which 10 were selected by lot method. Each centre was visited on their respective NCD (non-communicable diseases) clinic day for maximum data. The concerned medical officer of each institution was informed prior to data collection. Each centre was approached on their respective NCD clinic day and participants who met the following selection criteria were selected for the study.

- (i) Inclusion criteria
 - (a) All patients having type 2 diabetes mellitus irrespective of their duration of illness.
 - (b) All patients of either sex above 18 years of age.

- (ii) Exclusion criteria:
 - (a) Patients on corticosteroids or psychotropic drug therapy.
 - (b) Patients diagnosed or on treatment for any mental illness other than depression.
 - (c) Patients who are terminally ill.

2.5 Data Collection

The data were collected from 17th April 2023 till 31st May 2023. The principal investigator was collecting the data after obtaining the informed consent from each participant and no other person was employed for the same purpose. All procedures were conducted in the hospital premises only. First an interview schedule consisting of closed questions was administered to collect data regarding the socio demographic, behavioural, social support system, disease specific information. Then the PHQ9 was administered to assess the depression status of each participant.

2.6 Data Storage

For the purpose of analysis, along with data collection, the data was entered using ODK and then imported from excel version to IBM SPSS Statistics version 25. The hard copies of the interview schedule are stored in a locked chamber under the vigilance of the principal investigator. The privacy and confidentiality of the participants is being closely safeguarded.

2.7 Data Analysis and Statistical Methods

The data were analysed using IBM SPSS Statistics version 25. The baseline characteristics were analysed by descriptive statistical principles. The mean and standard deviation for normally distributed continuous data and the median and interquartile range for continuously skewed variables were used to summarize continuous variables. Frequencies and percentages were used to summarize categorical variables. The Chi-square test was used to determine the relationship between dependent variable (depression) and independent (categorical) variables. For modelling and calculating the crude and adjusted odds ratios, univariate and multivariate logistic regression models were used. For adjustment of possible confounding factors multivariate analysis was used. The effect measure used in the analysis is Odds Ratio, which denotes the ratio of odds of having the outcome among non-reference category compared to the odds of having the outcome among the reference category. The association was considered statistically significant when the null value of effect measure remained outside the 95% confidence interval or had a p value less than 0.05. Results with a significant or nearly significant bivariate p value were taken into account for the final modelling goal.

2.8 Study tools

The process of gathering data involved the use of two questionnaires. A semi-structured interview schedule was used to collect sociodemographic information as well as clinical status questions and diabetes-related data.

Patient Health Questionnaire-9 was used for the screening of depression as minimal (or no depression); mild, moderate, and severe depression are defined by total scores of 0–4, 5–9, 10–14, and 15 and above, respectively. It has nine questions in total, each having four options to choose from. The four options are scored as a) Not at all = 0; b) Several days – 1; c) More than half the days = 2; d) Nearly every day = 3. This questionnaire has been previously validated in similar study setting (Malhotra et al., 2004) and has a sensitivity of 73% and specificity of 98% (Kroenke et al., 2001; Spitzer et al., 1999). The following cut off values were considered to assess the severity of depression.

Table 2.1 Assessment of severity of depression

Total score	Severity of depression	Category
0 – 4	Minimal depression	Minor depression
5 – 9	Mild depression	
10 – 12	Moderate depression	
12 - 14	Moderate depression	Major depression
15 – 19	Moderately severe depression	
20 - 27	Severe depression	

2.9 Variables used in the study

(a) Dependant variable:

Depression is the dependent variable in this study and PHQ-9 was used to measure this variable.

(b) Independent variables:

Demographic variables: Demographic variables were age, sex, marital status, type of family, number of members in the family.

Socioeconomic variables: Level of education, current occupation, ration card status, presence of health insurance.

Behavioural variable: The habit of smoking or alcohol consumption, their frequency.

Dietary variable: Diet planner in the family, efforts put into and feelings about the diet restrictions, whether if dietary modifications was advised by the treating physician.

Variables related to physical activities: Whether advised by physician, frequency of physical activity on daily and weekly basis, time taken to relax, duration of sleep

Variables related to social support: Support received from spouse, family, friends and relatives, involvement in social activities

Variables related to diabetes: Duration of illness, family history of diabetes, treatment mode for diabetes, comorbidities and complications of diabetes, knowledge on diabetes, expenditure on diabetes.

Physical parameters: Height, weight, blood pressure, and either parameter of diabetes like FBS, PPBS, HbA1c whichever available was collected.

2.11 Ethical considerations

The study had obtained clearance from Technical Advisory Committee and Institute Ethical Committee of Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala prior to data collection. Permission from the District Medical Officer of Thiruvananthapuram district to conduct the study in the Urban primary health centres was also obtained. Those participants who met the selection criteria were directly administered the interview schedule. Informed written consent (Appendix-II) was requested and acquired prior to screening diabetic patients for the presence of depressive symptoms. When a person was eager to participate but unable or unable to sign, his or her thumb impression was used instead. Subjects were provided full disclosure of the study's goals and expected results. Before moving on to gather more information, the interviewer carefully and clearly discussed the risks and benefits of the study. The screening and interview were conducted in a separate room so as to ensure privacy and confidentiality properly.

CHAPTER 3

RESULTS

This chapter discusses the results of data analysis that were in line with the goals. The data entered were carefully examined before analysis. The data were analysed for determining the sample population's baseline characteristics and the relationships between several independent variables and the outcome variable (depression). The outputs are divided into two areas: sample characteristics and risk factor analysis, which is further divided into bivariate and multivariate analysis.

3.1 Sample characteristics

This section includes a thorough description of the participants in the studied sample. The following titles are used to explain specifics about the sample population: demographic information, socioeconomic information, personal habits, dietary adherence, physical activity characteristics, social support system features, anthropometric and biochemical measurement information, and diabetes-specific factors.

3.1.1 Demographic characteristics of the study population

The study enlisted the participation of 334 diabetic people. The mean age of the sample population was 59.99 years (SD 8.49 years). For further analysis, age was grouped into four categories as: less than 49 years, 50 – 59 years, 60 – 69 years and more than 70 years. For the entire sample, highest proportion of individuals was seen in the third age category (60 – 69 years).

Males made up to 148(44.3%) of the participants, while females made up 186 (55.7%) which may be due to the fact that data collection happened during day time during which men would be either working or unable to attend the clinic during work hours.

It can be observed in Table 3.1 that, majority of the sample (90.7%) were currently married and living with their spouse followed by widowed (23%). For analytical purpose the categories- never married, divorcee/separated and widowed were clubbed together as one. All participants were urban dwellers.

