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DIABETES DISTRESS AND RELATED FACTORS AMONGST TYPE 2 DIABETIC PATIENTS ATTENDING PRIMARY HEALTH CARE FACILITIES IN EKURHULENI HEALTH DISTRICT, GAUTENG

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine in Family Medicine

Johannesburg

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Declaration

I, Dr Sruthi Mohan, declare that this Research Report is my own, unaided work. It is being submitted for the degree of Master of Medicine in the branch of Family Medicine (MMed Fam Med) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



Sruthi Mohan 06 July 2020

Dedication

To God Almighty for giving me: the strength, courage and inspiration to complete this project.

To my husband, Rathish K.R. my pillar of strength: for his continuous support, inspiration, patience and technical advice.

To my parents, Mohanakumar TK and Vasanthi Mohan, and sister, Jyothi Mohan ,for their endless support and encouragement and always believing in me.

To my darling daughter, Shreya, for being such an understanding, happy and patient little girl and by my side from the beginning.

To my newborn son, Dev, for giving me the motivation to push through and complete this project.

Abstract

Background: Diabetes distress is common worldwide with a prevalence of nearly 40% in patients with Diabetes Mellitus. Many previous studies have shown that factors such as younger age, high body mass index, poor diet, and poor health care provider support may contribute to diabetes distress. The aim of this study was to identify the factors contributing to diabetes distress amongst patients with diabetes, attending peri-urban public primary health care facilities in South Africa.

Methods: A cross-sectional study using a self-administered questionnaire. Data was collected over a four month period from May to August 2018 from the two chosen facilities. Data were analysed using STATA, Release 15.0. Descriptive statistics was used to get frequencies and percentages. Chi-square tests and logistic regression was used to test associations between variables.

Results: Out of the 671 participants included in this study: some 36.8% of the participants were found to be distressed; with moderate distress (24.29%); and severe distress (12.52%). Amongst the distressed participants, emotional distress was the highest (74.8%) and physician related distress was the lowest (21.05%). There was a statistically significant association between employment (p=0.012), mode of treatment (p=0.016), frequency of glucose checks (p=0.000) and level of distress. On multivariate regression analysis, those who were unemployed (OR = 1.56; 95% CI 1.05; 5.20) or retired (OR = 2.84; 95% CI 1.56; 5.20) and on both injections and oral medications (OR = 1.74; 95% CI 1.13; 2.69) were found to be more distressed.

Conclusion: High levels of distress were detected amongst the diabetic population attending primary health care facilities in the peri-urban setting. Therefore, there is a need to create awareness amongst health care providers, improve screening and early detection of diabetes distress to improve overall patient outcomes**.**

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Nomenclature

BMI	Body Mass Index
CHC	Community Health Centre
DAWN 2	Diabetes attitudes, wishes, and needs: second study
DD	Diabetes Distress
DDS	Diabetes Distress Scale
DM	Diabetes Mellitus
HbA1c	Glycosylated Haemoglobin
KZN	KwaZulu Natal
PAID	Problem Areas in Diabetes
PHC	Primary Health Care
SD	Standard Deviation
SEMDSA	Society for Endocrinology, Metabolism and Diabetes of South Africa
SSDR	Southern sub-district region
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

1.1 Background

Diabetes Mellitus (DM) is a chronic disease that is characterised by abnormally elevated blood glucose levels. Moreover, DM is becoming a major global public health concern. According to the latest 2016 data from the World Health Organization (WHO), there were 422 million adults living with DM worldwide. It has also been reported that the most rapid increase in prevalence is amongst the middle- and low-income countries worldwide.[1] Prevalence studies done previously, rarely differentiate between type 1 and type 2 diabetes, however majority of the diabetes cases are reported to be type 2 DM.[1] According to the WHO, the number of patients living with type 2 DM will significantly increase over the next 20 years.[1] The International Diabetes Federation (IDF) stated that currently 425 million people between the ages of 20 and 79 years were living with DM and this number is projected to increase to 629 million by the year 2045.[2] A majority of people affected by diabetes were between the ages of 40 and 59 years. In the United States of America (USA) alone, some 30.3 million people were living with diabetes according to a report by the National Diabetes Statistics in 2015.[3] South East Asia had also documented a high number of 82 million diagnosed with DM in 2017.[2]

Diabetes was previously rare amongst people on the African continent, however statistics in 2013 reported that 4.9% of the population between the ages of 20–79 years were living with diabetes.[4] It is estimated that there will be an increase of 110% in the prevalence of type 2 diabetes in Africa by 2035, making it a total of 41.5 million according to the International Diabetes Federation of sub-Saharan Africa.[5] According to statistics, in 2013, a majority of patients with diabetes were from urban or high income settings on the African continent compared to the USA, where the prevalence was higher amongst the low- and middle-income classes.[3,5] Amongst the top ten countries with the highest prevalence of diabetes, Nigeria was reported as having the highest prevalence in Africa, followed by South Africa, Ethiopia, Tanzania and the Democratic Republic of the Congo.[5]

The IDF reported recently that 7% of the South African population was living with diabetes. In comparison with the statistics of 4.5% during 2010, there has been an almost 100% increase, certainly a cause for concern, considering the impact it has had not only on the

quality of life of the population but also on the financial burden. Cost per person per annum was approximately R26 743,69 in 2015.[2] With an increase in the prevalence every decade, the amount of expenditure towards managing diabetes will put a huge economic strain on the health system, which is already struggling to cope with other equally significant health problems. This attracts or focuses our attention on how much still needs to be done in order to prevent diabetes and limit its risk factors. It is equally important to ensure that those who are currently living with DM are well-controlled and limit complications, lead productive lives and contribute to the growth of their nations.

Achieving diabetes control is the main goal in the treatment of diabetic patients. Diabetes control or blood sugar control is assessed by means of glycosylated haemoglobin (HbA1c) levels in the blood. According to the latest 2017 guidelines of the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA), the target of HbA1C% is <7% for both type 1 and type 2 diabetic patients.[6] In healthy, newly diagnosed diabetics, one should aim for a HbA1C% < 6.5%; in the very ill and elderly patient with multiple comorbidities, levels between 7.1-8.5% are still acceptable.[6] The commonly known factors affecting diabetes control are, high body mass index(BMI), poor lifestyle, non-adherence, poor health care systems, depression and diabetes distress.[6]

Diabetes distress (DD) is defined as a psychological response to the diagnosis of diabetes.[7] DD involves a combination of emotions, coping mechanisms and illness outcomes in diabetes. There are multiple definitions and explanations for DD. As noted, when patients are diagnosed with diabetes and doubt whether they will have enough coping methods and support systems to successfully manage this condition. During 2012, Polonsky defined DD as the patients' perception of support, fears and concerns regarding the management, accessibility to health care services and the emotional burden associated with living with diabetes.[7] According to Rubin and Peyrot, diabetic distress is caused by concerns regarding living a life as a diabetic, which can lead to a reduced motivation, poor self-monitoring and care, uncontrolled glucose levels, risk of earlier complications and a poor quality of life.[8,9,10]

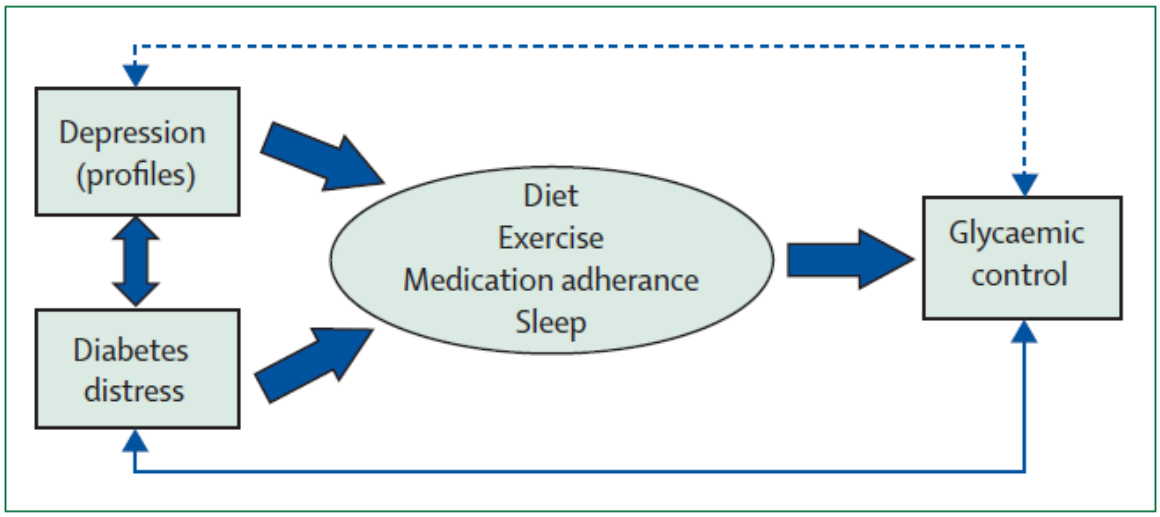
When compared to the general population, people living with diabetes have a higher risk of developing depression and distress, and both have been linked to worsening outcomes.[11] While depression is a commonly used term for patients presenting with mood symptoms, it is important to acknowledge the difference between depression and distress and the approach to managing the conditions respectively. For years it was believed that clinical depression was the main psychological factor affecting glycaemic control and patient motivation in terms of self-care and

management.[11] However, recent studies have now identified that a majority of patients do not fit the criteria of clinical depression but their emotional symptoms are reflective of DD.[12] Screening for depression amongst diabetic patients is often well done during chronic consultations, and most patients with any form of emotional stressors relating to the disease are often labelled as depression.[13] Studies have shown that although depression is common amongst diabetic patients compared with non-diabetics, management of depression has minimal effect on control of their blood sugar levels and improving outcomes.[13]

Depression is not the only psychiatric condition that affects diabetic patients. Other conditions such as adjustment disorders, anxiety disorders have also been reported amongst diabetic patients with symptoms overlapping with DD.[14] In a cross-sectional survey done in KwaZulu Natal, South Africa, type 2 diabetic patients in both private and public facilities were studied and the results showed that 31% of type 2 diabetics reported poor well-being, some 46% had mild to severe depressive features and 32% had anxiety symptoms related to the diagnosis and management of DM.[15] Depression affects 10–20% of adults with DM and is twice as common in type I and type II diabetes, compared to the general population. In a large study conducted by Fischer *et al*, some 70% of patients identified as having depression were not found to be clinically depressed according to the Centre of Epidemiological studies depression scale.[16]

The diagram in Figure 1.1 illustrates the direct and indirect effects of DD and depression on diabetes self-care and glycaemic control.[17] The solid line and the perforated line show respectively that there is a stronger association between glycaemic control and DD compared to depression. Depression and DD both influence diet, exercise, medication adherence and sleep of the patient which in turn negatively impacts on the glycaemic control. Elmira *et al* reported that patients with diabetes had a 60% greater chance of suffering from psychological distress as compared to a population of non-diabetics.[18]

Diabetes distress is a common response to the long term demands of diabetes and should not be approached in the same way as depression. In a German study, Reimer reported that reducing the levels of DD had a role in improving depressive symptoms in diabetics.[19] Diabetic distress has often been overlooked and a majority of healthcare professionals and patients are unaware of DD and its impact on glucose control. Frequently, diabetic distress has been confused or misdiagnosed as depression.