Table 3.1: Demographic characteristics of the study population

Variables	Participants (%)
Age	
Median (range)	61 (40 – 77)
Below 50 years	59 (17.7)
50 – 59 years	92 (27.5)
60 – 69 years	144 (43.1)
Above 70 years	39 (11.7)
Sex	
Male	155 (46.4)
Female	179 (53.6)
Marital status	
Currently married	303 (90.7)
Never married	4 (1.2)
Divorced or separated	4 (1.2)
Widow or widower	23 (6.9)
Family type	
Nuclear	159 (47.6)
Extended	173 (51.8)
Joint	2 (0.6)

Nearly half (47.6%) of the entire sample constituted nuclear families. Joint families were clubbed with extended family and categorised as non-nuclear family, as they contributed to only 0.6% of the study population.

3.1.2 Socioeconomic characteristics of the study population

86.5 percent of the sample had some form of schooling, whereas 13.5 percent did not. The majority of the sample had only completed high school or intermediate. For analytical purposes, the variable was reclassified as having no formal schooling, either primary or high school or intermediate schooling and up to or completed university.

Out of the total sample population, 19.2% were not having any employment in the last one year and 17.1% of the population were homemakers and hence were grouped together for further analysis. There was an almost equal distribution of skilled/unskilled or self-employed and those involved in clerical or medium business.

Table 3.2: Socioeconomic characteristics of the study population

Variables	Participants (%)
Level of education	
No formal schooling	45 (13.5)
Up to primary school	79 (23.7)
Up to high school	85 (25.4)
Up to intermediate	95 (28.4)
Up to university	20 (6.0)
Completed university or higher	10 (3.0)
Occupational status	
Professional/ executive/ big business	17 (5.1)
Clerical/ medium business	89 (26.6)
Self-employed/ skilled	88 (26.3)
Unskilled/ landless labourer	19 (5.7)
Homemaker	57 (17.1)
Unemployed	64 (19.2)
Socioeconomic status	
Yellow	96 (28.7)
Pink	105 (31.4)
Blue	75 (22.5)
White	58 (17.4)
Life/ health insurance	
Yes	292 (87.4)
No	42 (12.6)

For further analysis, socioeconomic status of the participants determined by their ration card had been clubbed together as Below Poverty Line (yellow and pink) accounting for 60.2% and Above

Poverty Line (blue and white) accounting for 39.8% of the study participants. It can also be observed that 12.6% of the population confirms no health insurance.

3.1.3 Personal habits of the study population

The overall proportion of smokers was 18% but being only males it accounted for 40.5% of men. Similarly, those who had consumed alcohol in the last month was in total 21.9% but in men alone was 49.4% owing to almost half of the males in the study.

Table 3.3 Personal habits of the study population

Variable	Participants
Smoking at least once a day	
Yes	60 (18.0) (40.5 % of males)
No	274 (82.0)
Alcohol consumption in last 1 month	
Yes	73 (21.9) (49.4 % of males)
No	261 (78.1)

3.1.4 Dietary and physical activity characteristics of the study population

Only 38% of the participants admitted to promptly following the dietary advice given and only 53.3% of the participants were indulged in regular physical training. Those involved with at least 4 hours of medium to vigorous house chores were also included in those physically active.

Table 3.4 Details of dietary adherence and physical activity of the study population

Variable	Participants
Dietary adherence	
Yes	127 (38.0)
No	207 (62.0)
Physical activity	
Yes	178 (53.3)
No	156 (46.7)

3.1.5 Details of social support system of the study population

Majority of the participants reported average or good social support from their spouse or family or friends. Only 8.7% reported minimal social activities. Though this small number are not at all socially active, 34.4.% of the total population reported that they do not share their concerns or open up with their near ones.

Table 3.5 Details of social support system of the study participants

Social support	Variables	Participants
From spouse	Average and above	257 (76.9)
	Poor support	77 (23.1)
From family	Average and above	264 (79.0)
	Poor support	70 (21.0)
From friends	Average and above	273 (81.7)
	Poor support	61 (18.2)
Socially active	Not at all	29 (8.7)
	Sometimes or quite often	305 (91.3)
Share concerns with near and dear ones	Yes	219 (65.6)
	No	115 (34.4)
Kind of care from others	Financial	45 (13.5)
	Daily activities	289 (86.5)

3.1.6 Anthropometric characteristics of the study population

Body mass index was higher for the pre-obesity category. Mean body mass index was found to be 25.88 with a standard deviation of 5.39.

Table 3.6 Details of body mass index of the study population

BMI classification (kg/m²)	Participants
Underweight (<18.5)	15 (4.5)
Normal weight (18.5-24.9)	154 (46.1)
Pre obesity (25.0-29.9)	102 (30.5)

Obesity class 1 (30.0-34.9)	44 (13.2)
Obesity class 2 (35.0-39.9)	15 (4.5)
Obesity class 3 (>40)	4 (1.2)
Mean BMI	25.88 ± 5.39

3.1.7 Diabetes specific characteristics of the study population

Mean duration of illness was 8.75 years. Only 30.8% presented with a family history of type 2 diabetes mellitus. 34.4% had a pill count of 2 or less. All participants were on Oral Hypoglycaemic Agents (OHAs) and 30.8% of the participants were additionally on insulin as well. 68.6% of the participants reported some form of diabetic complications and 84.4% of the total participants had existing comorbidities. 78% of the participants admitted that diabetic expense has had made them compromise on household expenses several times.

Table 3.7 Diabetic characteristics of the study population

Diabetes status	Variables	Participants
Duration of illness	Less than 5 years	70 (21.0)
	5 – 10 years	171 (51.2)
	More than 10 years	93 (27.8)
Family history	Yes	103 (30.8)
	No	231 (69.2)
Following diet	Yes	127 (38.0)
	No	207 (62.0)
Number of medicines	2 or less	115 (34.4)
	3 or more	219 (65.6)
Prescribed insulin	Yes	103 (30.8)
	No	231 (69.2)
Do you feel like skipping medicines	Yes	236 (70.7)
	No	98 (29.3)
Presence of diabetic complications	Yes	229 (68.6)
	No	105 (31.4)

Presence of diabetic comorbidities	Yes	282 (84.4)
	No	52 (15.6)
Do you feel like diabetic expense compromises household expenses	Yes	262 (78.4)
	No	72 (21.6)

Of the entire participants, though 26.9% of them had episodes of hypoglycaemia, hospitalisation was required for only 9.9%. Like literature suggests, diabetes can affect the heart condition owing to 30.5% of CVD cases among the study participants followed by only 10.5% of cases of diabetic ulcer. Owing to the disability stroke could manifest in the patients only 2 cases were identified as such in the study participants.

Table 3.8 Details of diabetic complications of the study participants

Variable	Category	Participants
Hospital emergencies in the past 1 year	None	300 (89.8)
	1 or more	34 (10.2)
Hospitalisation required	Yes	33 (9.9)
	No	301 (90.1)
CVD	Yes	102 (30.5)
	No	232 (69.5)
Stroke	Yes	2 (0.6)
	No	332 (99.4)
Diabetic ulcer	Yes	35 (10.5)
	No	299 (89.5)
Episode of hypoglycaemia in the past 1 year	Yes	90 (26.9)
	No	244 (73.1)
No complication		105 (31.4)

Considering the individual comorbidities existing with diabetes, dyslipidaemia was leading affecting 36.8% and hypertension affecting 33.8% of the participants. Following them, musculoskeletal conditions affect 24.9% and respiratory problems affected 22.5% of the participants.

18.8% of the females reported obstetrical and gynaecological problems and 12.2% of males reported genitourinary problems. Other frequently occurring diseases were that of skin (11.7%) and of ophthalmic origin (8.1%).

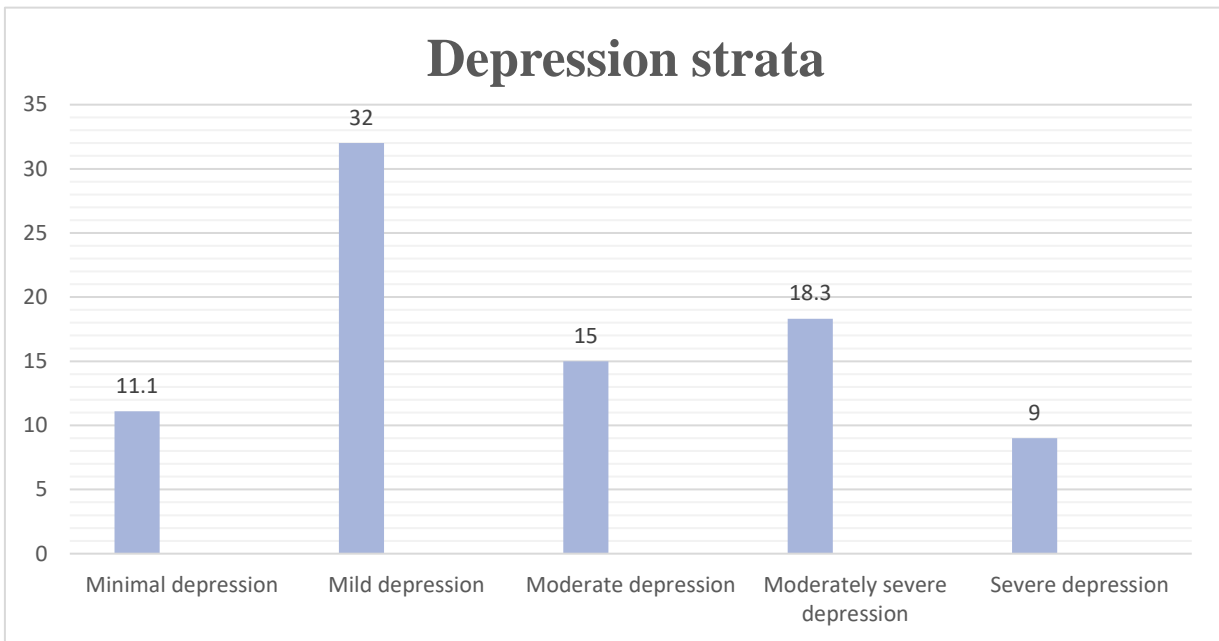
Table 3.9 Details of diabetic comorbidities of the study population

Variable	Category	Participants
Comorbidities	Present	282 (84.4)
Hypertension	Yes	113 (33.8)
	No	221 (66.2)
Dyslipidaemia	Yes	123 (36.8)
	No	211 (63.2)
Respiratory problems	Yes	75 (22.5)
	No	259 (77.5)
OBG	Yes	35 (18.8 % of females)
	No	151 (81.2)
Musculoskeletal	Yes	83 (24.9)
	No	251 (24.9)
GIT	Yes	59 (17.7)
	No	275 (82.3)
Eye	Yes	27 (8.1)
	No	307 (91.9)
Genitourinary	Yes	18 (12.2 % of males)
	No	130 (87.8)
Skin	Yes	39 (11.7)
	No	295 (88.3)

3.2 Severity of depression in the study population

Majority of the participants were showing mild to moderate depression. When compared across gender, more women were having depression than men. Only 9% of the study population showed severe depression.

Figure 3.1: Severity of depression among the study participants



3.3 Bivariate analysis

As an initial course in examining the associated factors of depression, simple bivariate analysis was performed for each variable to estimate the crude odds ratio and a p value was recorded. For better understanding, the independent variables were clubbed under specific groups. Each such variable was then cross tabulated with depression (dependent variable). If the p value was less than 0.5, then the association was considered statistically significant. Unadjusted for other variables, it was found that thirteen independent variables were statistically significantly associated with depression. For the purpose of analyses, outcome variable depression was narrowed down to either the presence or absence of depression using the cut off provided in the literature (van Steenbergen-Weijenburg et al., 2010).

3.3.1 Demographic factors and depression

Among the demographic variables sex was found to have a statistically significant association with depression. Though age is a known risk factor, it did not have a significant association with depression in this study.

Table 3.10 Association of demographic factors with depression

Variable	Category	No depression (%)	Depression (%)	Total	P value
Age	Less than 49 years	40 (67.8)	19 (32.2)	59 (100)	0.360
	50 – 59 years	53 (57.6)	39 (42.4)	92 (100)	
	60 – 69 years	78 (54.2)	66 (45.8)	144 (100)	
	>= 70 years	23 (59.0)	16 (41.0)	39 (100)	
Sex	Male	114 (77.0)	34 (23.0)	148 (100)	< 0.001*
	Female	80 (43.0)	106 (57.0)	186 (100)	
Marital status	Currently married	177 (58.4)	44 (14.5)	53 (17.5)	0.701

	Never married/ divorced/ separated/ widow/ widower	17 (54.8)	5 (16.1)	8 (25.8)	
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* p value <0.05

3.3.2 Socioeconomic factors and depression

In this category, only the socioeconomic status based on ration card i.e., APL (above poverty line) for white and blue and BPL (below poverty line) for pink and yellow was found to be statistically significantly associated with depression.