Source: Constructs of depression and distress in diabetes. *Lancet* 2015

Figure 1.1
Factors affecting Glycaemic control

A research study reported that depression is overly diagnosed in patients with diabetes whereas DD is often overlooked and missed during consultations.[20]A study done in Vancouver showed that of all type 2 diabetic patients attending a tertiary hospital, only 15% were actually depressed and it was alarming to see that 52.5% suffered from some level of DD as per the Diabetes Distress Scale (DDS). [21] Even though the symptoms overlap, the approach to management of both conditions is different and correct identification is needed for appropriate therapy. Another study conducted in India showed that 56.8% of patients had depression and only 2.4 % scored high on the distress scale.[22] In most cases there is an overlap of symptoms which makes it difficult to differentiate between them.[23]

Another study done by Zacharin and Allen shows that after diabetes education, the levels of diabetes related distress markedly reduced and glycaemic control improved but the depressive symptoms remained unchanged.[24] In diabetes patients, depression is correlated with diabetes-specific emotional distress, and observational studies have suggested that DD may have a greater impact on diabetes outcomes than depression itself. Another interesting finding reported by Beverley *et al*, was that 84% of patients with distress did not fit the diagnostic criteria for depression, however 67% of patients with depression did have DD.[25] A study by Chauhan & Pai, reported that treating patients suffering from diabetes distress with anti-depressants does help in improving the distress symptoms and that the important aspect is identifying the presence of either depression or distress.[26]

In primary healthcare screening for depression is undoubtedly an important aspect of chronic health care; notwithstanding, clinicians need to also focus on the possibility of DD being more common amongst patients living with diabetes. However, a majority of clinicians who encounter and treat diabetic patients are unaware of DD and the effect it has on the control of blood sugar levels.[27] Therefore, this means that the patient's emotional stressors and needs are not being managed appropriately and hence resulting in poor outcome, in this case poor glycaemic control. Diabetes distress is often not recognised and diagnosed as depression resulting in inadequate treatment as seen in previous South African studies.[26]

1.2 Rationale for the study

During primary care rotations, the researcher usually worked in the chronic section within the facility and was exposed mainly to cases of hypertension and diabetes and it was brought to the researcher's attention that diabetes control was poor amongst a majority of diabetics attending the clinic for routine visits. Despite chronic diabetics being on high doses of treatment and being given numerous health education and lifestyle counselling sessions, there seemed to be something lacking in their holistic care.

According to literature, diabetes related distress plays an important role in improving glycaemic control, hence health care providers need to ensure that patients with DD are identified at an early stage and necessary interventions are implemented. A multidisciplinary approach and patient involvement is needed to address the factors causing the distress, rather than simply providing patients with information that does not solve the problem.[27] There were not many studies done on diabetic distress in the African setting, including South Africa. The previous study was conducted mainly in private facilities and only one public primary care facility was included. Hence this study conducted in a primary care peri-urban setting will add to the current knowledge base of DD among diabetic patients in the country.

1.3 Study aim

The aim of this study was to assess DD and the related factors amongst the diabetic patients attending public primary health care facilities in the Ekurhuleni Health District.

1.4 Study objectives

The study objectives were:

- To determine the participant characteristics of type 2 diabetic patients;
- To determine the proportion of DD amongst the type 2 diabetic patients;
- To assess the level and nature of DD amongst the type 2 diabetic patients; and
- To explore the association between sociodemographic and clinical factors with the level of DD.

CHAPTER 2

LITERATURE REVIEW

2.1 Prevalence and level of diabetes distress

Diabetes distress is common and has a worldwide prevalence varying from up to 40% in patients with DM.[28] There are different levels of DD and their progression varies according to the levels of care and the settings where the patients are attended, whether peri-urban or rural. Studies have shown that DD increases over time if no intervention is implemented and can significantly affect the disease outcome.[29] According to Fischer *et al*,[13] some 18% – 35% of patients with DM experience DD. A recent Chinese study conducted at a tertiary health facility found that 58% had no DD, some 23% had moderate distress and 19% had high levels of DD.[30] A more recent study done in a rural setting in Saudi Arabia showed that 25% of diabetic patients had DD, which is low compared with other studies done in peri-urban and urban settings.[31] There is no documented evidence as to whether these findings are applicable to primary care settings, as a majority of the studies were done at different levels of care including tertiary and specialised diabetic clinics. A Canadian study explored the change in distress symptoms over a course of four years and found that most patients with moderate to severe diabetes related distress remained at same level of distress whereas 8% were noted as having increased distress levels.[32]

Research is lacking within the primary care setting with regard to the effect of treatment modality on the risk of developing DD, especially amongst diabetics who are on diet and exercise regimen only. As primary care physicians it is important to consider repeated screening for diabetics, at least annually.[33] There are multiple factors affecting diabetic distress including social, cultural, physician related, regimen related and interpersonal factors.

2.2 Nature of diabetic distress

Diabetes distress comprises of four categories of distress: emotional distress, physician related distress, interpersonal distress, and regimen related distress.[7] Emotional distress is mainly caused by a patient's emotional burden as well as the emotional impact such as feelings of guilt or concerns about complications and feeling demotivated, whereas physician related distress mainly

relates to the patient's dissatisfaction with the care provided by the treating physician, including the physician's attitude and lack of concern shown. Regimen related distress arises from the mode of treatment and its demands of being compliant, including lifestyle modification. Interpersonal distress is influenced by the need for family support, and encouragement to maintain such lifestyle changes.[7] Literature shows that emotional distress is commonest amongst the four categories.[7,29,30,32]

The largest and most extensive study into the psychological aspect of diabetes was done across 17 countries in 2013, the DAWN 2 study (Diabetes attitudes, wishes, and needs: Second study) .[34] The DAWN 2 study was an innovative study of the effect of diabetes on the family members of the patient across different countries. The results varied due to the cross-cultural differences in the countries. This is supported by the Genevieve study where it was found that the patient's social and cultural environment had a great influence on distress levels for women but had no effect on men.[35] Even though scales and tests to measure DD have been developed, a simple friendly enquiry into the social aspect of the patient's life will assist in identifying the possibility of emotional distress. An Indonesian study found that patients seen in primary health care facilities were more distressed compared with those seen at tertiary facilities which definitely shows the effect of the quality of care given to patients. [36] Simple questions, such as how they are coping with and feeling about their illness, can help to identify DD.

Empowerment based self-management programmes also play a significant role in improving psychological distress in patients identified as having diabetes related distress.[37]A Malay study reported that an emotionally focused educational programme improved their patients distress levels.[38] This programme included merely listening to patients' emotional experiences and supporting them through their journey with DM. A study done at a tertiary setting also reported that their patients scored very high in the emotional distress section compared with all other areas of distress.[39] Most clinicians are highly involved in the medical management of the condition, but as family physicians in primary healthcare, it is our responsibility to explore the psychosocial context of the patient and identify gaps that may be resulting in the poor glycaemic control.[40,41]As noted a majority of the studies showed high levels of distress amongst patients living with diabetes, however most of the studies were done at secondary and tertiary level with very few done at primary care level. A German study done at the primary care level showed that only 1.2% of outpatients attending primary health care facilities suffered from DD.[42]

2.3 Tools used to measure the level of diabetes distress

Two tools have been developed to assess DD, namely: the problem areas in diabetes (PAID) questionnaire; and the DD scale (DDS) .[43] The former, previously used extensively, has been shown to have a fair validity and reliability. The PAID consists of 20 questions which define patients' reactions and negative feelings to the burden of the disease and its treatment.[44] It is scored on a Likert scale of 0-4 with a score >40 indicating severe DD.

The DDS was developed more recently by Polansky in 2005 and addressed the limitations of the PAID scale [2]. For research purposes and clinical practice, the DDS scale is recommended as it has good reliability and validity, and the language is easily understood.[45]

Another modified version of DDS is the T1-DDS which has been developed for type 1 diabetes. The T1-DDS is a self-reported scale that focuses on challenges specific to patients with type 1 diabetes. These include helplessness, concerns about management, fear of hypoglycaemia, social beliefs, food related distress, healthcare related distress and family support.[46] Fischer and Polonsky have also developed a condensed version of DDS2: a two-question screening tool that can be used routinely to screen diabetics at risk of distress; and if they score positive for both questions, the DDS 17 may be administered.

2.4 Factors contributing to diabetes distress

Studies have shown that there are many patient related factors as well as social factors that may contribute to DD.[47] Significant factors that contributed to a high level of DD were younger age, high body mass index, poor health care provider support, and poor diet. An interesting finding was reported by the MILES- 2 study conducted in Australia, which stated that a low self-esteem and self-compassion/self-pity was a risk factor for developing DD.[48] Low self-esteem and self-pity may have an impact on self-care and adherence to treatment which in turn puts diabetics at risk of distress.[49] The Schwartz study showed that the doctor patient relationship has a big influence on patients' adherence to medication in addition to social support.[49] Other factors include level of care, role of health workers in explaining the illness to the patient. A South African cohort study showed that patients attending private facilities had less DD compared with patients attending public health facilities.[15] Patients attending private health sector are better

informed about their condition and hence have a higher self-efficacy in terms of managing their own illness, as opposed to patients attending the public health sector.[15] This emphasizes the need for public health practitioners to ensure that their patients understand their illness and are actively involved in the management plan. According Craven *et al*, even health care workers caring for diabetic patients play a role in the development of DD amongst their diabetic patients.[50] This included health care burn-out, frustrations with patient non-adherence, inadequate working environment etc. Fisher and Polonsky also emphasised the need to see DD as part of diabetes and not as a separate condition on its own and incorporate comprehensive management for the diabetic patient.[47]

2.4.1 Age

The patient's age plays a big role in the development of DD. A majority of the studies have shown varying levels of distress amongst the the different age groups depending on the cultural background as well as healthcare setting. Studies done amongst type 2 diabetic patients in Canada, South Africa, China, Iran and Malaysia show a greater increase in distress levels amongst the younger population compared to the individuals aged above 55 years.[15,29,32,51] Younger diabetic people may have other stressors and additional responsibilities at work, a family and social life as well as a financial burden. Besides, having to self-manage and cope with a demanding condition such as diabetes, it also puts patients in a very emotionally unstable point. These studies also reported that the type of distress was significantly different amongst the different age groups, with the younger population having mostly regimen related distress and the older population experiencing mostly emotional and interpersonal distress.[31]

Studies conducted amongst the diabetic population reports that the older population is at higher risk of distress due to other contributing factors such as longer duration of diabetes and presence of comorbidities. [52,53,54,55] Hence this shows that all the contributing factors are interlinked in causing distress. However, more research still needs to be done in the primary health care setting, to identify the effect of age on DD levels.

2.4.2 Gender

The female gender has also been found to be at higher risk of developing DD.[7,17,21,56] This may be due partly to the fact that a significantly higher number of females were attending health facilities as compared to males. Women tend to be more supportive of each other and more active in their health seeking behaviour, however they lack support when it comes to self-management.

An Indian study reported similar findings and stated that women tend to suffer more than men from DD due to their home and child care responsibilities, resulting in self-neglect and poor self-care.[57] Moreover, the South African study reported a higher level of distress amongst females.[15] Also, of note was that females were younger compared to the male population. However, some recent studies show no significant age difference between males and females.[27,54,58] The Saudi Arabian study also noted that the female population suffered from more severe distress and mainly had emotional and interpersonal distress.[31,59] However, this could be due to the gender inequality experienced in the Middle East, with fewer women seeking health care. The study done by Faridah *et al* in Indonesia showed a significant difference in levels of distress with 65% of women and 35% in men.[60] A Japanese study conducted amongst men showed that high levels of distress was directly linked to higher risk of causing mortality in men living with diabetes.[61] However, such studies are lacking in the female population.