Table 3.11 Association of socioeconomic factors with depression

Variable	Category	No depression (%)	Depression (%)	Total	P value
Educational qualification	No formal schooling	26 (57.8)	19 (42.2)	45 (100)	0.204
	Up to schooling	146 (56.4)	113 (43.6)	259 (100)	
	Up to university	22 (73.3)	8 (26.7)	30 (100)	
Work profile	Professional/ Executive/ Clerical/ Medium Business	69 (65.1)	37 (34.9)	106 (100)	0.318
	Skilled/ Unskilled/ Self Employed	60 (56.1)	47 (43.9)	107 (100)	
	Homemaker	32 (56.1)	25 (43.9)	57 (100.0)	

	Unemployed	33 (51.6)	31 (48.4)	64 (100)	
Socio economic status based on ration card	Below poverty line (yellow, pink)	127 (63.2)	74 (36.8)	201 (100)	0.020*
	Above poverty line (blue, white)	67 (50.4)	66 (49.6)	133 (100)	
Family type	Nuclear	98 (61.6)	61 (38.4)	159 (100)	0.210
	Extended	96 (54.9)	79 (45.1)	175 (100)	
Health insurance	Yes	175 (59.9)	117 (40.1)	292 (100)	0.071
	No	19 (45.2)	23 (54.8)	42 (100)	

* p value <0.05

3.3.3 Lifestyle and depression

Though indulging in habits like smoking, alcohol consumption and physical inactivity can deteriorate the physical and mental health, no such significant association could be established in this study.

Table 3.12 Association of personal habits and depression

Variable	Category	No Depression (%)	Depression (%)	total	P value
Smoking	Yes	37 (61.7)	23 (38.3)	60 (100)	0.535
	No	157 (57.3)	117 (42.7)	274 (100)	
Following diet	Yes	78 (61.4)	49 (38.6)	127 (100)	0.333
	No	116 (56.0)	91 (44.0)	207 (100)	
Physical activity (at	Yes	104 (58.4)	74 (41.6)	178 (100)	0.892
	No	90 (57.7)	66 (42.3)	156 (100)	

least 150 mins in a week)					
Alcohol consumed in last 1 month	Yes	46 (63.0)	27 (37.0)	73 (100)	0.334
	No	148 (56.7)	113 (43.3)	261 (100)	

3.3.4 Social support system and depression

Among the social support variables, support from spouse and family was found to be significantly associated with depression.

Table 3.13 Association of social support system and depression

Variable	Category	No Depression (%)	Depression (%)	total	P value
Support from spouse	Average or above	163 (63.4)	94 (36.6)	257 (100)	< 0.001*
	Poor support	31 (40.3)	46 (59.7)	77 (100)	
Support from family	Average or above	164 (62.1)	100 (37.9)	264 (100)	0.004*
	Poor support	30 (42.9)	40 (57.1)	70 (100)	
Support from friends	Average or good	160 (58.6)	113 (41.4)	273 (100)	0.681
	Not applicable or poor	34 (55.7)	27 (44.3)	61 (100)	
Socially active	Sometimes or quite often	181 (59.3)	124 (40.7)	305 (100)	0.130
	Not at all	13 (44.8)	16 (55.2)	29 (100)	
Sharing problems with dear ones	Yes	135 (61.6)	84 (38.4)	219 (100)	0.068
	No	59 (51.3)	56 (48.7)	115 (100)	

Support they provide	Financial	24 (53.3)	21 (46.7)	45 (100)	0.487
	Daily activities	170 (58.8)	119 (41.2)	289 (100)	

* p value <0.05

3.3.5 Association of Body mass index with depression

Body mass index was not found to be associated statistically significant with depression.

Table 3.14 Association of body mass index and depression

Body mass index	No Depression (%)	Depression (%)	total	P value
Underweight	11 (78.6)	3 (21.4)	14 (100)	0.263
Normal weight	86 (56.6)	66 (43.4)	152 (100)	
Over weight	92 (56.4)	71 (43.6)	163 (100)	

3.3.6 Association of diabetes specific factors and depression

Among the diabetes specific variables, family history of diabetes, advice from physician regarding physical activity and diet, insulin usage and those who had to compromise on household expenses to meet their diabetic expenditure were associated statistically significant with depression.

Table 3.15 Association of diabetes specific factors and depression

Variable	Category	No Depression (%)	Depression (%)	total	P value
Duration of illness	Less than 5 years	48 (68.6)	22 (31.4)	70 (100)	0.134
	5 – 10 years	95 (55.6)	76 (44.4)	171 (100)	
	More than 10 years	51 (54.8)	42 (45.2)	93 (100)	
Family history	Yes	69 (67.0)	34 (33.0)	103 (100)	0.028 *
	No	125 (54.1)	106 (45.9)	231 (100)	

Physical activity advice by physician	Yes	183 (60.0)	122 (40.0)	305 (100)	0.021 *
	No	11 (37.9)	18(62.1)	29 (100)	
Dietary advice by physician	Yes	188 (59.9)	126 (40.1)	314 (100)	0.009 *
	No	6 (30.0)	14 (70.0)	20 (100)	
Following diet	Yes	78 (61.4)	49 (38.6)	127 (100)	0.333
	No	116 (56.0)	91 (44.0)	207 (100)	
Number of medicines	2 or less	74 (64.3)	41 (35.7)	115 (100)	0.093
	3 or more	120 (54.8)	99 (45.2)	219 (100)	
Prescribed insulin	Yes	47 (45.6)	56 (54.4)	103 (100)	0.002 *
	No	147 (63.6)	84 (36.4)	231 (100)	
Do you feel like diabetic expense compromises other expenses	Yes	161 (61.5)	101 (38.5)	262 (100)	0.017 *
	No	33 (45.8)	39 (54.2)	72 (100)	

* p value <0.05

3.3.7 Complication of diabetes and depression

Among the complications of diabetes, the presence of cardiovascular diseases showed statistically significant association with depression.

Table 3.16 Association of complications of diabetes and depression

Variable	Category	No Depression (%)	Depression (%)	total	P value
CVD	Yes	48 (47.1)	54 (52.9)	102 (100.0)	0.007 *
	No	146 (62.9)	86 (37.1)	232 (100.0)	

Stroke	Yes	0	2 (100.0)	2 (100.0)	0.095
	No	194 (58.4)	138 (41.6)	332 (100.0)	
Diabetic ulcer	Yes	20 (57.1)	15 (42.9)	35 (100.0)	0.905
	No	174 (58.2)	125 (41.8)	299 (100.0)	
Hypoglycaemia	1 or more	55 (61.1)	35 (38.9)	90 (100.0)	0.496
	None	139 (57.0)	105 (43.0)	244 (100.0)	
None	Yes	136 (59.4)	93 (40.6)	229 (100.0)	0.475
	No	58 (55.2)	47 (44.8)	105 (100.0)	

* p value <0.05

3.3.8 Comorbidities and depression

In this category, the presence of comorbidities shows statistically significant association with depression. Additionally, hypertension, musculoskeletal pathologies, respiratory disorders and genitourinary problems in men also showed statistically significant association with depression.