2.4.3 Marital Status

Partners and spouses play a pivotal role in supporting and caring for patients with diabetes. The partner's perception of illness and beliefs regarding the course of the illness, the control, chronicity and role of lifestyle changes influences the level of emotional and interpersonal distress and patient experiences.[62] It has also been reported that couple counselling with regard to treatment plans and lifestyle changes may assist in relieving a lot of psychological distress for patients living with DD.[63] Another study looked at the type of relationship that women had and the impact on glycaemic control. This study reported that there was an indirect link between poor relationships and DD resulting in poor glycaemic control.[64] Even the number of children a woman has, was reported to have an impact on her distress levels, according to Chittem.[65] An interesting finding from a study done by Berry *et al* show that the partners of diabetic patients with distress also suffer from some form of distress, mostly emotional distress.[62]

2.4.4 Employment

Employment has been associated with DD.[66] However, the relation was not consistent in the different studies. Employment has been associated with lower levels of distress according to the studies done in China and Canada.[21,30] A cohort study done among South African teachers with type 2 DM found prevalent rates of psychological distress were high and this was attributed to high levels of work related stress, low income and poor support structures.[67] An Indonesian study looked at the level of emotional distress and quality of life. This study reported that people with

higher levels of education and employment had a better quality of life and hence a lower rate of emotional distress compared with their unemployed and lower level of education counterparts.[60] Moreover, unemployment places social stress on diabetics resulting in non-adherence and poor self-care which in turn may increase the risk of distress.[68]

2.4.5 Body mass index

Another association noted is high BMI, which is also higher amongst women. [21,66] A higher BMI was directly related to DD according to studies done by Jana and Fei Sun. [64] A high BMI was associated with female gender, old age, less social support, unhealthy eating habits and sedentary lifestyle. Overweightness in itself is an emotional distress, hence assisting patients to lose weight successfully may play a role in decreasing the distress level.[69] A Japanese cohort study found that higher levels of physical activity was associated with lower levels of diabetes related distress in patients with type 2 DM.[61] Australian studies also attribute high BMI and poor dietary patterns with higher levels of DD.[56] A study done amongst Chinese diabetic patients showed a marked improvement in distress symptoms once they took control of their eating habits, weight, physical activity and sleep routine. [70] They concluded that all these contributed to better well-being hence improving self-care and alleviating distress symptoms.

2.4.6 Mode of treatment

In some patient groups, the mode of treatment appeared to play a role in the development of DD with high levels amongst insulin users and lower levels amongst those on oral treatment.[66,71] However, in a study done by Delahanty *et al* the focus was mainly on a specialist endocrinology clinic with patients mostly on insulin therapy and with multiple complications.[72] The Delahanty study compared levels of distress amongst diet and exercise group, oral medication group and insulin group and found that distress levels were lowest amongst the diet and exercise group and highest amongst insulin users.[72] Japanese studies have shown that patients on insulin often have higher levels of HbA1c levels indicative of poor control that indirectly has an effect on the level of distress.[73] This shows that there is a link between the mode of treatment, glycaemic control and the level of distress. However, the link can also be reversed as reported in a study done by Hessler; that high levels of distress may affect patient adherence to treatment especially patients on insulin, leading to missed doses or miscalculations.[74]

2.4.7 Comorbidities

An Iranian study showed a significant increase in level of distress in patients with one or more comorbidities such as hypertension or cardiovascular disease.[51] Another study done South India mentions the association of comorbidities and complications with DD amongst the older patients attending a tertiary health care facility.[54] Other studies included comorbidities associated with depression and DD, and found that there was higher risk of depression and distress amongst patients with comorbidities.[21,58,75] The presence of complications has also been reported to have an effect on psychological distress in patients as noted in a Japanese study.[76] In a Canadian study, the presence of peripheral neuropathy as compared to all other complications was noted to have the most impact on the level of distress and mainly emotional distress.[77]

2.4.8 Duration of Diabetes Mellitus

Few studies were available regarding the duration of diabetes and its association with DD. A Dutch discourse study showed that a higher level of DD was associated with a longer diabetes duration.[78] This was noted to be mainly due to the presence of complications with longer duration of diabetes. A Mauritian study found a direct link between DD and the duration of diabetes.[79] The researchers noted that patients with diabetes for longer than nine years were at a higher risk of developing DD compared with diabetics of less than five years since diagnosis.[79] The presence of complications also directly increases the levels of distress. According to Peyrot *et al* in the DAWN study, the longer the duration of diabetes, the higher the chances of diabetics having complications and more intense treatment regimens, therefore contributing to development of higher levels of diabetic distress.[80]

A Malaysian study conducted amongst type 2 diabetics found that patients with diabetes duration of less than five years had significantly higher levels of distress followed by those with more than ten years duration.[29] On the contrary, the South African study done by Ramkisson *et al* showed no relation between DD and duration of diabetes amongst the South African population attending private and public health care facilities.[15] However, a Sudanese study showed that the duration of diabetes had no effect on DD.[81] They only found association between poor glycaemic control and emotional distress. Vesco *et al* reported that longer duration and continuous glucose monitoring were associated with lower levels of DD.[82]

2.4.9 Glycaemic control

In the aforementioned study done by Ramkisson *et al* in KwaZulu Natal, South Africa, the relation between DD and the HbA1c levels has also been pointed out. [15] Moreover, this supports the Fisher *et al* study whereby it is noted that higher levels of DD was associated with increased HbA1c levels. [46] The effect may be in either direction. Patients with high DD may have a negative effect on self-management and adherence to treatment with poor outcomes with regard to glycaemic control. However, in other cases patients with poor glycaemic control may develop DD as a result of poor self-management and control.[83] The BENCH study, reported an interesting finding that the DD levels were lower in patients who regularly self-monitored their blood sugars and recognised poor control compared with patients who are occasionally given their HbA1c results.[58] A study done amongst African- American women showed that decreasing their levels of emotional distress had a significant impact on their HbA1c levels over one year post-intervention.[84]This effect was partly due to improved self-care and better adherence.[84]The emotional burden associated with the diagnosis of diabetes not only affects the patient, but also the family and society.[85] Another study done in Japan shows there was a direct link between the mode of treatment, glycaemic control and emotional distress.[73]

Diabetes distress is an indirect cause of poor glycaemic control, as noted from literature, and improving these factors contributing to the distress has a great influence in improving glycaemic control and preventing complications. It is also reported that amongst all the factors contributing to DD, glycaemic control(HbA1c) was the main identifiable factor as per studies done in Australia amongst type 1 and type 2 diabetes patients.[86] However a study done by Indelicato showed no direct link between HbA1c levels and distress. [87] However, they did state that there was a link between poor self-care and DD. Studies from Beijing, China showed that only poor self-care had a direct effect on glycaemic control while distress may have an indirect effect on glycaemic control.[88]

A study looking at the association between depressive symptoms, distress and glycaemic control amongst newly diagnosed type 2 diabetic patients, reported that there was no effect of distress symptoms on glycaemic control after two years.[89] However depressive symptoms did have an effect on the development of macrovascular complications, attributed to the altered inflammatory mechanisms. An American study found that there was a direct relationship between HbA1c and distress/ depressive symptoms.[90] A study done in southern India, looked at the level of DD and

adherence to medication. This study reported that 45% of patients with DD had low adherence to treatment which in turn affected their glycaemic control.[91] However, it is unknown whether: the low adherence resulted in the distress; or the distress was a contributing factor towards low adherence and self-care.[92] According to the findings of an Indonesian study, the researchers concluded that emotional distress and regimen related distress had the most effect on glycaemic control compared with all other domains.[93]

2.5 Summary of literature review

A literature review has shown that the prevalence of DD is quite high amongst the diabetic population, with emotional distress as the most common. It also describes that factors such as age, gender, employment status and clinical factors such as duration of diabetes, mode of treatment, comorbidity, BMI and HbA1c play a role in the development of DD. Studies have reported a significant role of DD in achieving glycaemic control both directly and indirectly.

CHAPTER 3

METHODOLOGY

3.1 Research design

A descriptive cross-sectional study design was used.

3.2 Materials and methods

3.2.1 Site of study

The study was conducted at the Jabulane Dumane Clinic and Phola Park Clinic. Both are community health centres situated in the Ekurhuleni Health District, south of Johannesburg. The Jabulane Dumane Clinic is located in Vosloorus between Extensions 2, 14 and 28. It is one of the clinics in the Ekurhuleni south subdistrict region (SSDR) serving Vosloorus. It was founded in 1994 and caters for approximately 80,000 people living in the vicinity of Vosloorus with a monthly headcount of approximately 12,000 patients, a large percentage thereof being chronic patients. The Phola Park Clinic is situated in Thokoza serving the community east of Ekurhuleni within the SSDR. The two clinics provide primary health care services and are equipped with about four doctors (one family physician, one registrar and three medical officers), fifteen PHC trained nurses working full time, twenty professional nurses, ten enrolled nurses and two auxiliary nurses at each clinic. There is a rehabilitation team which includes a physiotherapist, a podiatrist, an occupational therapist and other members including a dietician, a psychologist and a social worker and who visits the facility twice a week.

Chronic care forms a major part of daily clinic visits in the primary health care facilities in Ekurhuleni. According to the data capturer's statistics, the clinics sees around 2 800 000 patients per year, with 104600 being chronic patients. Hypertension and DM are the two most common chronic conditions, followed by other conditions like asthma, osteoarthritis and epilepsy. Chronic patients are followed-up on a basis of monthly to 3–6 monthly depending on their blood pressure and glucose control. Well-controlled patients coming for follow-up are consulted by the PHC nurses and given appropriate treatment and follow-up appointments are scheduled. Acute cases

and any complicated chronic cases are referred to the doctor for consultation. Chronic patients coming for review of their blood results and for their annual check-up are also seen by the doctor in the clinic.

3.2.2 Study Population

The study population consisted of all patients: with a diagnosis of type 2 DM for at least a year; above twenty-five years of age; and attending the Phola Park and Jabulane Dumane Clinic for regular follow-up visits. The cut-off age of twenty-five was used according SEMDSA guidelines, as type 2 diabetes is becoming more prevalent amongst the younger population.[11]

3.2.3 Study Sample

The total number of type 2 diabetics seen monthly at the Jabulane Dumane Clinic and the Phola Park Clinic is about 3200 and 4300 respectively, according to the statistics register. The minimum sample size from the total number of patients who met the inclusion criteria was calculated to get the statistical value. This was done by using the online sample size calculator, survey software from RAO SOFT, and with a confidence level of 95%, degree of variability of 40% and margin of error of 5%. A 40% degree of variability was used as research has shown that 40% of all diabetic patients experience some form of distress.[13] A study sample of about 331 from the Jabulane Dumane Clinic and 340 participants from the Phola Park Clinic was needed for this study. Hence a total sample size of 671 participants was recruited for this study.

Inclusion criteria

Patients included were as follows:

- Patients with a diagnosis of type 2 DM for at least one year; and
- All patients above the age of 25 years diagnosed with type 2 DM.
- Patients with target organ damage or associated clinical conditions such as chronic kidney disease were included

Exclusion criteria

Patients excluded were as follows:

- Patients with type 1 DM;
- Patients with gestational DM;
- Newly diagnosed DM;
- Patients with mental illnesses or cognitive impairment;

- Patients who presented with acute complications such as Diabetic ketoacidosis, heart failure; and cerebrovascular accident.
- Patients who were critically ill.

3.2.4 Data collection tool

A comprehensive questionnaire was used for data collection. The questionnaire consisted of three sections. The first section included the demographic details such as age, gender, marital status, level of education, employment, socio-economic status and presence of comorbidities. This section also included information on the availability of glucometers and how glucose checks were done by the patient, mode of treatment and number of years the diabetic had been living with diabetes were included. The second section also included anthropometric measurements such as height and weight and the HbA1c levels done within the last six months. To measure the height and weight, a calibrated scale with a height rod in centre meters (cm) was used. The researcher ensured that the scale was calibrated every day before measuring participants. The third section included the DDS, which was developed by Polansky *et al* in 2005.[45] This scale consists of 17 items and measures four domains - emotional burden, physician related distress, regimen related distress and interpersonal distress. Patients were scored on a Likert scale of one to six, with one being no problem and six being a serious problem. The total score was then calculated for each section and divided by the number of questions in that section. The total score was divided by 17. A total average score of < 2.0 indicates minimal or no distress, 2.0–2.9 indicates moderate distress and ≥ 3.0 indicates severe distress. The reliability for the DDS done by Polansky *et al* was 0.93 per the Cronbach's alpha reliability test. A previous study conducted in South Africa used the DDS scale in public and private setting which reported the reliability with a Cronbach's alpha score of 0.93 for the total DDS and each subset included(Emotional burden = 0.86; Physician distress = 0.87; Regimen distress = 0.86; Interpersonal distress = 0.80) , hence no further modifications were made to the DDS prior to use in this study.[15]

3.2.5 Data collection

Data was collected over a four month period from May to August 2018 from the two chosen facilities. Diabetic patients who had completed their scheduled follow-up visits with the doctor or the sister were approached by the researcher. Chronic care patients were first seen by the sister, once they had obtained their files. The sister did the vitals for the patient, including blood pressure, random glucose, height and weight measurements. Thereafter the patients were

consulted by the doctor or the primary health care (PHC) sister. Once their consultation had been completed, they were approached and invited to voluntarily participate in this study. A patient information sheet was provided, and the study explained to the patients. If they volunteered to participate in the study and met the inclusion criteria, then a consent form was given to them and they were requested to sign it. Then the researcher accompanied them to a room where these questionnaires were completed by the participants. The anthropometric measurements were taken by the researcher. This was done by using a calibrated scale with a height rod. Participants were asked to remove any heavy clothing and shoes and to step on the scale for measurements. The weight was measured to the nearest 0.1kg and height to the nearest 0.5cm. These measurements were then recorded onto the questionnaire and the researcher calculated the BMI according to the formula Weight (Kgs)/Height(m^2).