Table 3.17 Association of comorbidities and depression

Variable	Category	No Depression (%)	Depression (%)	Total	P value
Comorbidities present	Yes	150 (53.2)	132 (46.8)	282 (100.0)	0.000 *
	No	44 (84.6)	8 (15.4)	52 (100.0)	
Dyslipidaemia	Yes	72 (58.5)	51 (41.5)	123 (100.0)	0.898
	No	122 (57.8)	89 (42.2)	211 (100.0)	
Hypertension	Yes	41 (36.3)	72 (63.7)	113 (100.0)	< 0.001 *
	No	153 (69.2)	68 (30.8)	221 (100.0)	
Musculoskeletal	Yes	40 (48.2)	43 (51.8)	83 (100.0)	0.035 *
	No	154 (61.4)	97 (38.6)	251 (100.0)	
Respiratory problems	Yes	33 (44.0)	42 (56.0)	75 (100.0)	0.005 *
	No	161 (62.2)	98 (37.8)	259 (100.0)	
Gastrointestinal	Yes	35 (59.3)	24 (40.7)	59 (100.0)	0.832

	No	159 (57.8)	116 (42.2)	275 (100.0)	
Dermatological	Yes	23 (59.0)	16 (41.0)	39 (100.0)	0.905
	No	171 (58.0)	124 (42.0)	295 (100.0)	
Ophthalmological	Yes	14 (51.9)	13 (48.1)	27 (100.0)	0.494
	No	180 (58.6)	127 (41.4)	307 (100.0)	
Obstetric or gynaecological problems	Yes	15 (42.9)	20 (57.1)	35 (100.0)	0.054
	No	179 (59.9)	120 (40.1)	299 (100.0)	
Genitourinary	Yes	15 (83.3)	3 (16.7)	18 (100.0)	0.026 *
	No	179 (56.6)	137 (43.4)	316 (100.0)	

* p value <0.05

3.4 Multivariate analysis (Binary logistic regression)

The associated factors of depression found out by means of multiple logistic regression is provided in table 3.18. The analysis measures the effect of change in variation in one of the independent variables on the variation of the dependent variable (depression) when adjusted for other independent variables in the model. The goal of the multivariate analysis is to comprehend the significance of the independent variables in explaining the variation in the dependent variable, both individually and collectively. The net bearing effect of different independent variables was explained in terms of odds ratio (OR). The analysis was done by backward stepwise (likelihood ratio) model in SPSS version 25. Four variables were found to be significantly associated with depression using this model

It is observed here that women if diabetic are eight times likely to be depressed and those with poor spousal support was in risk of depression three times that of those with good spousal support. Diabetic patients with comorbidities were four times at risk of depression than those without any. Patients with diabetic complications like cardiovascular diseases has a risk of six times of falling into depression than those without any heart diseases.

Table 3.18 Significant independent variables found in multivariate analysis #

Variable	Category	Odds ratio *	P value	Confidence interval
Sex	Male	**	**	**
	Female	8.72	0.000	4.22 -17.99
Spousal support	Yes	**	**	**
	No	2.91	0.001	1.52 - 5.57
Comorbidities	No	**	**	**
	Yes	4.65	0.001	1.86 - 11.63
CVD	No	**	**	**
	Yes	6.21	0.000	2.96 - 13.06

*Adjusted Odds Ratio

Other independent variables included in the model and dropped out from the final model are socioeconomic status, family support, family history of diabetes, advice from physician regarding physical activity and diet, Insulin usage and the diabetic expense.

CHAPTER 4

DISCUSSION

4.1 Discussion

The objectives of the study were to estimate the prevalence and to identify the associated factors for depression among diabetic patients residing in the urban area of Thiruvananthapuram district.

4.1.1 Sample characteristics

Almost equal proportion of the participants were of both sexes. Also noticed was an almost equal proportion of both nuclear and extended type of family. Only 13.5 percent have had not received any formal schooling owing to the high literacy rate of the state. 40 percent of the participants were above poverty line and 12.6 percent of the them had no health or life insurance. This could be explained by the government schemes provided with the BPL status and not with the APL cards.

4.1.2 Pattern of depression in the study population

The prevalence of depression found in this study was 41.9 percent [CI (32.71-51.69)] which indicates the high burden in the community resembling an iceberg phenomenon. Of them 9 percent was screened for severe depression affecting women more than men.

4.1.3 Associated factors of depression among the diabetic patients

Several factors associated with depression among diabetic patients were derived from this study, some of which are consistent with previous findings and some not. One of the most relevant findings was that women were 9 times at risk of developing depression than men consistent with other literature findings (Anderson et al., 2001; Téllez-Zenteno and Cardiel, 2002).

Another interesting finding in the study was the influence of spousal support. Those who reported poor spousal support were almost 3 times at risk of developing depression than those who received good or average support. This could be explained by the nuclear mode of family wherein the only means of support for a couple is one another and the lack of it can have a detrimental impact on the mental as well as physical health.

4.2 Strengths of the study

To our knowledge no authentic studies have been undertaken in similar settings considering urbanisation, to determine the prevalence and risk factors for depression among diabetic patients. Most importantly, the tool used in the study to assess depression is internationally, nationally and also in the very same region has been validated

4.3 Limitations of the study

This is a cross-sectional study, which makes it difficult to draw conclusions regarding the cause and effect of the association between diabetes and depression hence cannot demonstrate a temporal relationship between the two. Secondly, this study made use of a clinic registered patient population and so the results could be limited to similar clinic or hospital setting populations. Another limitation is that a gold standard clinical diagnosis of a depressive condition was not employed in this study therefore it is unclear if the findings would have changed. Lastly, this study lacks a comparison group to act as a reference in precisely determining the difference in depression prevalence between diabetes and normal persons.

4.4 Recommendation and policy implications of the study

Every diabetic patient should have depression ruled out. Depression in people with diabetes typically arises in the context of countless social and physical issues that conceal or obstruct the treatment of diabetes itself, leading to a poor quality of life in terms of health and grave consequences for morbidity and death. Finding and addressing these risk factors and depression can enhance the effectiveness of diabetes therapy.

People with diabetes themselves, as well as those who care for them should be thoroughly informed about depression, its risk factors, and the fact that the symptoms of depression are not a normal side effect of diabetes. This goes for both physicians and policy makers as well. Therefore, community awareness efforts are now more important than ever. To recognise and treat the risk factors and depression in diabetic patients, health care professionals must get adequate training. The need for social and moral assistance becomes more critical as urbanisation expands and community behaviour changes, whereby the role of informal carers, such as family and friends, should be crucial giving them the care and assistance they need. Therefore, by improving the informal social support system and providing

suitable social security measures, many diabetics would be able to stay in the community feeling supported and in good health.

The complexities of the human brain and how it functions have remained a mystery; these problems must be resolved using exhaustive studies. Further research is required to understand the mechanisms of depression in diabetics. Studies are required to pinpoint the risk variables at play in communities and other contexts. Finding out the system, provider, and patient-level obstacles to diagnosing and treating depression in diabetic patients is also necessary.

4.5 Conclusions: Time to act now

This study found significant levels of depression in the Indian type 2 diabetes mellitus community and established depression as a comorbidity in type 2 diabetes mellitus patients. This burden is predicted to expand along with the epidemiological shift from infectious to non-communicable diseases, with demographic transition in low- and middle-income countries, and with an increase in the incidence of various social determinants linked to these illnesses. The findings suggest diabetes treatment programs in the state to explore early depression screening in type 2 diabetes patients focusing on the primary health centres. Well-controlled and better-reported studies are needed to inform the development and maintenance of effective therapies for depression in these people. Although there are a number of significant challenges to expanding the health system, this can be implemented only by political will and commitment to allot the appropriate resources and offer technical leadership for the drive of change. Finally, our data implies that clinicians should be aware of the increased likelihood of depression in people with diagnosed and treated type 2 diabetes and recommend routine screening for these patients. To reduce pain and further medical consequences, therapy for both diabetes and depression symptoms should be implemented.

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Appendix-I

Achutha Menon Centre for Health Science Studies

Sree Chitra Tirunal Institute for Medical Sciences and Technology,

Trivandrum Kerala - 695011, India

PARTICIPANT INFORMATION SHEET

Dear Sir/Madam,

I am Dr Catherine Suresh Emmanuel, studying Master of Public Health (MPH) at Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum. As part of my course, I am required to do a study. My topic is- “Prevalence and associated factors of depression among diabetic patients- A multi-institutional study in Thiruvananthapuram Corporation”.

I kindly request you to spend some time & participate in the study.

The purpose of the study:

Depression is a common mental disorder, characterized by sadness, loss of interest or pleasure, feelings of guilt or low self-worth, disturbed sleep or appetite, feelings of tiredness, and poor concentration. Depression has been identified as both cause and consequence of diabetes. This bidirectional relationship requires attention because depression is associated with hyperglycaemia, which, in turn can increase the diabetes related complications and consequently mortality. It is documented that the prevalence of depression among diabetic patients in Kerala is 49%. In spite of high prevalence and serious complications, depression is not identified in general practice and primary care.

As the first step of intervention, screening of depression for diagnosed diabetics is recommended to reduce the treatment gap. The purpose of my study is to understand the load of depression, its predictors among diabetic patients attending the urban health centres in Trivandrum Corporation.

About the study:

In this study, I am conducting interviews with diabetic patients attending the Urban Primary Health Centres in Thiruvananthapuram Corporation. Total of 300 interviews will be conducted in the UPHCs over a period of 2 months.

This study is being conducted by me as Principal Investigator (PI) under supervision of Dr P Sankara Sarma, Senior Grade Professor at Achutha Menon Centre for Health Science Studies Trivandrum. The ethics approval for this study has been obtained from Institutional Ethics Committee of Sree Chitra Tirunal Institute for Medical Sciences and Technology

What participation will be required from your side?

Participation involves answering some questions regarding your socioeconomic details, behavioural queries, health status and a questionnaire for screening depression. If you agree to participate in the study, then I will interview you for about 30 minutes. The information given by you will be documented. After the interview I

may contact you again only if it is found that the information documented is either incomplete or any further clarification is needed.

How the study will benefit you?

While at present, there is no significant individual benefit; your participation in this study will help you to know your depression status. If the status is significant, you will be notified and can seek necessary help needed for your condition by consulting the medical officer and requesting a referral for further services. There will be no incentive in any form for participating in the study. But the results of the study will be helpful in further research and policy making which may benefit the society as a whole.

What are possible harms from the study?

Some of the questions will be of a personal nature which may make you uncomfortable. In such case you are free to take time to answer or if you are not willing to answer, you can ask me to skip the question. If still you are not willing to answer further, you will be free to terminate the interview without any obligation.

Confidentiality of your data:

Whatever information you share will be kept highly confidential and will only be accessible to me and my supervisor. All the information that is being collected will be used solely for research. Your personal details will not be shared with anyone at any stage. The data other than your personal identifiers will be used for analysis of the study. The results of the study will be published and presented in public forums.

Can I Withdraw from the study?

Your participation in the study will be completely voluntary. You are free and have the right to withdraw during the interview at any time. There will be no penalty for withdrawal or not participating in the study. If there is any query or doubt you want to ask, I will try to clarify it to the best of my ability.

Name of the Principal Investigator: Dr Catherine Suresh Emmanuel

Signature of Principal Investigator:

Contact No. of Principal Investigator: 8105752299

If you have any doubt/query on the authentication of this study, you may contact the SCTIMST Institutional Ethics Committee Secretary - Dr Srinivas G (email iec.mem.sec@sctimst.ac.in)

Are you willing to participate in the study? - Yes / No.

If yes – please fill up and give signature on the informed consent provided.

Appendix-II

“Prevalence and associated factors of depression among diabetic patients- A multi-institutional study in Thiruvananthapuram Corporation”.

Written informed consent

I, _____ have read/heard and understood all the information provided in the ‘Participant information sheet’ and I have clarified all my doubts. By signing/putting thumb impression I confirm my voluntary participation in this study. I agree to be contacted again if any missing information or further clarification is needed. I understand my right to withdraw from the interview anytime without any obligation. I also understand that my identity will not be revealed in any published or released information from this study.

Name of the respondent:

Signature of the respondent or Thumb impression (if unable to sign):

Date:

Place:

Name of the Principal Investigator: Dr Catherine Suresh Emmanuel

Signature of the Principal Investigator:

Appendix-III

INTERVIEW SCHEDULE

Patient ID:		Age:	Sex:	Date of interview:
UPHC:				
G	General Information	Code Label		Value
G01	Name of the respondent			
G02	Age in completed years			
G03	Sex	Male	1	
		Female	2	
		Transgender	3	
G04	Marital status	Currently Married	1	
		Never married	2	
		Divorcee /separated	3	
		Widow/widower	4	
		Others (specify)	5	
G05	Highest level of education attained	No formal schooling	1	
		Up to primary school	2	
		Up to high school	3	
		Up to intermediate	4	
		Up to university	5	
		University completed or higher	6	
		Others (specify)	7	
G06	Which of the following best describes your main work status?	Professional / Executive / Big business	1	
		Clerical/ medium business	2	
		Self-employed/ skilled	3	
		Unskilled/ landless laborer	4	
		Homemaker	5	
		Retired	6	
		Unemployed (able to work)	7	
		Unemployed (unable to work)	8	
		Others (specify)	9	
G07	What color is your ration card?	Yellow	1	
		Pink	2	
		Blue	3	
		White	4	
G08	Place of residence	Urban	1	
		Rural	2	
		Semi- urban	3	
G09	Type of family	Nuclear	1	
		Extended	2	