The HbA1c levels done within the last six months were obtained from the medical record and documented onto the respective patient's questionnaire. In cases where there was no HbA1c done within the previous six months, the researcher made sure that the bloods were taken and follow-up care was arranged for that patient. Thereafter, the patient was given the questionnaire to complete. The research assistant assisted with interpreting the questionnaire for the participant who had insufficient knowledge and fluency to speak the English language. Once the questionnaire was completed, the patient was scored according to the DDS and a total calculated to determine the level of distress. If a patient was found to be distressed, necessary actions were taken to assist the patient to overcome the distress, including counselling sessions and referral to the social worker within the facility to assist with appropriate further management. The completed questionnaires were stored safely at the researcher's property and an electronic version on the researcher's external hard disk where only the researcher had access to ensure confidentiality.

3.2.6 Data analysis

Data were entered into a Microsoft Excel spread sheet and then imported into STATA version 14 of statistic software. The initial step of the analysis was descriptive analysis. The categorical sociodemographic characteristics such as gender, marital status and mode of treatment were reported as frequencies, percentages and appropriate charts. The continuous sociodemographic variables such as age, HbA1C and BMI were reported as mean +- SD on median (Interquartile

range). The continuous variables were checked for normality by means of skewness kurtosis, Shapiro Wilk test, Histogram (normal distribution), mean against median

To determine the proportion of participants in each type of DD, the number of participants in each section was divided by the number of total participants.
The level of distress was categorized into not distressed, moderate distress and severe distress with a cut-off value of ≥ 2 for moderate distress and ≥ 3 for severe distress. To determine the association between categorical variables such as gender, marital status, employment and distress status (no distress, moderate and severe distress), a Pearson's chi square test was used. If any cell was less than five, the Fischer's exact test was used.
Where significant associations were noted, further analysis was done by means of logistic regression. For the logistic regression, the moderate and severe distress levels were combined to represent distressed and not distressed.

Univariate logistic regression was conducted with distress status as the outcome with exposure/explanatory variables that have a p value of < 0.2 in stepwise forward regression analysis.
The final multivariate model used to predict distress status was then obtained and the odds ratio of the predictors reported and explained. The level of statistical significance was set at confidence interval of 95% and p value of < 0.05. Two tailed tests of the hypothesis were assumed.

3.3 Ethical considerations

Approval to conduct this study was obtained from Human Research Ethics Committee (HREC) of the University of the Witwatersrand (M171065). To carry out the research, written permission was also obtained from the Ekurhuleni District Research Committee (GP_201709_026) to carry out this study in Ekurhuleni health district.(Appendix VII**)** Permission was also obtained from the facility manager at Jabulane Dumane Clinic and Phola Park clinic to conduct the study in the facility. During data collection, if a patient was found to have any level of distress, there was prompt interventions put in place to relieve the distress. Such measures included counselling, referral to social worker, psychologist and community support groups.

Information sheets were provided to participants and their consent obtained. Participants were assured of confidentiality and no negative consequences if they decide not to take part in this study.

CHAPTER 4

RESULTS

This chapter deals with the study findings of this research report. The sociodemographic characteristics of the participants include details such as age, gender, marital status, employment, and clinical factors (number of years living with diabetes, treatment, availability of glucose machine, frequency of glucose checks and presence of comorbidities). The HbA1c and BMI results are also included in this section. Thereafter the association between the demographic and clinical factors and DD have been described. There was a 100% response rate, and none were excluded.

4.1 Sociodemographic and clinical factors of participants

Table 4.1: Sociodemographic and clinical factors of participants

Age group	**Number (n=671)**	**Percentage (%)**
< 30yrs	9	1.34
30-39yrs	65	9.69
40-49yrs	94	14.01
50-59yrs	191	28.46
>60yrs	312	46.5
Gender		
Male	270	40.30
Female	401	59.70
Marital status		
Single	123	18.33
In a relationship	125	18.63
Married	423	63.04

Employment	**Number(n=671)**	**Percentage (%)**
Employed	182	27.12
Unemployed	331	49.33
Retired	158	23.55
No of years living with diabetes		
1-5yrs	264	39.34
6-10yrs	212	31.59
>10yrs	195	29.06
Mode of treatment		
Oral	474	70.64
Injections	29	4.32
Both	168	25.04
Availability of glucose machine		
Yes	123	18.18
No	548	81.72
Frequency of glucose check		
Daily	25	3.73
Weekly	51	7.60
Twice-monthly	22	3.28
Monthly	286	42.62
Never	287	42.77
Comorbidities		
Hypertension	452	67.36
Heart Disease	24	3.58
Asthma	26	3.87
Arthritis	59	8.79
Other	41	6.11

Body Mass Index	**Number (n=671)**	**Percentage (%)**
Normal	127	19
Overweight	216	32.34
Obese	323	48.14
HbA1c		
<6.5	124	18.48
6.5-6.9	42	6.26
7.0-7.9	101	15.05
8-10	171	25.48
>10	233	34.72

Table 4.1 shows that the mean age of participants was 57.11 with a standard deviation (SD) of 12.20. The oldest and youngest participants were 94 and 26 years old respectively. Some 74.96% of participants were in the categories aged 50 and above (28.46%) and above 60 years (46.50%). The participants in this study included 59.70% females and 40.30% males. Some 18.33% of the participants were single, some 18.63% in a relationship and 63.04% were married. Some 49.33% of the participants were unemployed with only 27.12 % being employed and 23.55% retired. 39.34% of the participants had been living with diabetes for five years or less and 29.06% of them for more than ten years.

As depicted in Table 4.1, some 70.64 % of participants were only on oral treatment for their diabetes whilst 25.04% were on both oral and injectable agents. Only 4.32% of patients were on injections alone. Only 18.18 % of participants had a home glucose monitoring machine. 42.77 % of participants reported to having never had their blood sugar levels checked and only 3.73 % checked their blood sugar levels daily. 76.30% of participants had one or more comorbidities: some 67.36%, the highest percentage had hypertension as comorbidity; with arthritis being the second highest percentage at 8.79%. Amongst the participants, 19% had a normal BMI, some 32.34% were overweight and 48.14% of the participants were classified as obese. Table 4.1 indicates that 24% of participants had good control of HbA1c, and 62% had HbA1C of 8 and above.

4.2 Proportion of diabetes distress

Table 4.2 Total number of particpicants with distress

	Number (n=671)	**Percentage%**
Total distress	247	36.81
Not distressed	427	63.63

As noted in the Table 4.2, some 36.81% of all participants were found to be suffering from some level of distress.

4.3 Levels and nature of diabetes distress

Table 4.3 Frequency of participants with different levels of distress

Level of distress	**Number (n=671)**	**Percentage(%)**
No distress (<2)	424	63.19
Moderate distress (≥2)	163	24.29
Severe distress(≥3)	84	12.52

Table 4.3 shows that 24.29% of participants were suffering from moderate distress and 12.52% from severe distress.

Table 4.4 Frequency of the nature of distress amongst participants with different levels of distress

		Level of distress		
Nature of distress	Meanscore (≥2= Moderate) (≥3=Severe)	Moderate n=(163) (%)	Severe n=(84) (%)	Total n(247) (%)
Emotional distress	2.29	96 (58.8)	76 (90)	185 (74.8)
Physician related distress	1.63	9 (5.5)	41 (48.8)	52 (21.05)
Regimen related distress	1.97	18 (11.04)	71 (84.52)	90 (36.43)
Interpersonal distress	1.70	70 (42.9)	74 (88.09)	149 (60.32)

As shown in Table 4.4, among those with DD, 78.4% had emotional distress, followed by interpersonal distress at 60.32%. Among the different types of distress, physician related distress was the lowest amongst participants at 21.05%.

4.4 Association between sociodemographic variables, clinical factors and diabetic distress

Table 4. 5 Association between sociodemographic variables, clinical factors and diabetic distress

Age (years)	**No Distress (<2)**	**Moderate (≥2)**	**Severe Distress (≥3)**	**Total**	**p value/chi^2**
	(n)= 424 (%)	(n)=163 (%)	(n)= 84 (%)	(n)= 671 (%)	p=0.249 chi^2= 10.23
<30yrs	3 (0.45)	5 (0.75)	1 (0.15)	9 (1.34)	
30-39yrs	44 (6.56)	12 (1.79)	9 (1.34)	65 (9.69)	
40-49yrs	53 (7.9)	25 (3.73)	16 (2.28)	94 (14.01)	
50-59yrs	128 (19.08)	41 (6.11)	22 (3.28)	191 (28.46)	
>60yrs	196 (29.21)	80 (11.92)	36 (5.37)	312 (46.5)	
Gender					
Male	166 (24.74)	68(10.13)	36 (5.37)	270 (40.24)	p = 0.742 chi2-0.596
Female	258 (38.4)	14.16	48 (7.15)	401(59.76)	
Marital status					
Single	80 (11.92)	29 (4.32)	14 (2.09)	123 (18.33)	p= 0.099 chi^2= 7.805
In a relationship	66 (9.84)	41 (6.11)	18 (2.68)	125 (18.63)	
Married	278 (41.43)	93 (13.86)	52 (7.75)	423 (63.04)	

Employment	**No distress**	**Moderate Distress**	**Severe Distress**	**Total**	**p value/chi^2**
	n=424(%)	**n=163 (%)**	**n=84(%)**	**n=671(%)**	
Employed	132(19.67)	33(4.92)	17(2.53)	182(27.12)	p =0.012
Unemployed	207(30.85)	81(12.07)	43(6.41)	331(49.33)	chi^2= 12.950
Retired	85(12.67)	49(7.3)	24(3.58)	158(23.55)	
Duration of Diabetes					
1-5yrs	175(26.08)	52(7.75)	37(5.51)	264(39.34)	
6-10yrs	135(20.12)	53(7.9)	24(3.58)	212(31.59)	p = 0.157
>10yrs	114(16.99)	58(8.64)	23(3.43)	195(29.06)	chi^2= 6.617
Mode of Treatment					
Oral	310(46.2)	104(15.5)	60(8.94)	474(70.64)	
Injection	22(3.28)	3(0.45)	4(0.6)	29(4.32)	p =0.016
Both	92(13.71)	56(8.35)	20(2.98)	168(25.04)	chi^2=12.149
Availability of glucose machine					
Yes	67 (9.99)	39 (5.81)	16 (2.38)	122 (18.18)	
No	357 (53.2)	124 (18.48)	68 (10.13)	549 (81.82)	p = 0.072 chi^2= 5.272
Frequency of glucose level checks					
Daily	15(2.24)	4(0.6)	6(0.89)	25(3.73)	
Weekly	26(3.87)	17(2.53)	8(1.19)	51(7.6)	
Twice-monthly	15(2.24)	6(0.89)	1(0.15)	22(3.28)	p =0.000 chi^2=39.9694
Monthly	149(22.21)	99(14.75)	38(5.66)	286(42.62)	
Never	219(32.64)	37(5.51)	31(4.62)	287(42.77)	

Comorbidities	No Distress	Moderate Distress	Severe Distress	Total	p value/chi^2
	n=424(%)	n=163(%)	n=84 (%)	n=671(%)	
Yes	325 (48.44)	116 (17.29)	71 (10.58)	512 (76.3)	p = 0.062 chi^2=5.5475
No	99 (14.75)	47 (7.00)	13 (1.94)	159 (23.7)	
BMI					
Normal	81 (12.07)	37 (5.51)	13 (1.94)	131 (19.52)	p =0.289 chi^2=5.0767
Over-weight	141 (21.01)	54 (8.05)	22 (3.28)	217 (32.34)	
Obesity	202 (30.1)	72 (10.73)	49 (7.3)	323 (48.14)	
HbA1c Levels					p=0.331 chi^2= 9.1348
<6.5	83 (12.37)	26 (3.87)	15 (2.24)	124 (18.48)	
6.5-7.0	25 (3.73)	13 (1.94)	4 (0.6)	42 (6.26)	
7.0-8.0	72 (10.73)	22 (3.28)	7 (1.04)	101 (15.05)	
8.0-10.0	98 (14.61)	45 (6.71)	28 (4.17)	171 (25.48)	
>10	146 (21.76)	57 (8.49)	30 (4.47)	233 (34.72)	

Table 4.5 shows that there was statistically significant association between employment and level of distress (chi^2, p=0.012). Association between mode of treatment and level of distress was also statistically significant (chi^2, p =0.016). Diabetes distress and the frequency of checking glucose levels was found to be highly statistically significant (chi^2, p =0.000).

The results in Table 4.5 indicate that there was no association between participant's HbA1c levels and level of distress **(chi^2, p=0.331)**.

4.5 Logistic regression

Significant associations were found amongst some variables and distress level. These variables were then used to conduct a univariate logistic regression- analysis to identify the strength of the association between each variable and distress level. As per statistician's advice, variables with a p value of <0.2 were included in the further analysis with logistic regression. Variables that were found to be statistically significant were- employment, mode of treatment and frequency of

glucose level checks. Marital status, years living with diabetes, availability of glucose machine and presence of comorbidities were also included as they were found to have p values of <0.2. Multivariate logistic regression was performed to identify the strength of associations between the abovementioned variables and distress levels.

4.5.1 Univariate logistic regression

Table 4.6 Univariate logistic regression

Variable		Odds ratio	p value	95% Confidence interval
Marital status	Single	1	1	1
	In a relationship	1.66	*0.051	(0.99-2.77)
	Married	0.97	0.889	(0.63-1.47)
Employment	Employed	1	1	1
	Unemployed	1.58	*0.023	(1.06-2.34)
	Retired	2.26	*0.000	(1.44-3.56)
No of years living with diabetes	1-5yrs	1	1	1
	6-10yrs	1.12	0.553	(0.76-1.63)
	>10yrs	1.39	0.087	(0.95-2.04)
Mode of treatment	Oral	1	1	1
	Injections	0.60	0.253	(0.25-1.43)
	Both	1.56	*0.015	(1.09-2.23)

Variable		Odds ratio	p value	95% Confidence interval
Availability of glucose machine	Yes	1	1	1
	No	0.65	*0.037	(0.44-0.97)
Frequency of glucose level checks	Daily	1	1	1
	Weekly	1.44	0.459	(0.54-3.80)
	Twice-monthly	0.7	0.561	(0.21-2.32)
	Monthly	1.37	0.449	(0.599-3.17)
	Never	0.46	0.076	(0.20-1.08)
Presence of comorbidities	Yes	1	1	1
	No	1.05	0.78	(0.72-1.52)

In Table 4. 6 employment was noted to be statistically significant, the likelihood of being distressed was 2.26 and 1.58 more likely amongst retirees and the unemployed respectively compared with those who were employed. Participants in a relationship were 1.66 times more likely to be distressed compared with those who were single. The mode of treatment was also noted to be statistically significant, where participants on both oral and injectable treatment were 1.56 times more likely to be distressed compared with those only on oral treatment.

The availability of a glucose machine was noted to be associated with higher levels of distress compared with participants without access to glucose machines. Participants who monitored their glucose levels weekly or monthly were more distressed compared with those who checked their levels daily. Participants who never monitored their glucose levels were least likely to be distressed.

4.5.2 Multivariate logistic regression

The variables such as marital status, employment, mode of treatment, frequency of glucose level checks, found to be statistically significant in univariate analysis was subjected to multivariate logistic regression analysis predicting the factors associated with DD. The result showed that unemployment (p=0.04) or retirement (p=0.001) had statistically significant association with DD levels. The mode of treatment was also shown to be statistically significant. Participants on both

oral and injectable treatment were 1.7 times more distressed (p=0.012) than those on either injection or oral medications alone.

Table 4.7 Multivariate logistic regression

Variable		**Odds ratio**	**p value**	**95% Confidence interval**
Marital status	Single	1	1	1
	In a relationship	1.57	0.125	(0.88-2.82)
	Married	0.75	0.242	(0.47-1.20)
Employment	Employed	1	1	1
	Unemployed	1.56	**0.04	(1.05-2.41)
	Retired	2.84	**0.001	(1.56-5.20)
Mode of treatment	Oral	1	1	1
	Injection	0.71	0.475	(0.27-1.81)
	Both	1.74	**0.012	(1.13-2.69)
No of years living with diabetes	1-5yrs	1	1	1
	6-10yrs	1.06	0.76	(0.69-1.63)
	>10yrs	1.31	0.24	(082-2.09)
Availability of glucose machine	Yes	1	1	1
	No	1.23	0.580	(0.58-2.57)

Variable		Odds ratio	p value	95% Confidence interval
Frequency of glucose level checks	Daily	1	1	1
	Weekly	1.54	0.412	(0.54-4.34)
	Twice-monthly	0.70	0.598	(0.19-2.54)
	Monthly	1.27	0.649	(0.44-3.67)
	Never	0.40	0.111	(0.13-1.22)
Medical condition	Yes	1	1	1
	No	0.90	0.61	(0.59-1.35)

Table 4.7 depicts the variables such as marital status, availability of a glucose machine and frequency of glucose level checks as not showing any significant association with DD level as per multivariate logistic regression analysis. These results will be further discussed in Chapter 5.

CHAPTER 5

DISCUSSION

This study on DD and related factors is one of few studies conducted in South Africa and in an African setting respectively. There are not many studies that have researched DD in the peri-urban or in the rural South African settings. The previous studies were done mainly in the private and urban setting. This study was conducted at the Jabulane Dumane Clinic and the Phola Park Clinic which are the public CHC's in the Ekurhuleni Health District, situated south of Johannesburg. The participants had high unemployment rates, a large immigrant population and less job opportunities in this peri-urban area.[98] The study population consisted of all patients diagnosed with type 2 DM; having been diabetic for at least a year; aged above 25 years; and had been attending these clinics for regular follow-up visits.

In this chapter, the study findings are discussed in accordance with the study objectives, namely:

- To determine the participants' characteristics as type 2 diabetic patients;
- To determine the proportion of DD amongst type 2 diabetic patients;
- To assess the level and nature of DD amongst the type 2 diabetic patients; and
- To explore the association between sociodemographic and clinical factors with the level of DD.

5.1 Characteristics of study participants

In this study, the mean age of participants was 57.1 years; a majority of them falling in the above 50-year-old category. Generally, this is consistent with other previous studies conducted amongst patients with type 2 DM.[15,91,92] This may be attributed to the fact that majority of patients with type 2 DM are diagnosed at an older age.[13] However, literature does suggest that more younger people, from age 25, are being diagnosed with type 2 DM.[6]

Age has been a very controversial factor with regard to DD. A majority of the studies report that age does play a role in DD but whether an older or younger age is considered a higher risk is still debatable. Studies done globally show a greater increase in distress levels amongst the younger population compared with individuals aged above 55.[15,29,32,51]

In this study, more than 60% of participants were females which is consistent with studies done internationally.[7,17,21,56] This may be due to the health seeking behaviour of women. Women are generally known to religiously attend health care facilities for their medical needs as opposed to their male counterparts.[20] This also affects their perception of health and well-being. This is however the opposite according to studies done in the Middle East, where men were found to be more active in their health seeking behaviour, mostly due to gender inequality and the restrictions placed on women and their access to healthcare. Globally, studies have reported that the females are at higher risk than the males of developing DD.[7,17,21,56] This may be attributed to the poor support systems, being single parents and sole breadwinners of their families. The higher distress levels may also be due to the health seeking behaviour of females, with more females attending health care facilities compared with their male counterparts.[7,17,21,56]

A larger proportion of participants reported being married (63.04%). Marital status has been shown as a protective factor in development of DD, mostly due to more emotional and interpersonal support obtained from a married relationship.[61] The other participants in this study were either living alone, single or in a relationship which contributed together to less than half of the study population.

According to STATS SA, the overall unemployment rate is 29.1% in South Africa.[98] The employment status of the study participants was quite alarming with close to 50% being unemployed, some 23.5% retirees, and only 27% employed. This may be attributed to the peri-urban setting in which the study was conducted.[15,29,32,51] Moreover, this may be due to a majority of the participants being in the age groups of above 50 to more than 60 years of age. Diabetics' employment opportunities may also be affected by interference with their working hours in terms of the number of sick leave days taken due to their increased chance of getting other infections as well as days needed to attend the clinic for their regular check-ups. This may also be a reason why the unemployment rate is high among diabetic patients. A majority of the previous studies were conducted in developed countries such as Canada, Denmark and Malaysia; the percentages were also different compared to the previous South African study done among the different facilities in a peri-urban area, where 50% were employed, which reiterates the fact that employment rates are higher in these peri-urban communities.

Almost 39% of patients were living with diabetes for less than five years and 29% for more than ten years. These findings are consistent with the few other studies done in Europe and Canada

looking at the duration of diabetes.[78] A majority of the participants (70%) were on oral treatment alone with about a quarter of them on both oral treatment and injectables and only 4% were on injections alone. This shows that a majority of participants were being treated with oral agents only.

The availability of glucose machines was quite disappointing, as very few patients had access to glucose machines. Less than 20% of the population had access to a glucose monitoring machine. However, this could be attributed to the protocol in place at public facilities, whereby patients are only provided with glucose machines if they are on injectable regimens. Literature shows that the value of having a glucometer is still controversial as there is not enough evidence as to whether self-monitoring is effective in controlling diabetes.[97] Glucose level checks were done monthly for more than 40% of the participants. Mostly patients who did not have a glucose machine attended the clinic for check-up or routine visits to collect their medications on a monthly basis. Only 3% of the participants checked their glucose levels daily, despite close to 20% of the participants having access to glucose monitoring machines.[97] This may have been attributed to a shortage or being out of stock of strips and needles needed for use in the glucose monitoring machines.