		Joint	3
		Others	4
G010	How many members are there in your household? (Number of members currently sharing the same kitchen)		
G011	Is (Are) there any earning member(s) in your family?	No	0
		Yes	1
G012	Do you have any life/health insurance?	No	0
		Yes	1

B	Core Behavioral Measures	Code Label	Value
B01	Tobacco Use		
B01T1	Have you ever smoked cigarette or bidi or any other tobacco containing products?	No	0
		Yes	1
B01T2	Do you currently smoke cigarette/bidi or any other tobacco containing products?	No	0
		Yes	1
B01T3	On average how many of the following do you smoke each day? (pack years)	Cigarette	1
		Bidi	2
		Others	3
		Pack years calculated	
B01T4	Have you ever used any smokeless tobacco products?	No	0
		Yes	1
B01T5	Do you currently use any smokeless tobacco product?	No	0
		Yes	1
B01T6	Any of the following products you use currently on average?	Pan with tobacco	1
		Ghutka	2
		Khaini	3
		Snuff	4
		Others (specify)	5
B02	Alcohol Usage		
B02A1	Have you ever consumed a drink that contains alcohol such as beer, whisky, rum, gin, brandy or other local products?	No	0
		Yes	1
B02A2	In the past 12 months how	1-4 days a week	1

	frequently have you had at least one drink?	5 or more days a week	2
		1-3 days a month	3
		Less than once a month	4
B02A3	Have you consumed any products in the last month?	No	0
		Yes	1
B02A4	On average how many drinks do you have during one day?		

B03	Diet		
B03D1	Who plans the food menu for each day at home?	Self	1
		Others (specify)	2
B03D2	Have you received advice regarding diet from your physician or dietician?	No	0
		Yes	1
B03D3	Are you currently practicing the advice received regarding diet?	No	0
		Yes	1
B03D4	Is there any diet restriction for you?	No	0
		Yes	1
B03D5	What prompted you for diet restriction?	Self	1
		Family members	2
		Friends	3
		Physician	4
		Dietician	5
		Others (specify)	6
B03D6	How much effort did you make for this restriction?	A lot of effort	1
		Moderate effort	2
		Little effort	3
		No effort at all	4
		Don't know	5
B03D7	How was it to restrict the diet?	Very difficult	1
		Somewhat difficult	2
		Easy	3
		Don't know	4
B03D8	What do you feel about the diet restriction?	Feeling frustrated	1
		Not feeling good	2
		Feeling good	3
		No effect	4
		Don't know	5
B03D9	Do you think the diet restriction given makes you sad or down?	No	0
		Yes	1

B03D10	Has your appetite reduced	No	0
		Yes	1

B04	Physical activity		
B04P1	Does your work involve any kind of physical activity of more than 10 minutes at a time?	No	0
		Yes	1
B04P2	Have you received any advice regarding exercise from your physician?	No	0
		Yes	1
B04P3	Are you doing any kind of physical activity currently?	No	0
		Yes	1
B04P4	What kind of physical activity do you currently do?	Specify	Duration per Day (minutes)
		1.walking	
		2. jogging	
		3. running	
		4.cycling	
		6.others (specify)	
B04P5	For how many days do you do this activity in a typical week?		
B04P6	For how long do you do this activity in a week?		
B04P7	How many hours do you spend sitting or reclining in a typical day?		
B04P8	How many hours do you sleep in a typical day?		
B04P9	Do you feel like your sleep is not disturbed	No	0
		Yes	1

S	Social factors (social support, social networks, family support)		
S01	How do you grade help and support from your spouse?	Very good	1
		Good	2
		Average	3

		Poor	4
		Not applicable	5
		Don't know	6
S02	How do you grade help and support from other family members?	Very good	1
		Good	2
		Average	3
		Poor	4
		Not applicable	5
		Don't know	6
S03	How do you grade help and support from your friends or neighbors?	Very good	1
		Good	2
		Average	3
		Poor	4
		Not applicable	5
		Don't know	6
S04	Do you engage in social activities often? (e.g., weddings, parties etc.)	No	0
		Yes	1
S05	In which social activities do you involve yourself?	Family get together	1
		Parties conducted by working organizations	2
		Attend social events like weddings	3
		Attend religious ceremonies	4
		Community activities like social services	5
		Others (specify)	6
S06	Are there enough friends or relatives who can share your problems?	No	0
		Yes	1
S07	Who is the care-giver for you?	Self	1
		Others (specify)	2
S08	What is the exact nature of care they provide you?	Financial	1
		Daily activities	2
		Others (specify)	3
S09	Do you often share your troubles in mind with others?	No	0
		Yes	1

D	Diabetes specific	Code Label	Value
D01	When was your diabetes was first diagnosed?		
D02	How old were you at the time of diagnosis? (in years)		
D03	Is there any family history of diabetes?	No	0
		Yes	1

D04	What type of treatment are you receiving now?	Only diet	1
		Only OHAs	2
		Only Insulin	3
		Both OHAs and Insulin	4
		OHAs, Insulin and others	5
D05	Number of prescription medications currently on		
D06	Do you ever forget to take your medicines?	No	0
		Yes	1
D07	Do you feel like medicines will cure or improve your diabetes?	No	0
		Yes	1
D08	Do you ever feel like not complying to your treatment?	No	0
		Yes	1
D09	No of diabetes related emergency department visits during last one year		
D10	Any diabetic complications present	Cardiovascular disease	1
		Stroke	2
		Diabetic neuropathy	3
		Diabetic nephropathy	4
		Diabetic retinopathy	5
		Diabetic ulcer	6
D11	No of episodes of DKA during last one year (rapid breathing/fruity breath odor/confusion/coma etc.)		
D012	No of episodes of hypoglycemia during last one year (with blurred vision/sweating/reeling of head etc.)		
D013	Were you hospitalized for diabetic complications in the last one year?	No	0
		Yes	1
D014	How many days were you hospitalized for diabetes related causes in the last year?		
D015	Are you currently suffering from any other disease?	No	0
		Yes	1

D014	From which other diseases do you suffer currently? What are the diseases you take medications regularly for?	Condition	Response ('√')	Remarks	Code
		Hypertension			1
		Cardiovascular diseases			2
		Neurological disorders			3
		Stroke			4
		Eye problems			5
		Cancer			6
		Mental disorders			7
		Obstetrical Problems			8
		Gynecological Problems			9
		Respiratory diseases			10
		Asthma			11