There are common problems encountered within the public primary healthcare setting. There is overreliance by diabetic patients for the treatment of their conditions at the expense of the government at these facilities. The availability of glucose machines and the glucose strips at the facility remains a challenge as it is reserved for diabetics taking insulin injections in public service settings. At some level, patients should be educated about the importance of glucose machines in relation to controlling their stress levels and encouraged to buy glucometer of their own. Though evidence has proven that regular glucose checks still may not affect the level of glucose control but may help to reduce their stress levels in relation to the thoughts of control of sugar level.[97]

A majority of the participants reported having comorbidity: most of them were found to be hypertensive; a minority of the participants had other comorbidities such as asthma, arthritis and heart disease; and some patients had one or more comorbidities. Studies report the significant increase in DD amongst patients with one or more comorbidities, especially in patients with hypertension along with complications such as peripheral neuropathy and retinopathy.[51]

The BMI of the participants was unevenly distributed with close to 50% being obese and 32% being overweight. Only 19% had a normal BMI. This is similar to findings from other studies, whereby a majority of diabetic patients had been found to be either obese or overweight. This had a direct effect on DD as noted in studies done in Japan and China.[61,70]

Generally, the glycaemic control was found to be poor in this population. The HbA1c levels amongst participants in this study showed that more than 60% of the participants were poorly controlled with HbA1c levels above eight and 34% with levels greater than ten. This is similar to the South African study where the average HbA1c was around 12% with poor control mainly amongst participants attending public health care facilities compared with those attending private facilities.[26] In the African setting, less than 45% of diabetics on treatment are well controlled.[5] The other common factors contributing to poor glycaemic control are socio-economic status, sedentary lifestyles, dietary habits, food insecurity, adherence and knowledge of diabetes itself.[2,3,5]

5.2 Proportion of diabetes distress

Total level of distress as per the findings of this study was that 36.81% of the participants suffered from DD which is consistent with the worldwide prevalence of 40%.[15,18,26,28] There are minute differences in prevalence of DD amongst the different ethnicities and developed or developing countries as reported in the studies.[30,31] However a majority of the previous studies have been conducted in the urban, peri-urban settings and private health care facilities.[30,31] This shows that despite differences, prevalence remains comparable in all these settings. A similar study conducted in South Africa, mainly amongst the private sector, reported 44% DD amongst the type 2 diabetic population.[26] Other countries also report similar findings with percentages ranging between 40 and 50%.[15,18,31] The difference in the distress levels could be due to urban/non urban setting, knowledge of diabetes, support systems and food security.

5.3 Level and nature of diabetes distress amongst participants

From the participants who reported distress, some 25% were moderately distressed and 12% were severely distressed. These findings are similar to a Chinese study, whereby 23% had moderate distress and 19% had severe distress though this study was conducted in a tertiary facility. [30] As per studies done by Fischer *et al*, some 18%–35% of patients living with type 2 DM have been reported to suffer from some form of DD. [13]

Emotional distress in this study was 27.57% which was the highest amongst the four categories of DD. Previous studies done in countries such as Australia and Canada showed a similar trend with majority of diabetics suffering mostly from emotional distress.[21,56] Some studies also looked at the gender and age differences amongst emotional distress and found that females were at higher risk of emotional distress than any other form of diabetic distress.[21,56] This may be due to the lack of support that women get from their male partners as well as the other life responsibilities that women have including home and childcare, which results in poor self-care and self-neglect. In the South African peri urban setting, majority of women are single parents and the sole breadwinners of their families. Therefore, having a mentally demanding, chronic condition such as diabetes, may have a negative impact on a woman's emotional wellbeing, placing them at risk of emotional distress. Patient empowerment about how to improve self-management and self-care or emotion focussed educational programmes can help in improving the emotional distress in these patients as mentioned in the previous studies.[17,20,38, 39]

Physician related distress was found amongst 7.75% of the study participants. It was the lowest amongst the four categories of distress and this provided a sense of comfort and relief that patients are generally happy and confident with their treating doctors. Studies have shown that physician related distress was higher amongst the newly diagnosed diabetics and those who belong to the younger age group.[52]This may be due to more emphasis needed on educating and explaining diabetes and treatment options to newly diagnosed patients, and very often medical practitioners neither have the time nor make the effort to ensure that their patients understand their condition well. This creates a sense of dissatisfaction amongst patients. An Indonesian study compared DD amongst patients attending primary healthcare facilities and tertiary facilities. It was found that the distress levels were much lower amongst patients attending tertiary facilities compared with those attending primary healthcare facilities.[36]This was mainly attributed to the fact that at tertiary level facilities patients are often treated by a specialist physician and at

primary healthcare facilities mostly by general practitioners. There may be a difference in the quality of care provided. Specialist physicians may be more aware of DD and may have a more holistic approach to their patients. However, there may also be the placebo effect of being taken care of by a specialist versus a general practitioner. Patients perceive specialist physicians as more experienced and are more confident in their specialist knowledge. Therefore, the presence of at least one specialist physician in every primary care facility, in order to provide support and guidance to the general practitioners, especially regarding approach and creating awareness around such conditions, would play a big role in reducing distress levels. All of our patients in these facilities are consulted by general practitioners and specialist family physicians (FP) and this also may have contributed to the reason for the level of physician related distress being the lowest amongst the four categories. This clearly points out the role of doctors in managing this category of distress, by making sure that clear explanations are provided, and patients are well-educated and understand their condition. It also includes making sure that patients' concerns are taken into consideration and properly addressed. This is where the leadership and competence of specialist family physicians can play an important role in minimising physician related distress.

Regimen related distress was found amongst 13.41% of the participants in this study. Regimen related distress has been reported to be higher amongst patients with comorbidities and on injection therapy as per previous studies.[31] Regimen related distressed may also be influenced by the patient's adherence to medication as well as difficulties in maintaining adherence. Good support systems and having someone to regularly remind the diabetic to take medication may have a positive effect on regimen related distress. Patients on insulin may be at greater risk of distress due to the routine involved in storage and administering the insulin, which is much more tedious than just taking a tablet. Medical practitioners need to ensure that there is a special focus on younger patients especially, to ensure they understand their disease process, progression, complications, treatment regimens and any side effects addressed. A negotiated treatment plan should be implemented where the patients play an important role in managing their condition.

Interpersonal distress was found to be the second highest, after emotional distress, with 14.29% of participants reporting interpersonal distress in this study. This is mainly caused by old age, lack of family support and self-care.[31] This can be managed by encouraging the family to get involved in the care plan and provide on-going support earlier in the diagnosis.

5.4 Association between sociodemographic and clinical factors with level of diabetes distress

Age did not show any significant association with the level of DD as per this study's findings (p=0.249). However, it was noted that a majority of the participants who were distressed were above the age of 50 years. This may have been due to the age distribution of the participants, with 74% of the total participants being older than 50 years of age. Previous studies have shown that age plays a major role in developing distress. [15,29,32,51] There may be multiple factors that may result in the older population being at higher risk of distress, including, lower income, poor support from family and disabilities such as impaired vision and mobility. The elderly are also highly likely to have developed complications from poorly controlled diabetes , further resulting in higher levels of distress. All these factors may even contribute to difficulty accessing healthcare and hence feeling a lack of control over their own health. However studies from India and the Middle-East suggest a higher risk of DD in people above the age of 55 years, which is similar to the findings in this study.[31,54] A recent study reported that the different age groups were more prone to the different types of distress. Older people being at higher risk for emotional and interpersonal distress and the younger population at higher risk of regimen related and physician related distress though this was not analysed in this study.[31] In contrast, a few studies reported higher levels of distress amongst the younger population compared with those above 55 years of age.[15,29,32,51] This may be due to the fact that younger people have numerous other responsibilities, including education, employment, starting a family and financial instability.

In studies done globally, the female gender was found to be at a higher risk of developing DD compared to the male gender though it was not the case in this study.[7,17,21,56] In these studies, numerous factors were found to be contributing to the higher risk of distress amongst women. These included a higher number of women attending health care facilities, their responsibilities to home care and childcare which result in poor self-care and more distress.[32,62] The South African study also reported higher distress levels amongst females as compared with males and this was attributed to the fact that the female population was generally younger compared to the male population.[26] Literature shows physical inactivity as one of the main factors amongst females with moderate to severe DD, whereas it is associated with severe distress in males.[32,62]

Marital status did not show any association in the initial analysis (p=0.099). On further logistic regression analysis, participants who reported being in a relationship were having higher levels

of DD (OR = 1.57; 95% CI 0.88, 2.82) compared with those who were living single or married. A relationship may be associated with multiple other stressors and the pressure to keep up with partner's demands depending on the type of relationship.[67] Matrimony was found to have lower risk of developing distress compared to being single (OR = 0.75; 95% CI 0.47, 1.20) . This may be due to the consistent level of support amongst married couples as compared to couples in a relationship. Moreover, this is consistent with other studies where it is noted that spouses or partners play an important role in supporting and caring for people with diabetes.[62] In this study, more than half the participants reported married, with an equal number being either single or in a relationship. This may have had an influence in the total level of distress amongst the participants. An intervention that has been found successful is couples counselling with regard to treatment and lifestyle changes, which includes not only the patients, but also their partners. This intervention showed that there was a marked decrease in distress levels as their partners were better equipped and knowledgeable of the condition in order to provide better care and support to their partners.[63] In cases where there are female headed households and single parents, such as in this study setting, a supportive relative or friend may be encouraged to get involved in such interventions in order to provide on-going support and care.

There was a strong association seen between employment and DD in this study (p= 0.012), which on further analysis showed that being unemployed or retired was found to be at higher risk of distress compared to being employed (OR = 1.56; 95% CI 1.05, 2.41) and (OR = 2.84; 95% CI 1.56, 5.20) respectively. This may have been due to other stressors associated with being retired such as advanced age and poor support systems. In the study setting, financial security is a major contributor to stress as the pension received by the elderly may not be adequate to support themselves and the family. In most cases, a family of multiple members may be living off one elderly person's pension, resulting in poor financial status. Another common cause of distress is that most elderly and retired persons, being grandparents, are burdened with the task of taking care of their grandchildren, especially in cases where their own adult children are away at school, work or looking for work elsewhere. Studies done worldwide had inconsistent results with some studies showing a direct relation between employment and higher risk of distress, whilst others showed similar findings to this study.[67] A study done amongst South African teachers, in a similar setting showed high levels of distress due to additional work related stressors, low income and poor support structures.[67]

From all these abovementioned factors affecting DD there is need to focus on vulnerable groups of diabetic population like females, unemployed, not married or staying alone and to target interventions to this population for earlier identification and management. The strategies could be referral to social workers who can assist with employment opportunities. Another main targeted intervention would be referral to psychologists, services which are available in these settings. There is adequate evidence on psychological interventions such as individual or group or family community interventions that has shown effects to reduce DD with either emotion focused or cognitive focused interventions.[93] Emotion focused interventions mainly aim to address patients' self-management practices while cognition focused interventions involve education and acquisition of diabetes related skill training.[88]

In this study, the duration of diabetes did not show any association with level of distress as seen in previous studies. This finding is consistent with a South African study done by Ramkisson *et al* in both private and private settings that also showed no relationship between the duration of diabetes and distress.[15] However, this study's finding is different from the Dutch Discourse study which showed that there was a higher risk of distress with increasing duration of diabetes. The DAWN study conducted by Peyrot *et al* reported that the longer the duration of diabetes the higher the chances of diabetics having complications and more intense treatment regimens, therefore contributing to development of higher levels of diabetic distress.[80] This study's finding was different from the previous studies where they found a link between duration of years being diabetic and DD. It could also be that the study did not show a statistical significance due to the smaller numbers in some cells during statistical analysis.

The mode of treatment was found to be one of the factors associated with DD (p=0.016). On further analysis, the participants who were on both injectable and oral treatment had a higher level of distress (OR = 1.74; 95% CI 1.13, 2.69) compared with those who were on oral treatment alone. This is consistent with the findings of previous studies done in this field.[69,74] However very few studies have been done looking at the relationship between distress levels and mode of treatment. In this study it was found that patients who are on both injectable and oral treatment were at higher risk than those on only oral or injectable alone. Moreover, this finding is similar to the study conducted by Delahanty *et al*, where distress was high amongst patients on insulin and lower amongst those only on oral treatment.[72] Patients who are on both injectable and oral treatment may be more distressed due to stress related to change in regimen because they are not adequately controlled or have not met their treatment goals. Being on strict, intensive therapy

also requires being consistent with the treatment regime, which in this case requires meticulous attention to storage, measuring and administration of Insulin. Repeated daily injections may not be a pleasant experience for most patients, hence resulting in poor compliance and distress. Being on insulin also requires persistent planning ahead of daily activities and meals. This may interfere and restrict their day to day activities hence resulting in further risk of distress. It may also be linked to regimen related distress and physician related distress whereby the medical practitioner starts the patient on injectables with neither the patient's consent nor negotiating the management plan.

No studies have been conducted previously regarding the relationship between availability of glucose monitoring machines and levels of DD, though in this study availability of a glucose monitoring machine did not have significant associations with level of DD. On further analysis with logistic regression it was shown that that the participants who did not have glucose monitoring machines were noted to be 1.23 times more likely to be distressed compared with those who had a glucometer. (OR = 1.23; 95% CI 0.58, 2.57).

The other factor in this study which was found to be highly associated with DD was the frequency of glucose checks among these patients (p=0.000). On further analysis, participants who monitored their glucose levels weekly (OR = 1.54; 95% CI 0.54, 4.34) and monthly (OR = 1.27; 95% CI 0.44, 3.67) were more distressed than those who checked their levels daily. This may have been attributed to the fact that patients who monitored their glucose levels on a daily basis felt that they had more control over their condition and could observe the progress that they were making by being compliant to treatment and instituting lifestyle changes. They were unlikely to be overwhelmed or distressed by their glucose levels as compared with those who checked their levels monthly. This is one of the factors that can easily be modified, by enabling a system whereby every diabetic patient has access to a glucose monitoring machine, hence be empowered to take control and be in charge of their own health. However, an interesting finding was that participants who never monitored their glucose levels were least distressed. This may have been due to poor awareness of their condition and not knowing whether they were controlled. Checking glucose levels also causes stress for patients who repeatedly have elevated glucose levels despite being compliant with treatment. Hence participants who have no knowledge of their glucose levels are less likely to be worried about it.

Level of distress did not have any association with the presence of comorbidities (p=0.062). This is in contrast to studies done in India and Iran whereby a strong association between the presence of comorbidities and distress levels was found.[51,54] This was mainly attributed to the presence of multiple complications and large pill burden.

Level of distress and BMI were found to have no significant association, according to this study's findings. This finding is contrary to studies done in China and Japan, whereby a higher BMI was found to have a greater risk of developing DD compared to those with normal BMI.[61,70] Higher BMI was also associated with the female gender, old age, poor social support and unhealthy lifestyles, which are all factors that contribute to distress. Overweightness was found to be an emotional stressor.[69] In this study, close to 80% were noted to be either overweight or obese. In this study population, there is a constant struggle to reinforce healthy lifestyle habits. In most cases this may be due to lack of knowledge. But most times patients are referred to dieticians but are still unable to keep up or even follow the diet plan and advice given due to food insecurity and poor income. Most of the patients generally eat what is available at home, which is usually highly processed starchy food, and do not always have the opportunity to choose the healthier option. Being over weight or obese is seen as a norm amongst the population, especially women, with the African belief that associates being overweight with beauty. Hence most patients do not even see the need to control their weight, therefore not a cause for concern or distress amongst the patients. Intervention programmes that included, dietary assistance and physical activity guidance, as well as improved general well-being were all found to markedly improve the levels of distress according to a Chinese study.[70]

In this study, the findings were quite interesting as analysis showed no association between HbA1c levels and level of DD. Therefore, whether a participant's HbA1c levels were high or low had no effect on them developing distress. This may have been due to a majority of the participants lacking knowledge of their glycaemic control or HbA1c levels. Diabetic patients are often seen 6 monthly or annually for review of blood results, where the glycemic control is assessed by means of the HbA1c. In most cases, the health care practitioner makes adjustments to the treatment depending on the glycemic control, but often without informing the patient what their HbA1c is or what the target is. Hence whether they were controlled or uncontrolled may have had no influence on their distress. Patients often try to follow the lifestyle and dietary advice given by their medical practitioner and religiously take their treatment, however the outcome of the treatment and lifestyle changes is often not of any concern to the patients. This is

an important finding, as it highlights the need for medical practitioners to ensure that their patients know the treatment goals and outcomes, and what it means in terms of disease progression. This is supported by only one study done by Indelicato *et al*, which showed no direct link between HbA1c levels and distress symptoms.[87] However, they did point out a relationship between poor self-care and DD. This is very different from study findings done globally that report poor glycaemic control was directly related to higher levels of distress.[15,58]

Amongst all the clinical factors assessed in this study, the mode of treatment, whether taking oral and injection, was the only clinical factor identified to be associated with level of DD. Other factors like duration of diabetes, frequency of glucose monitoring, presence of other medical conditions, HbA1c, BMI were not found to be associated with level of DD. More studies need to be done to identify the relationship between availability of glucose machines and level of distress.

On initial analysis, employment, mode of treatment and frequency of glucose checks was noted to be statistically significant with frequency of glucose checks being highly statistically significant (p=0.000). On further analysis with univariate logistic regression, marital status, employment, mode of treatment and availability of a glucose machine was noted to be associated with DD. However, on further analysis with multivariate logistic regression, employment and mode of treatment was noted to be the most important predictors of DD, with these two factors being consistently associated with DD through each level of analysis.

5.5 Bias and Limitations

The sampling method used was convenience sampling, hence it may not be a true representation of the population and may have resulted in selection bias. It is especially important as a majority of the population was non-English speaking and the use of an interpreter may have altered the response of the participants, hence not giving a true reflection of the population. The questionnaire was self-administered and self-reported. It is well known that patients tend to report what is socially acceptable even though it is not the truth, especially with regard to behavioural and emotional aspects such as in this case. Patients were reassured that all information collected would be kept confidential and encouraged to be truthful as possible. The tool used (Diabetes Distress Scale) was not validated for South Africa, this may affect the

reliability of the results. Another limitation noted was that the study population selection was from only two clinics, the generalizability of the results to all the facilities may be limited. The study is cross-sectional and hence may have precluded a longitudinal relationship. A significant source of bias was also that no participant met the exclusion criteria hence 100% of the participants were included. A limitation noted in the analysis was that the variations of gender and age on nature of DD was unexplored in this study.

CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

The aim of this study was to identify DD and the related factors amongst the diabetic patients attending public primary health care facilities in the Ekurhuleni Health District.

The study findings showed that 36.81% of the participants attending the Phola Park Community Health Centre and the Jabulani Dumane Community Health Centre suffered from DD. Being unemployed or retired, and mode of treatment, being on both oral and injectables were found to be the most important predictors of DD. Age, gender and BMI and comorbidities were found to have no effect on distress levels.

The glycaemic control of the patients did not affect the DD in this study population. The findings of this study made the researcher aware of the need of screening every diabetic patient for diabetic distress especially if there are risk factors like female gender, unemployed, and using multiples modes of treatment. On reflection the researcher thought about possible areas where interventions can be implemented in order to reduce the levels of distress experienced by type 2 diabetic patients attending primary health care facilities. Interventions could be implemented at different levels within the healthcare system.

6.1 Facility level

6.1.1 Health care worker level

Interventions that may be implemented on this level include educating and creating awareness amongst health care workers regarding DD, as well as on approach to high risk patients especially the newly diagnosed, elderly and women by informing patients of treatment goals and negotiating a management plan. Executing routine screening and identifying patients at risk of DD. Implementing the use of the DDS-2, which is a two-item screening tool, with two questions (1) feeling overwhelmed by the demands of living with diabetes, and (2) feeling that I am often failing with my diabetes regimen. If the patient scores positive in these questions, then to administer the DDS-17 questionnaire to assess the severity of the DD. Once distress is identified in these patients, offer help and engage family to improve support systems. Involving the multidisciplinary team, including social worker and psychologist once patient is identified as having distress.

6.1.2 Patient level

Intervention may include educating patients on what DD encompasses and the different types and factors which affect them can help in early reporting of any type of distress. Getting partner and family members involved with diabetic in managing his/her diabetes and ensuring patients are adequately educated regarding adherence to their treatment plan and on the importance of lifestyle changes.

6.2 Community level

At community level, organising support groups for diabetic patients, whereby patients can come together and share their challenges and success with each other, and in turn support one another in managing their condition. Involving the ward-based outreach team in home-based screening and creating awareness of DD. The community health workers can be educated on the screening questions and the need of referring these patients to the nearby clinics for further assessments. Utilisation of technology and social media in providing platforms for creating awareness and support groups for diabetic patients.

6.3 District /Provincial/National level

Allocating at least one family physician per primary care facility to provide leadership and guidance to general practitioners. Ensuring adequate staffing at all primary care facilities in order to enable quality health care delivery;
Create a smart phone application that is approved by the Department of Health for patients to be part of support groups and have healthcare advice online, including recording their blood sugar levels, medication reminders and BMI. This will encourage patients to feel in control of their illness and hence may reduce the risk of developing DD.

The association between sociodemographic and clinical factors with the nature of DD was unexplored in this study. Other factors such as adherence, food insecurity and access to healthcare, that may have had an influence on the results, were not assessed in this study. This could be scope for future research.

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Appendices

APPENDIX I: PATIENT QUESTIONAIRE

DEMOGRAPHIC DETAILS AND DIABETES DISTRESS SCALE

Age in years					
Gender	Male		Female		
Marital Status	Single		In Relationship	Married	
Employment	Employed		Unemployed	Retired	
Number of years being diabetic	1-5		6-10	>10	
Type of treatment	Tablets		Injections	Both	
Do you have a glucose machine at home?	Yes		No		
If yes, how often do you check your sugar levels?	Daily	Weekly	Bimonthly	Monthly	Never
Do you have any other medical conditions?	Yes		No		
If yes	High BP	Heart Disease	Asthma	Arthritis	Other
BMI (Weight/Height(m^2)					
HbA1c result (%)					

THE DIABETES DISTRESS SCALE

	Not a problem	**A slight problem**	**A moderate problem**	**Somewhat serious problem**	**Serious problem**	**Very serious problem**
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	**1**	**2**	**3**	**4**	**5**	**6**
2. Feeling that my doctor does not know enough about diabetes and diabetes care	**1**	**2**	**3**	**4**	**5**	**6**
3. Feeling angry, scared, and/or depressed when I think about living with diabetes.	**1**	**2**	**3**	**4**	**5**	**6**
4. Feeling that my doctor does not give me clear enough guidelines on how to manage my diabetes.	**1**	**2**	**3**	**4**	**5**	**6**

5. Feeling that I am not testing my blood sugars frequently enough	**1**	**2**	**3**	**4**	**5**	**6**
6. Feeling that I am often failing with my diabetes routine.	**1**	**2**	**3**	**4**	**5**	**6**
7. Feeling that friends or family are not supportive enough of self-care efforts (e.g encouraging me to eat the "wrong" foods).	**1**	**2**	**3**	**4**	**5**	**6**
8. Feeling that diabetes controls my life.	**1**	**2**	**3**	**4**	**5**	**6**
9. Feeling that my doctor doesn't take my concerns seriously enough.	**1**	**2**	**3**	**4**	**5**	**6**
10. Not feeling confident in my day-to-day ability to	**1**	**2**	**3**	**4**	**5**	**6**

manage diabetes.						
11. Feeling that I will end up with serious long-term complications, no matter what I do.	**1**	**2**	**3**	**4**	**5**	**6**
12. Feeling that I am not sticking closely enough to a good meal plan.	**1**	**2**	**3**	**4**	**5**	**6**
13. Feeling that friends or family do not appreciate how difficult living with diabetes can be	**1**	**2**	**3**	**4**	**5**	**6**
14. Feeling overwhelmed by the demands of living with diabetes	**1**	**2**	**3**	**4**	**5**	**6**
15. Feeling that I do not have a doctor who I can see regularly enough about my diabetes.	**1**	**2**	**3**	**4**	**5**	**6**

16. Not feeling motivated to keep up my diabetes self-management.	**1**	**2**	**3**	**4**	**5**	**6**
17. Feeling that friends or family do not give me the emotional support that I would like.	**1**	**2**	**3**	**4**	**5**	**6**

DDS17 SCORING SHEET

INSTRUCTIONS FOR SCORING:

The DDS17 yields a total diabetes distress scale score plus 4 sub-scale scores, each addressing a different kind of distress. To score, simply sum the patient's responses to the appropriate items and divide by the number of items in that scale. The letter in the far right margin corresponds to that item's sub-scale as listed below. We consider a mean item score of 3 or higher (moderate distress) as a level of distress worthy of clinical attention.