		Skin Diseases		12
		Dental ailments		13
		Gastrointestinal disorders		14
		Musculoskeletal Problems		15
		Genito-urinary Problems		16
		ENT problems		17
		Any Others		18
		None		99
D015	Do you know something about Diabetes?	No		0
		Yes		1
D016	What do you know about Diabetes?	Causes		0
		Symptoms		1
		Treatment		2
		Complications		3
D017	Have you ever been counselled about the symptoms, long term effects, lifestyle changes etc. by treating doctor?	No		0
		Yes		1
D019	Do you feel like diabetic treatment expense has made you compromise on household expense or any other expenses?	No		0
		Yes		1
P	Physical Measurements			Value
P01	Weight in kg			
P02	Height in cm			
P03	BMI			
P04	Blood Pressure in mm Hg			
L	Laboratory Information			Value
L01	FPG in mg/dl (within last 3 months)			
L02	PPPG in mg/dl (within last 3 months)			
L03	HbA1c (%) (measured in last 3 months)			
L04	Total cholesterol (measured in last 3 months)			

Appendix- IV

PATIENT HEALTH QUESTIONNAIRE 9

This questionnaire is an important part of providing you with the best health care possible.

Your answers will help in understanding problems that you may have. Please answer every question to the best of your ability unless you are requested to skip a question.

Over the last **2 weeks**, how often have you been bothered by any of the following problems?


Sl. No	Description	Not at all (0)	Several days (1)	More than half the days (2)	Nearly every day (3)
1	Little interest or pleasure doing things				
2	Feeling down, depressed or hopeless				
3	Trouble falling or staying asleep or sleeping too much				
4	Feeling tired or having little energy				
5	Poor appetite or over eating				
6	Feeling bad about yourself, or that you are a failure, or have let yourself or your family down				
7	Trouble concentrating on things, such as reading the newspaper or watching television				
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 the usual				
9	Thoughts that you would be better off dead, or of hurting yourself in some way				

Total score =

Interpretation of score:

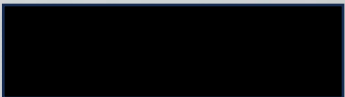
Total score	Depression Severity
1-4	Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

Appendix V: IEC Approval


श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/2007/MARCH/2023 18.04.2023



Dear Dr. Catherine Suresh Emmanuel,

The Institutional Ethics Committee held on 18th March, 2023, reviewed and discussed your application to conduct the study titled "PREVALENCE AND PREDICTORS OF DEPRESSION IN DIABETIC PATIENTS - A MULTI-INSTITUTION CROSS SECTIONAL STUDY IN THIRUVANANTHAPURAM CORPORATION (IEC/2007)".

The following members of the Ethics Committee were present at the meeting held on 18th March, 2023.

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
2.	Dr. Pradeep S	MBBS, MD	Male	Basic Medical Scientist	No
3.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
4.	Dr. P. Manickam	BSMS, MSc (Epid), PhD	Male	Health Science Expert/ Social Scientist	No
5.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
6.	Dr. Biju Soman	MBBS, MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
7.	Dr. Syam K	MBBS, MD, DM	Male	Clinician	Yes
8.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

The following documents were reviewed:

Original submission

1. Covering letter addressed to the Chairman, IEC, SCTIMST dated 02.03.2023
2. Checklist Form
3. Responses/Amendments made based on the Reviewer's comments
4. IEC Application Form
5. Research Proposal
6. Participant Information Sheet and Written Informed Consent in English and Malayalam
7. Interview schedule in English and Malayalam
8. CV of Principal Investigator and Guide
9. Letter from DMO requesting IEC clearance from institution to permit the study
10. Declaration Form
11. SRC Recommendation Letter

Revised submission

1. Covering letter addressed to the Chairman, IEC, SCTIMST dated 03.04.2023
2. Copy of IEC Recommendation letter dated 03.04.2023
3. Checklist Form
4. Responses/Amendments made based on the Reviewer's comments
5. IEC Application Form
6. Research Proposal
7. Participant Information Sheet and Written Informed Consent in English and Malayalam
8. Interview schedule in English and Malayalam
9. Patient Health Questionnaire in English and Malayalam
10. CV of Principal Investigator and Guide
11. Letter from DMO requesting IEC clearance from institution to permit the study
12. Declaration Form

IEC Decision

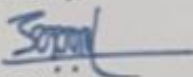
The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team / Guide who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,



Dr. G. Srinivas
Member Secretary, IEC



MEMBER SECRETARY
SCTIMST
SRINIVASAPURAM

Appendix VI: Approval letter from DMO

DISTRICT MEDICAL OFFICE (HEALTH)
RED CROSS ROAD, VANCHIYOOR.(P.O), THIRUVANANTHAPURAM – 695 035
PHONE: 0471 - 2471291, E.mail dmohealthtvm@gmail.com.

No.C4-11457/23/DMOH

Dated:25/04/2023.

ETHICS COMMITTEE

Members

- D M O
- Additional D M O
Vigilance & Additional D
M O Public Health
- Deputy D M O
- R C H O
- J A M O

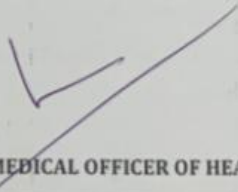
Approval of Research project

The Ethics committee has evaluated the protocols of dissertation data collection "Prevalance and predictors of depression in Diabetic patients – a multi-institution cross sectional study in Thiruvananthapuram corporation (IEC/2007)".

Name of Researcher

S

The committee has provisionally approved the study.


DISTRICT MEDICAL OFFICER OF HEALTH

Appendix VII: Plagiarism check

Document Information		
Analyzed document	word file to check plagiarism.docx (D171843970)	
Submitted	2023-07-07 08:43:00	
Submitted by	Sankara Sarma	
Submitter email	sarma@sctimst.ac.in	
Similarity	6%	
Analysis address	rasma.sctims@analysis.urkund.com	

Sources included in the report		
W	URL: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0267848 Fetched: 2022-05-03 22:11:58	1
W	URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4863499/ Fetched: 2019-11-04 12:28:46	9
SA	urkund.docx Document urkund.docx (D126138576)	1
SA	Chapter 02 Review of Litratue.docx Document Chapter 02 Review of Litratue.docx (D110815909)	1
SA	Sree Chitra Tirunal Institute, Thiruvananthapuram / Multimorbidity_PC.docx Document Multimorbidity_PC.docx (D125451658) Submitted by: jeemon@sctimst.ac.in Receiver: jeemon.sctims@analysis.urkund.com	3
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W	URL: https://www.cureus.com/articles/94398-depression-among-patients-with-type-2-diabetes-mellitus- Fetched: 2022-08-18 10:47:39	2
W	URL: https://www.kerrvillefamilydoctor.com/images/pdf/depression_questionnaire.docx Fetched: 2021-06-17 05:16:23	4