Total DDS Score:	a. Sum of 17 item scores.	_____
	b. Divide by:	____17_____
	c. Mean item score:	_____ ≥ 3 ____
A. Emotional burden:	a. Sum of 5 items (1, 3, 8, 11, 14)	_____
	b.Divide by:	_____5_____
	c. Mean item score:	_____ ≥ 3 ____
B. Physician related distress:	a. Sum of 4 items (2, 4, 9, 15)	_____
	b. Divide by:	_____4_____
	c. Mean item score:	_____ ≥ 3
C. Regimen related distress:	a. Sum of 5 items (5, 6, 10, 12, 16)	_____
	b. Divide by:	_____5_____
	c. Mean item score:	_____ ≥ 3 ____
D. Interpersonal distress:	a. Sum of 3 items (7, 13, 17)	_____
	b. Divide by:	_____3_____
	c. Mean item score:	_____ ≥ 3 __

APPENDIX II: PARTICIPANTS'S INFORMATION SHEET

Good Day,

How are you?

I am Dr Sruthi Mohan, a second year registrar in the Department of Family Medicine at the University of the Witwatersrand, Johannesburg and allocated to Ekurhuleni Health District. I am conducting a research study on "Diabetes distress and related factors amongst type 2 diabetic patients attending primary health care facilities in Ekurhuleni health district, Gauteng".

I would like to invite you to participate in the abovementioned study. This study is aimed at identifying the levels of distress amongst type 2 diabetic patients and the factors contributing to it. The information will be obtained by voluntary completion of a questionnaire, which explores some emotional aspects of a patient living with diabetes. There are national guidelines available to guide health care workers when consulting patients with type 2 Diabetes Mellitus. However, the emotional stress that patients go through is not very well explored by the health care workers. This study aims to explore the emotional distress that patients with type 2 diabetes experience with regard to their patient-doctor relationship, their treatment and its effect on their social lives. This study will also assess the factors contributing to the distress. Participating in this study will require you to answer 17 questions on a questionnaire, and your height and weight will be measured and your latest blood sugar level will be recorded on your questionnaire.

Participation in this study is fully voluntary and you may withdraw from the study at any time and without any consequences or loss of benefits.

Confidentiality of your personal details will be strictly observed and protected. You will be required to complete a questionnaire but it will not include personal details such as your name or address. Your medical records will be reviewed to collect data that are relevant to the study and also does not include any personal information. This will be done with your consent and on voluntary basis. The findings and possible recommendations of the study will be reported to the staff members working at the Jabulane Dumane Clinic and authorities in the Ekurhuleni District to improve the quality of care given to diabetic patients and to improve their outcome

The participant may contact the researcher regarding queries or complaints relating to the study on 0834577493 or email: sruthimkumar@gmail.com.

The supervisor can be contacted on 011 0898500 or email: neetha.erumeda@wits.ac.za.

If a participant wishes to direct queries, complaints or concerns regarding the ethical activities surrounding the study please contact the HREC Chair/Administrator for participants as follows:

Prof P Cleaton Jones, Tel 011 717 2301, email peter.cleaton-jones1@wits.ac.za; or the administrative officers at 011 7172700/2656/1234/1252, Ms Z Ndlovu, zanele.ndlovu@wits.ac.za; Mr Rhulani Mkansi, Rhulani.mkansi@wits.ac.za; and Mr Lebo Moeng, Lebo.moeng@wits.ac.za

Thank you.

Yours sincerely

Dr S Mohan

APPENDIX III: CONSENT FORM

JABULANE DUMANE CLINIC / PHOLA PARK CLINIC

Dear Patient,

You are currently attending the Jabulane Dumane Clinic or the Phola Park Clinic for the treatment of diabetes. These facilities do not only render treatment but are also actively involved in conducting research aimed at improving the quality of care we deliver. From time to time, such research involves the use of questionnaires and patient records from which information is extracted. The use of such information is subject to:

1. Approval from the Committee for Research on Human Subjects, University of the Witwatersrand, Johannesburg;
2. Approval from the district research committee;
3. Anonymity i.e. the identity of the patient from whose file information is extracted or who completed the questionnaire is never revealed to anyone but the researcher unless specific consent is obtained to do so.

The researcher would like to obtain your consent to take part in this study and complete the questionnaire and use information from your file for the purpose of the study "Diabetes distress and related factors amongst type 2 diabetic patients attending primary health care facilities in Ekurhuleni health district, Gauteng", subject to the aforementioned conditions.

HREC protocol approval number**-----M171065-----**

I hereby confirm that I have been informed about the abovementioned project. I have understood the nature, the benefits and risk related to this project as explained to me by the study doctor and as stated in the above participant's information. I am aware that the result of this project, including personal details regarding my age, sex and other medical conditions will be dealt with anonymity in this project. If required, I agree that the data collected during this study can be processed in a computerized system by the study doctor.
All my concerns and questions being fully addressed by the study doctor; I offer my consent to participate in this study. If I choose not to give consent, this will not comprise my treatment in

any way. If at any time I choose to withdraw my consent, I am free to do so and will not be prejudiced in any way.

Should you wish to contact the researcher at any stage regarding this consent, contact Dr S Mohan on 0834577493

A. Consent Given

I_____ hereby give consent for my participation in the abovementioned study.

PATIENT: _____ DATE: _____

B. Consent Not Given

I _____ do not give consent for my participation in this study.

PATIENT: _____DATE: _____

APPENDIX IV: REQUEST FOR PERMISSION TO CONDUCT STUDY



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Dr Sruthi Mohan

Family Medicine Registrar

Ekurhuleni Health District

01/07/2017

The Facility Manager

Phola Park Clinic

Jabulane Dumane Clinic

Dear Sir/Madam,

Request for permission to conduct research project at the Phola Park Clinic/Jabulani Dumane Clinic

My name is Sruthi Mohan, a second-year Registrar in the Department of Family Medicine, University of the Witwatersrand, Johannesburg.

As part of the MMed studies, the Department of Family Medicine requires that I undertake a research project at a health facility.

The title of the project is "Diabetes distress and related factors amongst type 2 diabetic patients attending primary health care facilities in Ekurhuleni health district, Gauteng".

This study is aimed at identifying the levels of distress amongst type 2 diabetic patients and the factors contributing to it. The information will be obtained by voluntary completion of a

questionnaire, which explores some emotional aspect of a patient living with diabetes and some anthropometric measurements. There are national guidelines available that guide health care workers when consulting patients with type 2 Diabetes Mellitus. However, the emotional stress that patients go through is not very well explored by the health care workers. This study aims to explore the emotional distress that patients with type 2 diabetes experience with regards to their relationship with their doctor, their treatment and its effect on their social lives. This study will also assess the factors contributing to the distress. Confidentiality of personal details will be strictly observed and protected. The medical records will be reviewed to collect data that are relevant to the study and exclude any personal information such as name or address. This will be done with the patient's consent and on a voluntary basis. The findings and possible recommendations of the study will be reported to the staff members and management of the Jabulani Dumane Clinic and the authorities of the Ekurhuleni District to improve the quality of care given to type 2 Diabetes Mellitus patients in their routine follow- up visits.

I have applied for an Ethics Clearance Certificate from the University of Witwatersrand Health Research Ethics Committee and pending approval. I would like to request permission to conduct this quality improvement project at the Jabulani Dumane Clinic/Phola Park clinic once I have obtained approval from the WITS Health Research Ethics Committee.

I look forward to your positive response.

Date: 01/07/2017

Dr S Mohan

Family Medicine Registrar

University of the Witwatersrand, Johannesburg

APPENDIX V: NO OBJECTION LETTER FROM THE JABULANE DUMANE CLINIC

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

JABULANE DUMANE CLINIC
Enquiries:
Tel:

DR SRUTHI MOHAN
FAMILY MEDICINE REGISTRAR
EKURHULENI HEALTH DISTRICT

SUBJECT: NO OBJECTION LETTER FOR RESEARCH PROJECT

"Diabetes distress and relate factors amongst patients with Type II diabetes mellitus in Jabulane Dumane Clinic"

I have acknowledged your request to conduct the study named **"Diabetes distress and relate factors amongst patients with Type II diabetes mellitus in Jabulane Dumane Clinic"** done by Dr Sruthi Mohan as part of the requirement for the MMed Family medicine degree. I have no objection for conducting the study at Jabulane Dumane Clinic which is chosen as the site of study, provided it is approved by the WITS health research ethics committee and the Ekurhuleni research committee.

Kindly submit the results of this research outcome to the management office at Jabulane Dumane Clinic at the end of this study.

2017/06/29
Date

Facility Manager

APPENDIX VI: NO OBJECTION LETTER FROM PHOLA PARK CLINIC

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

PHOLA PARK CLINIC
Ekurhuleni Health District

DR SRUTHI MOHAN
FAMILY MEDICINE REGISTRAR
EKURHULENI HEALTH DISTRICT

SUBJECT: NO OBJECTION LETTER FOR RESEARCH PROJECT

"Diabetes distress and related factors amongst patients with Type II diabetes mellitus attending a primary care health facility in the Ekurhuleni Health District, Gauteng"

I have acknowledged your request to conduct the study named **"Diabetes distress and related factors amongst patients with Type II diabetes mellitus attending a primary care health facility in the Ekurhuleni Health District, Gauteng"** done by Dr Sruthi Mohan as part of the requirement for the MMed Family medicine degree. I have no objection for conducting the study at Phola Park Clinic which is chosen as the site of study, provided it is approved by the WITS health research ethics committee and the Ekurhuleni research committee.

Kindly submit the results of this research outcome to the management office at Phola Park Clinic at the end of this study.

17 August 2017
Date

Facility Manager

APPENDIX VII: EKURHULENI RESEARCH CLEARANCE CERTIFICATE

Ekurhuleni
METROPOLITAN MUNICIPALITY

GAUTENG PROVINCIAL GOVERNMENT

EKURHULENI RESEARCH CLEARANCE CERTIFICATE

Research Project Title: Diabetes Distress and related factors amongst Type 2 Diabetic patients attending Primary Health Care facilities in Ekurhuleni Health District, Gauteng.

NHRD No: GP_201709_026

Research Project Number: 23/10/2017-4

Name of Researcher(s): Dr Sruthi Mohan

Division/Institution/Company: University of Witwatersrand

DECISION TAKEN BY THE EKURHULENI HEALTH DISTRICT RESEARCH COMMITTEE (EHDRC)

- *THIS DOCUMENT CERTIFIES THAT THE ABOVE RESEARCH PROJECT HAS BEEN FULLY APPROVED BY THE EHDRC. THE RESEARCHER(S) MAY THEREFORE COMMENCE WITH THE INTENDED RESEARCH PROJECT.*
- *NOTE THAT THE RESEARCHER WILL BE EXPECTED TO PRESENT THE RESEARCH FINDINGS OF THE PROPOSED RESEARCH PROJECT AT THE ANNUAL EKURHULENI RESEARCH CONFERENCE.*
- *THE RESEARCH COMMITTEE WISHES THE RESEARCHER(S) THE BEST OF SUCCESS.*

Dr. T. SEPUYA

DEPUTY CHAIRPERSON: EKURHULENI METROPOLITAN MUNICIPALITY
Dated: 23/10/2017

Dr. R. Kellerman

CHAIRPERSON: GAUTENG DEPARTMENT OF HEALTH (EKURHULENI REGION)
Dated: 23/10/2017.

APPENDIX VII: WITS HUMAN RESEARCH ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE
WITWATERSRAND
JOHANNESBURG

R14/49 Dr Sruthi Mohan

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M171065

NAME: (Principal Investigator)	Dr Sruthi Mohan
DEPARTMENT:	Family Medicine Jabulani Dumane Community Health Centre Phola Park Community Health Centre
PROJECT TITLE:	Diabetes Distress and Related Factors amongst Type 2 Diabetic Patients Attending Primary Health Care Facilities in Ekurhuleni Health District, Gauteng
DATE CONSIDERED:	27/10/2017
DECISION:	
CONDITIONS:	
SUPERVISOR:	Dr Neetha J. Erumeda
APPROVED BY:	Prof C Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in October and will therefore be due in the month of October each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

03/02/2018
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES