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Perceived quality of life of patients with diabetes attending the out-patient department at Dr Yusuf Dadoo hospital, Gauteng province, South Africa

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PERCEIVED QUALITY OF LIFE OF PATIENTS WITH DIABETES ATTENDING THE OUT-PATIENT DEPARTMENT AT DR YUSUF DADOO HOSPITAL, GAUTENG PROVINCE, SOUTH AFRICA

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

Supervisor: Dr Elizabeth Reji

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DECLARATION

I, Ejiroghene Bishop Uwakata, declare that this research report is my own work. It is submitted for the degree of Master in Family Medicine in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

Student number: 798263

Signature of candidate:

this 25th day of October 2017 in Johannesburg, South Africa.

DEDICATION

In loving memory of my dear mother-in-law

Agnes Osa-Osagie

1954-2014

May God continue to rest you peacefully

ABSTRACT

BACKGROUND: According to a 2014 WHO report, 347 million people globally are diabetic. South Africa has the highest prevalence in Sub-Saharan Africa, which is expected to rise from the 2010 figure of 4.5% to 4.9% by 2030. The purpose of treatment is not solely symptom remission but a comprehensive approach to enhance the overall quality of life, despite the limitations connected with the disease. The aim of the study is to assess the quality of life (QOL) in diabetic patients attending the Out-Patient Department at Dr Yusuf Dadoo Hospital in Gauteng Province, South Africa, using the Short Form 36 version 2 (SF-36v2) tool.

METHODOLOGY: The study is a prospective descriptive cross-sectional study on 270 diabetic patients, undertaken over a three-month period (November 2016 to January 2017) in a district hospital in South Africa. The SF-36v2 tool was used to collect the data. Ethical approval was granted by University of the Witwatersrand.

RESULTS: A majority of the participants were black South African married females who had a primary school education, were employed, and had a monthly income of <R5,000. The mean age with standard deviation was 55.1±8.6. A majority (74%) of the participants had been diagnosed with diabetes ≥5 years previously. Although 62% and 63% of the participants reported a low score in the physical component summary (PCS) and mental health component summary (MCS) of QOL respectively, the mean scores in the PCS and MCS were 50.44±12.3 and 51.38±11.53 respectively. This was due to high scores in four out of eight items in the SF-36 tool, particularly the physical functioning (PF).

CONCLUSION: Health workers should consider the symptom stressors, functional status, emotional well-being/mental health and multiple chronic diseases of the patients during assessment. Allied health workers play a major role in the QOL of diabetic patients.

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ABBREVIATIONS

ADDQoL: Audit of Diabetes Dependent Quality of Life

BMI: Body Mass Index

BP: Body Pain

COPD: Chronic Obstructive Pulmonary Disease

DM: Diabetes mellitus

DYDH: Dr Yusuf Dadoo Hospital

EQ-5D: Euro-QoL 5-Dimensions

GH: General Health

HRQOL: Health Related Quality of Life

MCS: Mental Health Component Summary

MH: Mental Health

OPD: Out-Patient Department

PF: Physical Functioning

PCS: Physical Component Summary

QOL: Quality of Life

QOLID: Quality of Life Instrument for Indian Diabetic patients

RE: Role limitations due to emotional problems

RP: Role limitations due to physical problems

SF: Social Functioning

SF-20: Short Form 20

SF-36V2: Short Form 36 Version 2

UK: United Kingdom

US: United States

USA: United States of America

VT: Vitality

WHO: World Health Organization

WHO-QoL-Bref: World Health Organization Quality of Life-Brief

CHAPTER 1

INTRODUCTION

1.1 Background

Diabetes mellitus (DM) is a chronic disease characterized by absolute or relative insulin deficiency, hyperglycaemia and untoward multi-organ and multi-system complications.[1] It is a major non-communicable disease with high prevalence and increasing incidence globally. The global prevalence of diabetes among adults (aged 20–79 years) is expected to rise from 285 million (6.4%) in 2010 to 439 million (7.7%) by 2030,[2] with type 2 diabetes accounting for over 90% of all cases.[3] According to a report by the World Health Organization(WHO), 347 million people globally are diabetic.[4] South Africa has the highest prevalence in Sub-Sahara Africa, which is expected to rise from 4.5% in 2010 to 4.9% by 2030.[2]

Cause for concern is not just the increased prevalence of diabetes in South Africa and globally, but also patients' challenges to meet with the day-to-day management demands to approximate to the non-diabetic metabolic state, related complications and huge economic cost. When considering the impact on health, DM is one of the most prominent chronic diseases in the population.[5] Even when it is not deadly, it can cause permanent disabilities like kidney dysfunction (25% of patients on dialysis are diabetics), blindness in adults and non-traumatic amputation (50-70% involve diabetic patients)[6]. The risks of heart attacks and coronary heart disease are respectively three and two times greater in diabetics compared to non-diabetic individuals.[6] A World Health Organization report revealed that approximately 1.5 million deaths in 2012 resulted directly from diabetes, and that over 80% of the deaths were in developing countries.[4] The report anticipated that diabetes will be the seventh leading cause of death by 2030.[4]

Advances in management of diabetes have led to a longer lifespan for individuals

affected. The purpose of treatment is no longer solely symptom remission. Instead it entails a comprehensive approach to enhance the overall quality of life (QOL), despite the limitations connected with the disease.[1]

Diabetes plays a huge role in health-related quality of life (HRQOL) because it poses numerous lifestyle demands, incapacitating complications, and can occasionally be tough to live with.[7] Unfortunately, the impact of the disease on these patients' QOL is often ignored during consultation with health care workers. The focus rather is on glycaemic control, prevention and management of complications. The World Health Organization defines QOL as individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. Quality of life is a complex concept determined by the individuals' physical health, psychological state, level of independence, social relationships, personal beliefs and their relationships to salient features of their environment.[8]

1.2 Motivation for this research

The researcher worked in a district hospital, the Dr Yusuf Dadoo Hospital (DYDH), which is situated in the West Rand District Municipality of Gauteng, South Africa. The district has a population of 848,597 [9] and DYDH caters for two of the three sub-districts (Mogale City and Rand West City). This hospital provides comprehensive health care services, including its Out-Patient Department (OPD). The OPD sees between 100 and 150 diabetic patients monthly.

While the researcher was working in the OPD, he realized that despite adequate management of the patients with DM, their overall QOL was poor. This led him to carry out this study so that a holistic approach can be given to them. The focus of this study was to assess the QOL in diabetic patients using the SF-36v2 tool, and to see if there is any association between the sociodemographic characteristics and the two component summaries of the SF-36v2 tool. The outcome of this study is hoped to develop possible interventions to improve the quality of care in these patients.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

The quality of life of patients with diabetes is not a new concept in the literature.[3] However, there is a paucity of local information on HRQOL, which does not permit us to look into this health challenge effectively.[10] The issue in dispute is whether factors associated with diabetes QOL in the literature apply in South Africa. Quality of life is a personalized criterion, on the basis of a person's feelings regarding his or her status of health or other facets of his or her life, and therefore it could be efficiently surveyed only by determining the person's opinions and perceptions.[6] It represents the effect of an illness on a patient, as perceived by the patient,[5] and as such, patients predominantly rate their own QOL with regard to their health.

A large body of work has been done regarding the factors affecting the QOL among diabetic patients.[1] There is a need for awareness of these factors since QOL is sensitive to distress in numerous domains of living. If clinicians are to assist patients to live more satisfying lives, it is essential for them to have a comprehensive understanding of how satisfied those patients are regarding their lives.

2.2 How quality of life is measured

Measuring QOL changes usually involves seeking an individual's self-reported feelings, behaviour and attitude either through interviewing or appraising response to a questionnaire. Though reviews have revealed that there is an absence of homogeneity in evaluating QOL across studies, evaluating QOL in diabetes can be carried out by utilizing generic or diabetes-specific QOL measures.[1,5] Examples of the generic measuring tools are the SF-36 tool, EuroQoL (European Quality of Life) or EQ-5D (Euro-QoL 5-Dimensions); the QWB-SA (Quality of Well-Being Questionnaire), and the WHO-QoL-Bref (World

Health Organization Quality of Life-Brief), etc. Examples of diabetes-specific QOL assessment tools are DRQOL (Diabetic Diet-Related Quality of Life), ADDQoL (Audit of Diabetes Dependent Quality of Life) instrument, the DQLCTQ-R (Diabetes Quality of Life Clinical Trials Questionnaire Revised), and the DTSQ (Diabetic Treatment Satisfaction Questionnaire), etc.[11] Quality of life domains consist of at least mental health or emotional well-being (e.g. depressive symptoms, positive affect); functional status (e.g. whether a patient is able to manage a household, use the telephone, or dress independently); social engagement (e.g. involvement with others, engagement in activities); and symptom states (e.g. pain, shortness of breath, fatigue). These domains represent typical outcomes in medical and social science research.[11]

The Short Form 36 version 2 (SF-36v2) questionnaire was the instrument used for collecting and measuring data in this study (see Annexure 1). Compared to the standard SF-36 version 1, improvements have been made in the content and layout of SF-36v2. The wording is now clearer due to amendments in some instructions and questions.[12] The SF-36 questionnaire was of interest to this study for the following reasons:

- It has a high internal consistency reliability (on all scales of the questionnaire, Cronbach's alpha is 0.76-0.86).[13]
- It has a high construct validity.[12]
- It is sensitive to change.[13]
- It has been translated and adapted in 29 countries and in over 30 languages, including English and Afrikaans.[13]
- It has been found to be acceptable, valid and reliable for use among diabetic patients in studies in different countries.[14,15,16,17] In South Africa, the SF36 questionnaire has been used to assess QOL in patients with chronic diseases (such as rheumatoid arthritis[18] and HIV[19]), and surgical patients discharged from ICU.[20] Since no study has used the SF-36 questionnaire for diabetic patients in South Africa, the researcher thought that it would be a useful measuring tool.

2.3 Sociodemographic characteristics of patients with diabetes and their association with quality of life

2.3.1 Age

The mean age in studies done on QOL of patients with diabetes was found to differ widely across the globe. A cross-sectional study conducted among patients with type 2 diabetes attending the diabetic clinic in the biggest referral hospital in Nairobi, Kenya showed the mean age to be 56.37 years.[21] This was the only African study that was found to report mean age. The finding was higher than those of studies done in Iran[6] (52.3 years), Brazil[22] (52.7 years) and Catalonia[23] (47.38 years), but lower than those of studies conducted in the Netherlands[24] (64.9 years), the United Kingdom[25] (64.8 years), and the USA[26] (60.8 years). This may be a reflection that the lifespan of diabetic patients is lower in developing countries. There is a paucity of reports on age groups. In a cross-sectional study on the effect of type 2 diabetes on HRQOL among 281 black patients attending a diabetic out-patient clinic in a township (Mamelodi) in Pretoria, South Africa,[10] it was found that the commonest age group of the participants was 55-64 years, closely followed by ≥65 years. In contrast, a Ugandan study[3] reported the commonest age group to be below 50 years, followed by 50-59 years. However, this study also included patients with type 1 diabetes. Studies have shown age to be associated with QOL.[3,6,7,10,21,24,25] The Pretoria study,[10] which used the Short Form-20 (SF-20) tool, showed that older respondents had significantly poorer functioning and general health than their younger counterparts ($P = 0.01$). The Kenyan study,[21] which used the WHO-QoL-Bref tool, found that older patients had worse HRQOL ($P = 0.037$). Similar findings were found in studies in Iran,[6] the Netherlands,[24] and the UK[25]. Contrary to these findings, a cross-sectional study done among diabetic patients in a private clinic using the ADDQoL instrument in Alberton, Johannesburg, South Africa,[7] didn't find a significant association between age and QOL. The report was, however, based on a small sample size (68).

2.3.2 Gender

Gender distribution among studies done on the QOL in patients with DM varied quite a lot. Most studies in Africa reported more females than males.[3,10,21] In the Pretoria study[10] discussed above, 71% of the participants were female. This result was similar to the Ugandan study[3] and the Kenyan study[21] where 73% and 61% respectively were female. These findings conflicted with the Alberton study,[7] which reported less females than males (47%). Also, a study in Canada[27] showed that 47% of participants were females, as well as studies in the Netherlands[24] and Spain,[23] with half of the participants being female. Compared to their male counterparts, female diabetic patients have been reported across studies[5,7,10,24,25] to have a poor QOL

2.3.3 Country of birth

A Swedish study,[28] which looked at the association between foreign- and Swedish-born diabetic participants with QOL, found that the QOL was poor for both groups but was worse in the foreign-born subjects. This was a cross-sectional study that used the SWED-QUAL survey in three community health centres, where 62 foreign-born and 351 Swedish-born people participated. There is a paucity of studies on this aspect in Africa and other parts of the world. This Swedish study was the only one found that looked at country of birth.

2.3.4 Race

The private care diabetic clinic study in Alberton, Johannesburg[7] discussed above, was the only African study that showed race distribution. This study was conducted among residents in an urban community. The majority (75%) of participants were white, followed by black participants, who accounted for just 21%. The rest were Indian and some of mixed race. The black subjects perceived their QOL more negatively than their white counterparts (P = 0.03).

A cross-sectional study in United Kingdom[25] that investigated the association between ethnicity and HRQOL among patients with type 2 diabetes using the EQ-5D tool,

reported that 1,486 (75%) of the subjects, who were of south Asian origin, reported worse QOL when compared to 492 (25%) respondents of white European origin ($p = 0.01$). A study in the USA[29] compared HRQOL among older African Americans with chronic diseases (including DM) to the norms for the US general population, and found worse HRQOL among the older African Americans. The sample size in this study was quite small (83).

2.3.5 Level of education

Some African studies revealed that participants with primary levels of education made up a majority of the study samples (Uganda [3] [48%] and Kenya [21] [45%]). Similar findings were reported in the USA[29] (48%). Contrary to these, a private diabetic clinic study in Alberton, Johannesburg[7] done among residents in an urban community reported that 49% and 41% of the participants had a degree/diploma and matric respectively. A study in Catalonia[23] revealed that participants with high school levels of education (47%) made up most of the study sample. Diabetic subjects with secondary and tertiary levels of education were found to have significantly higher QOL in the Ugandan study[3] ($p < 0.05$). Lower educational levels were reported to be predictors of impaired HRQOL in a systematic review done in Europe[5]. However, the Alberton stud [7] revealed that QOL was not significantly related to level of education.

2.3.6 Marital status

Studies from across the globe showed that married participants made up a majority of the samples[7,10,21,23,25,26,27]. The Pretoria study,[10] showed that a majority (54%) of the patients were married, followed by those who were widowed (29%). The high proportion of elderly participants (36%) in this study probably explains the high percentage of widowed subjects. The Alberton study[7] also reported a majority of married participants (75%). Similarly, in the studies in Kenya.[21] Europe,[23,25] and America,[26,27] most of the subjects were married. The Pretoria study[10] showed that widows had significantly poorer QOL than married or single respondents ($p< 0.01$). Married and divorced subjects had significantly

worse QOL when compared to their single counterparts in the UK study ($p < 0.05$ and < 0.01 respectively).[25]

2.3.7 Employment status and income

There appeared to be conflicting results of employment status in developing countries. The Mamelodi, Pretoria study[10] (conducted among residents in a township) showed that 72% of the participants were unemployed. An Iranian study[6] done in a major city (Tabriz) reported 79.5% unemployed participants. Contrary to these, 60.1% of the participants were employed in a study done in a diabetic clinic in the biggest referral hospital in Nairobi, Kenya [21]. Very few studies (Kenya[21] and the USA[29]) were found that classified participants on the basis of income. The Pretoria study,[10] which used the SF-20 tool, revealed that employed respondents had significantly better physical and role functioning, mental and general health, than their unemployed counterparts ($p = 0.01$). Level of income was significantly related to the overall QOL ($p = 0.029$) in the Kenyan study,[21] which used the WHO-QoL-Bref tool.

2.3.8 Dependents

There was a paucity of studies on the aspect of dependents. The Iranian study,[6] which was a cross-sectional study, looked at factors affecting QOL in 117 type 2 diabetic outpatients at a diabetic education centre, using the SWED-QUAL and diabetes-specific QOL instruments. It found that many of the participants (50%) had three to five children, and there was a significant negative correlation between treatment satisfaction and number of children ($p < 0.05$).

2.3.9 Duration of diabetes

The Alberton study[7] reported the average duration of DM in the participants to be 7.43 years, while the United Kingdom study[25] reported that a majority of their subjects had been diabetic for between two to five years. Quality of life was shown to be related to duration of diabetes across studies in varying extents.[5,7,21,25,26] The Alberton study[7] (using the

ADDQoL questionnaire) did not find a significant correlation between duration of diabetes and QOL (P = 0.08). However, the Kenyan study[21] reported a significant association between QOL and duration of diabetes (P = 0.007) using the WHO-QoL Bref tool. A systematic review on QOL of patients with DM in primary health care in the Nordic countries[5] mentioned duration of DM as one of the predictors of impaired HRQOL. Similar findings were reported in United Kingdom[25] and USA.[24]

2.3.10 Comorbid diseases

In the Alberton study,[7] 39% and 48% of the participants had hypertension and hyperlipidaemia respectively. Although, these participants reported lower QOL when compared to those without hypertension and hyperlipidaemia, there was no statistical significant relationship. Of note, the sample size (68) was a limitation in this study. Also, the Ugandan study[3] (a cross-sectional study on 219 diabetic outpatients in a national referral hospital using the Quality of Life Instrument for Indian Diabetic patients [QOLID]) found that 26% of the respondents were hypertensive and there was no significant relationship of the comorbid disease with their QOL. The USA study[26] also found no significant relationship between QOL and dyslipidaemia. However, the Canadian study[27] reported a significant association between QOL and number of comorbid diseases.

2.4 Physical and mental health component summaries of the quality of life of patients with diabetes

Very few studies were found that solely analysed the physical component summary (PCS) and mental health component summary (MCS) of QOL. A cross-sectional study in the USA[29] compared low-income older African Americans with chronic diseases (of which DM was one) with the general population of ≥ 60years. It revealed the respective mean score with standard deviation for the two study groups in the physical component (M = 46.06, SD = 15.76 vs M = 61.79, SD = 6.99, P < 0.001) and mental health component (M = 58.52, SD = 13.72 vs M = 71.17, SD = 4.51, P < 0.001). It showed that low-income African Americans had significantly lower HRQOL in the PCS and MCS than the general population. This study used the SF-36 questionnaire, and hence the PCS included physical

functioning (PF), role limitations due to physical problems (RP), body pain (BP), and general health perception (GH), while the MCS included social functioning (SF), vitality (VT), role limitations due to emotional problems (RE) and mental health (MH). This study also reported that participants with DM had the lowest score among all the chronic diseases in the MCS, and the third lowest (after COPD and hypertension) in the PCS. The sample size for the low-income African Americans (83) and the focus on older patients were the limitations of this study. In another study done in Australia[30] that looked into the association between QOL and the prevalence of diabetes and depression, it was found that the PCS score was lower in DM patients when compared to those without DM or depression (PCS 43.0 vs 49.4), while the MCS score was (53.4 vs 50.8). It also showed that PCS and MCS scores among participants with DM and depression were significantly lower than those without DM or depression (PCS 34.0 vs 49.4, MCS 36.1 vs 50.8, $p = 0.05$).

2.5 Association between sociodemographic characteristics and physical and mental health component summaries of the quality of life

There was no study that looked into the association between sociodemographic characteristics and PCS/MCS, but there were some studies that looked into the association of demographic factors and QOL using different survey tools.[5,6,7,10,21,24,25,26]

2.6 Conclusion

Quality of life seems to be an important aspect in patients with DM, and it is associated with various demographic factors using different measuring instruments. They were few articles around the physical and mental health components of QOL around the world, and these articles did not relate the sociodemographic characteristics of the participants with their physical and mental health components of QOL. This study hopes to bridge that gap.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

This chapter poses the research question and describes the aim, objectives and various components of the study (the study design, setting, population, sample size and selection, procedures undertaken and data analysis).

3.2 Research question

What is the quality of life in diabetic patients attending the Out-Patient Department at Dr Yusuf Dadoo Hospital, using the SF-36v2 tool?

3.3 Aim and objectives

3.3.1 Aim

To assess the quality of life in diabetic patients attending the Out-Patient Department at Dr Yusuf Dadoo Hospital using the SF-36v2 tool.

3.3.2 Objectives

1. To describe the sociodemographic characteristics of participants in the study sample;
2. To assess the physical component summary (PCS) and mental health component summary (MCS) of quality of life (QOL) in diabetic patients attending the OPD at DYDH;
3. To correlate the sociodemographic characteristics of the participants with their PCS and MCS of QOL.

3.4 Study design

A prospective descriptive cross-sectional study was undertaken at the OPD of DYDH.

3.5 Study site

The study was conducted at the OPD of DYDH, a district hospital in West Rand, Gauteng. The OPD operates from Monday to Friday (08:00-16:00). Five doctors care for patients seen at the OPD. About 120 patients were seen daily. Of these patients, eight to twelve were patients with diabetes.

3.6 Study period

- After approval by the Human Research Ethics Committee of University of the Witwatersrand, the first part of the study period, the pilot study, commenced from 8th to 11th August 2016.
- The second part of the study period involved the data collection, which took place from 1st November 2016, to 31st January 2017.

3.7 Study population

All type 1 and type 2 diabetic patients who presented to the OPD at DYDH during the period of the research formed the study population.

3.8 Study sample

The study sample comprised of patients with diabetes who presented to the OPD during the study period and who met the inclusion criteria. Sample size was calculated using a Raosoft calculator; the confidence interval was 95% and the expected sample error was 5% with the power of 80%. The sample size for this study was 270 people. Convenience sampling was used to select the participants.

3.9 Inclusion criteria

- Patients with type 1 and type 2 diabetes, 18 years and older;
- Diagnosed with DM for at least one year; and
- Patients who were able to give consent.

3.10 Exclusion criteria

- Diabetes in pregnancy;
- Patients who were too sick/ill to participate;
- Pilot study participants; and
- Diabetic patients seen during weekends and after working hours (casualty ward).

3.11 Data collection

The researcher worked at the OPD of DYDH during the study period (from Monday to Friday between 08:00 and 16:00). Patients with diabetes were selected by the nurse when they arrived at the reception of the OPD for registration. The nurse greeted the patients and directed them to the researcher's consultation room. The researcher briefly introduced himself to the patients and explained the purpose of the study to them. He informed them that any information they provided would be treated with confidentiality. Each patient was given an information sheet (which explained the purpose of study and provided contact details of the researcher) and consent form.

Patients who refused to participate in the study and those who did not meet the inclusion criteria, were excluded from the initial interview. These patients were treated for their reasons of encounter by the researcher as per the 2012 Hospital Level Standard Treatment Guidelines and Essential Medicines List.[31] Patients who met the inclusion criteria and decided to participate in the study were requested to sign a consent form after consultation with the researcher. The researcher then proceeded to interview the patients and completed the questionnaires with them. Thereafter, the patients went back to the reception area where they were directed to the pharmacy. The researcher collected all the

questionnaires at the end of each day. The questionnaires were safely kept by the researcher. Each patient's file was colour coded and the data information was transferred to an MS Excel spreadsheet on the researcher's computer, which was password coded.

3.12 Measuring tool/instrument

An interviewer-administered questionnaire, written in English, was the primary tool for collecting the data. A validated SF-36 version 2 questionnaire[12] was modified for this study. The first part of this questionnaire was modified to suit the sociodemographic characteristics of the participants in this context (questions 1-17). These characteristics were age, gender, level of education, marital status, income, admission, time of diagnosis with DM, etc. The second part of the questionnaire was SF-36 version 2, which was used to collect data about the QOL of the participants (annexure 1: part 1, questions 1-11). Questions 3b and 3d-i of the second part of the questionnaire (annexure 1: part 2) were modified for this study. The words "pushing a vacuum cleaner, bowling, or playing golf" were removed and replaced by "sweeping". "Climbing 10 steps of stairs and walking 10 steps up a steep road" replaced "flights of stairs". "Mile" was changed to "kilometer" and "yard" to "meter".

The SF-36 questionnaire had 36 items measuring eight scales of health: social functioning (SF; 2 items; questions 6 and 10), vitality (VT; 4 items; questions 9a, 9e, 9g and 9i), role limitations due to emotional problems (RE; 3 items; questions 5a-5c), mental health (MH; 5 items; questions 9b, 9c, 9d, 9f and 9h), physical functioning (PF; 10 items; questions 3a-3j), role limitations due to physical problems (RP; 4 items; questions 4a-4d), body pain (BP; 2 items; questions 7 and 8), and general health perception (GH; 5items; questions 1 and 11a-11d). There was an unscaled single item asking respondents about health changes over the past year (question 2). These eight scales of health were summarized into two major components:

- the physical component summary (PCS) comprising PF, RP, BP and GH.
- the mental health component summary (MCS) comprising SF, VT, RE and MH.[12]

For each scale of the SF-36 questionnaire, item scores were coded, summarized and transformed onto a scale from 0 (lowest well-being) to 100 (highest well-being).[12] Participants with scores of <50% were classified as low QOL and participants with scores of ≥50% were classified as high QOL. This was done in accordance with the standardized scoring (<50= low QOL, ≥50 = high QOL) for the SF-36 summary scores (PCS and MCS) [12]. In this study, the researcher chose 50% of the total score of PCS and MCS as the cut-off point in categorizing the QOL as high or low.

3.13 Pilot study

A pilot study was conducted in August 2016 at the OPD of DYDH with a sample of eight participants. The OPD was the chosen venue because the researcher was working in that department during that period and thus it was a convenient site for him. The selection of participants and the data collection followed the same process as the main study. The data was coded and analysed, and participants in the pilot study were then excluded from the research sample. The aim was to estimate the time to complete the questionnaire and to see if the participants understood the questions. It was found that the questionnaires could be answered within 20 minutes and that there were no questions needing modification or removal. The participants had no complaints with the questionnaire and the data collection process went smoothly, allowing for the final questionnaire for the main study to be prepared.

3.14 Data analysis

Data was entered into the windows 7 MS-Excel spreadsheet and imported to the statistical software (STATA 14) for coding and analysis. Descriptive statistics was used to describe the sociodemographic features of the diabetic participants, the PCS and MCS of the QOL. The association between the sociodemographic characteristics and the PCS/MCS were tested using chi square, logistic regression and multilogistic regression. Results of the study were considered to be statistically significant if p-value is ≤0.05 with confidence interval of 95%.

3.15 Ethical considerations

- Confidentiality was maintained by ensuring that all questionnaires were anonymous. The patient's identity was coded and a coding number was given to each patient's file and entered on a separate MS Excel spreadsheet, which had a password. Only the researcher was able to access this information.
- Participant information letters and informed consent forms were provided to the patients who participated in the study (annexures 2 and 3 respectively).
- Patients who agreed to participate and who were eligible according in the inclusion criteria, signed the consent form (annexure 3).
- Participants who refused to participate in the study were treated according to the 2012 Hospital Level Standard Treatment Guidelines and Essential Medicines List,[31] and their right to refuse was respected.
- Written permission to conduct this study was obtained from the CEO of Dr Yusuf Dadoo hospital (annexure 5).
- Licence agreement to use SF-36v2 questionnaires was obtained (annexure 6).
- Ethics clearance was obtained from the Human Research Ethics Committee of the University of Witwatersrand (annexure 4).

3.16 Funding of the research

The cost of the study was funded by the researcher.

CHAPTER 4

RESULTS

This chapter presents the results of the data collected during the three-month study period. A flow chart showing the selection process of participants is presented in Figure 1 below.

4.1 Methodology

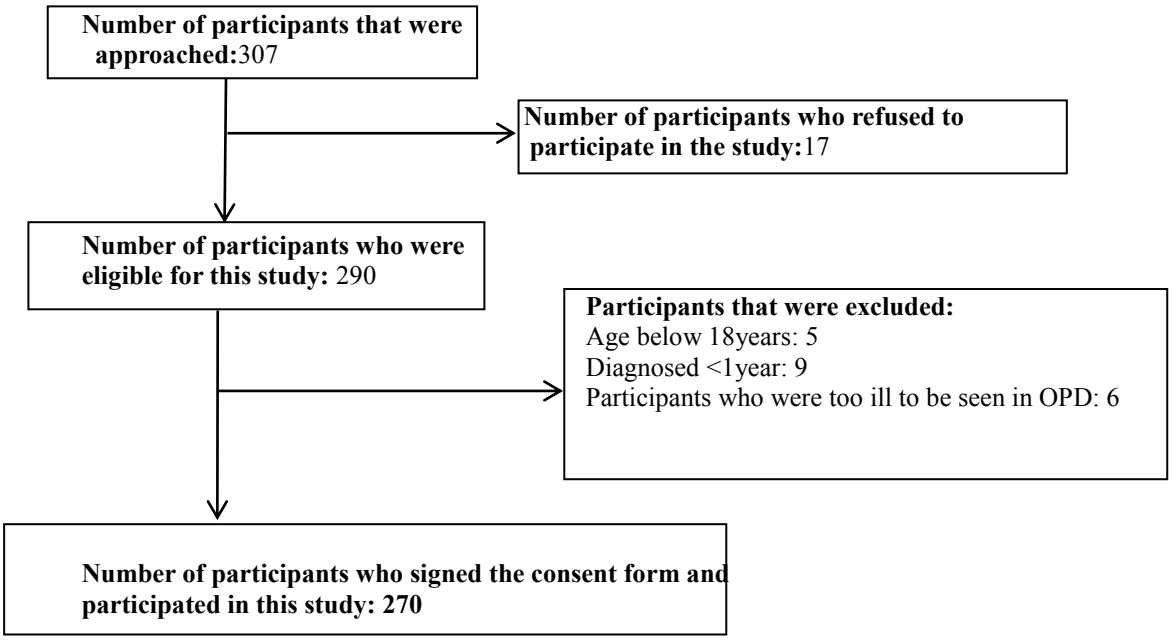


Figure 1 Flow chart showing the selection process of the participants

4.2 Sociodemographic and clinical characteristics of the participants

Table 1: Sociodemographic characteristics of the participants

Characteristics	**Frequencies (N=270)**	**Percentages (%)**	**Mean ± SD**
Age (years)			
≤ 39	12	4.44	55.1 ± 8.6
40-49	62	22.96	
50-59	116	42.96	
> 60	80	29.63	
Gender			
Male	109	40.37	
Female	161	59.63	
Country of birth			
South African-born	249	92.22	
Foreign-born	21	7.78	
Race			
Black	184	68.15	
White	45	16.67	
Coloured	41	15.19	

Level of education			
No educational background	38	14.07	
Primary	135	50.00	
High school and above	97	35.92	
Marital status			
Single	28	10.37	
Married (married and cohabiting)	142	52.59	
Divorced/Separated	67	24.81	
Widowed	33	12.22	
Income			
< R5,000/month	149	55.18	
≥R5,000/month	121	44.81	
Source of income			
Employment	111	41.11	
Pension	4	1.48	
Depending on family member	84	31.11	
More than one source	71	26.30	
Number of dependents			
None	2	0.74	

1-2	97	35.93	
3-4	142	52.59	
>4	29	10.74	
Employment			
Unemployed	129	47.78	
Employed	141	52.22	
Unemployed Category N=129			
No work	84	65.12	
Pensioner	45	34.88	

The majority of participants were South African-born black married females with primary school education, who were employed at a monthly salary of less than R5,000. The largest age group was 50-59 years, with a mean and standard deviation of 55.1 ±8.6. Although most of the study subjects were employed (141/270, 52%), 26% (71/270) had more than one source of income. Four out of the 45 pensioners relied only on their pension as a source of income. Up to 63% (171/270) of the sample population had three or more dependents. Clinical characteristics of the participants are shown in Table 2.

Table 2: Clinical characteristics of the participants

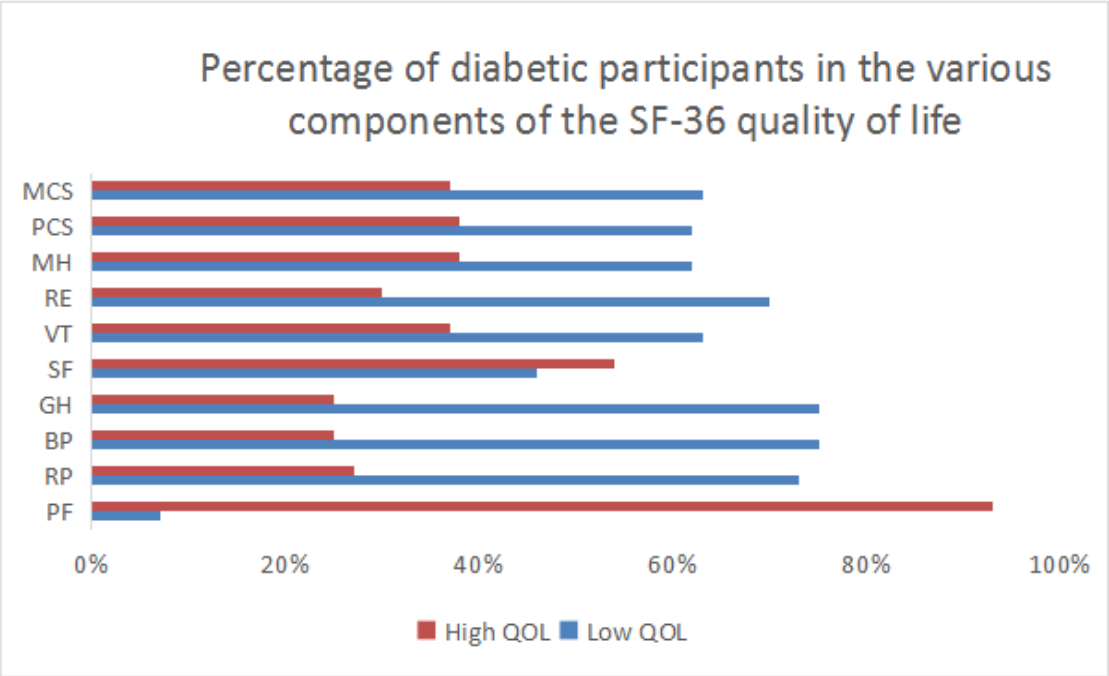
Characteristics	**Frequencies (N=270)**	**Percentages (%)**
Hospital admission		
Admitted	226	83.70

Not admitted	44	16.30
Reason for admission		
Hypertension	2	0.88
Diabetes	34	15.04
Hypertension and diabetes	12	5.31
Tuberculosis	4	1.77
Acute infection	35	15.49
Acute coronary syndrome	10	4.42
Mixed i.e. ≥2 of the above reasons for admission	76	33.63
Others e.g. cardiac disease, renal disease, surgical and orthopaedic conditions	53	23.45
Duration of hospital admission		
<1 week	193	85.40
1- <2 weeks	31	13.72
2- <3 weeks	2	0.88
Time of diagnosis of diabetes		
<5 years ago	71	26.30
≥ 5 years ago	199	73.70
Comorbid disease		

No comorbid disease	38	14
Hypertension & dyslipidaemia	67	25
Tuberculosis & HIV	3	1
Arthritis	3	1
Mixed i.e. >2 of the above comorbid diseases and others	159	59

Although clinical characteristics were not part of the objectives of this study, the researcher found some crucial factors that could have affected the QOL of the participants. A majority of the study population had been diabetic for more than five years (199/270, 74%) and had comorbid diseases (232/270, 86%). Up to 84% (226/270) of the subjects had a history of hospital admission, and 85% (193/226) of them had been admitted for less than one week. Mixed medical conditions (e.g. acute infections like pneumonia with controlled or uncontrolled hypertension/diabetes, hypertensive and diabetic complications, etc) accounted for the reason of admission for most of these participants (76/226, 34%). Of note is that these mixed medical conditions had included more than one admission.

4.3 Physical and mental health component summaries of the quality of life of the participants



Footnote: MCS: Mental Health Component Summary, PCS: Physical Component Summary, MH: Mental Health, RE: Role limitations due to emotional problems, VT: Vitality, SF: Social Functioning, GH: General Health, BP: Body Pain, RP: Role limitations due to physical problems, PF: Physical Functioning. QOL: Quality of life.

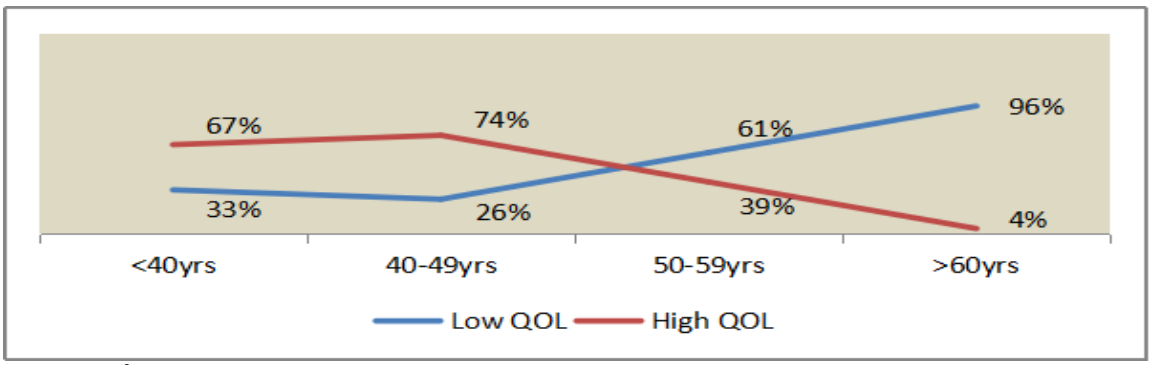
Figure 2: Percentage of diabetic participants in the various components of SF-36 quality of life

Figure 2 above shows that the participants reported high QOL in PF and SF (physical and social functioning), while they reported low QOL in the rest of the items. Sixty-two percent of participants reported low QOL in the physical component with a minimum score of 28 and a maximum of 83, and a mean score of ±SD (50.44 ±12.3). Sixty-three percent of the participants reported low QOL in the mental health component, with a minimum score of 33 and a maximum score of 90, and a mean score of ±SD (51.38 ±11.53).

4.4 Association between sociodemographic characteristics of the participants and their quality of life in the physical and mental health component summaries.

The figures show chi square association, and comments below each figure show the association using logistic regression.

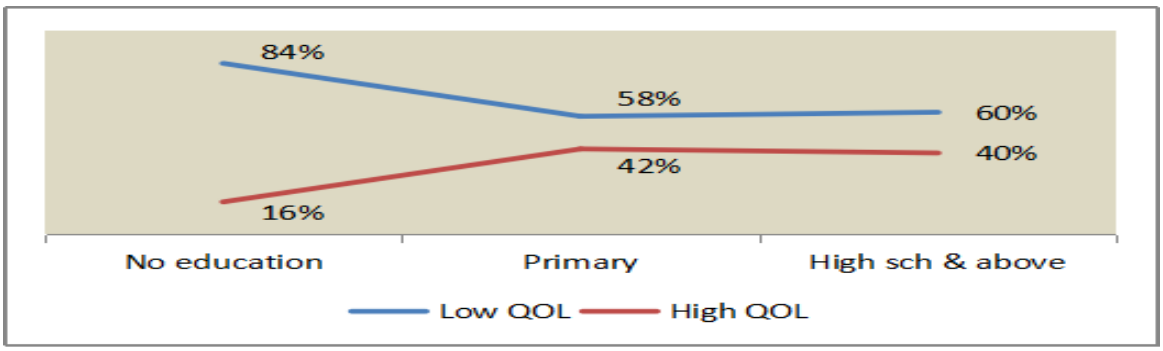
4.4.1 Association between sociodemographic characteristics of the participants and their quality of life in the physical component summary.



Person chi^2 (3)= 78.70, P= 0.000.

Figure 3: Physical component summary versus age group

Participants who were above 60 years were 51 times more likely to report low QOL when compared to those below 40 years (OR= 51.33, P= 0.000, 95% CI= 9.72-271.23).

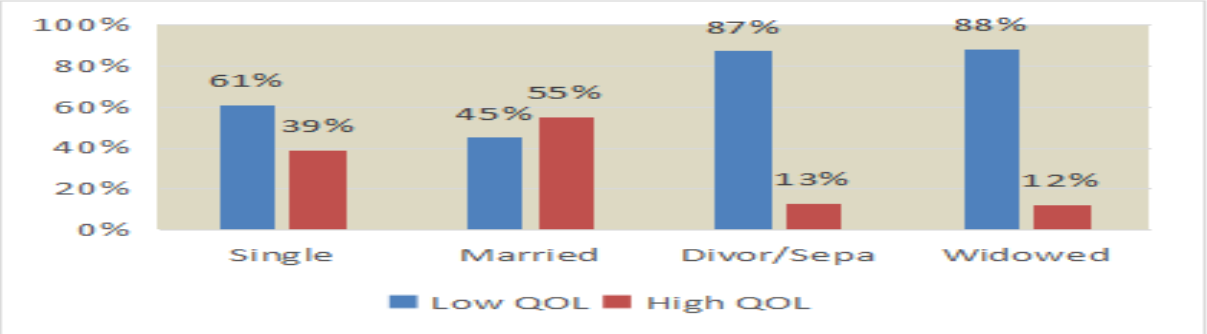


Person chi^2 (2)= 9.19, P= 0.010, Fisher's exact= 0.007.

Figure 4: Physical component summary versus education

Participants with primary levels of education and above, were less likely to report low QOL when compared to uneducated participants (participants with primary levels of

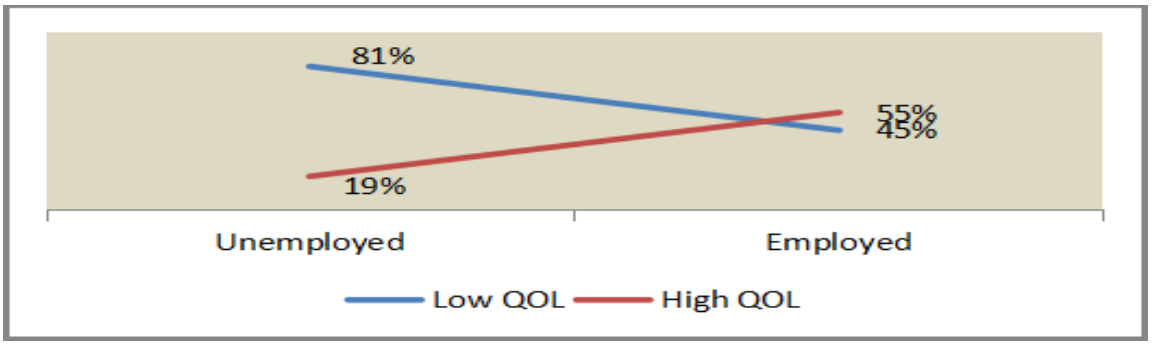
education had OR= 0.26, P= 0.004, 95% CI= 0.10-0.65 and participants with high school and above education had OR= 0.28, P= 0.009, 95% CI= 0.11-0.73).



Person chi^2 (3)= 43.93, P= 0.000.

Figure 5: Physical component summary versus marital status

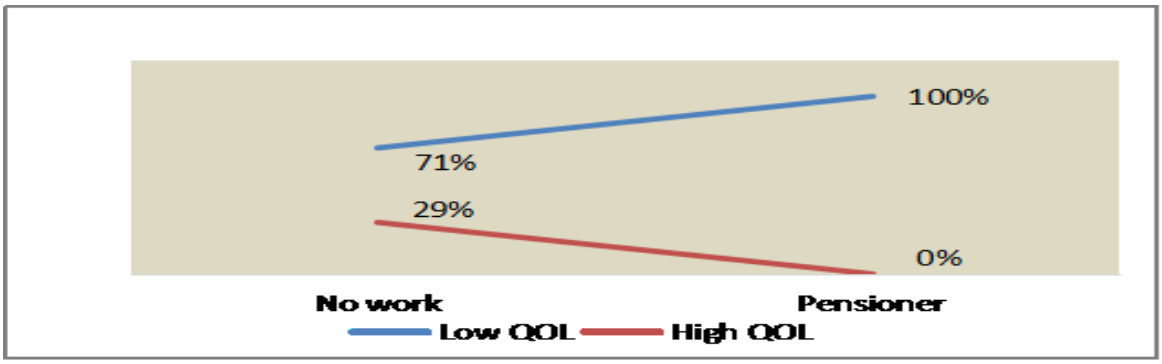
Participants who were divorced/separated/widowed were two times more likely to report low QOL when compared to those who were married (OR= 2.17, P= 0.007, 95% CI= 1.48-11.72).



Person chi^2 (1)= 38.63, P= 0.000.

Figure 6: Physical component summary versus employment status

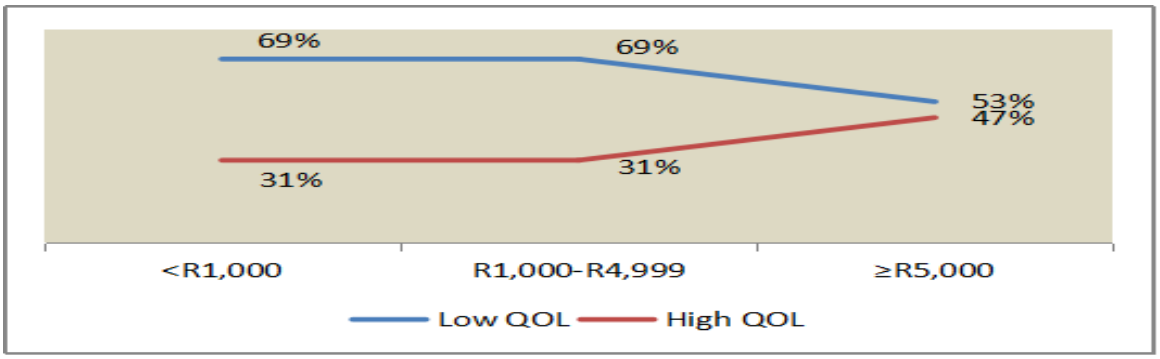
Participants who were employed reported to be less likely to have low QOL when compared to unemployed participants (OR= 0.18, P= 0.000 and 95% CI= 0.11-0.32).



Person chi^2 (1)= 15.80, P= 0.000.

Figure 7: Physical component summary versus unemployment category

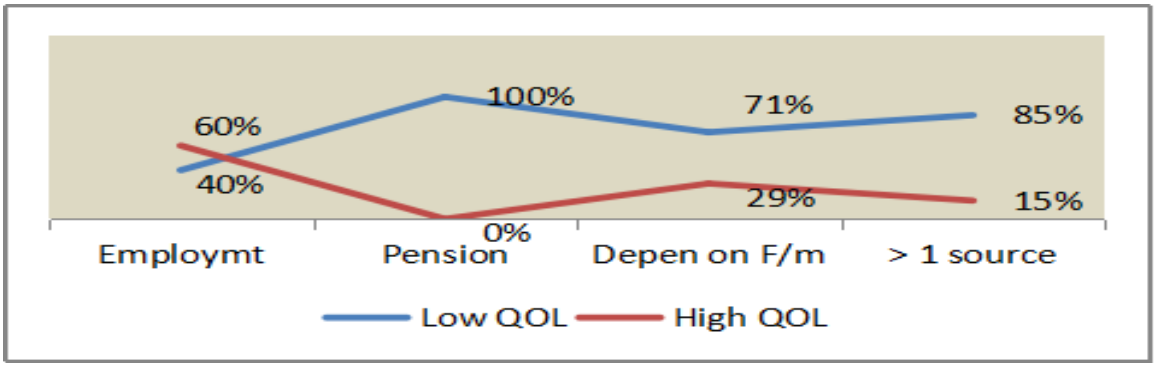
Pensioners reported that they had low QOL when compared to participants who had no work, although logistic regression did not show any statistical significance.



Person chi^2 (2)= 6.83, P= 0.033.

Figure 8: Physical component summary versus income

Participants who earned monthly income of ≥ R5,000 reported that they had better QOL than those who earned < R5,000 although logistic regression showed no statistical significance.

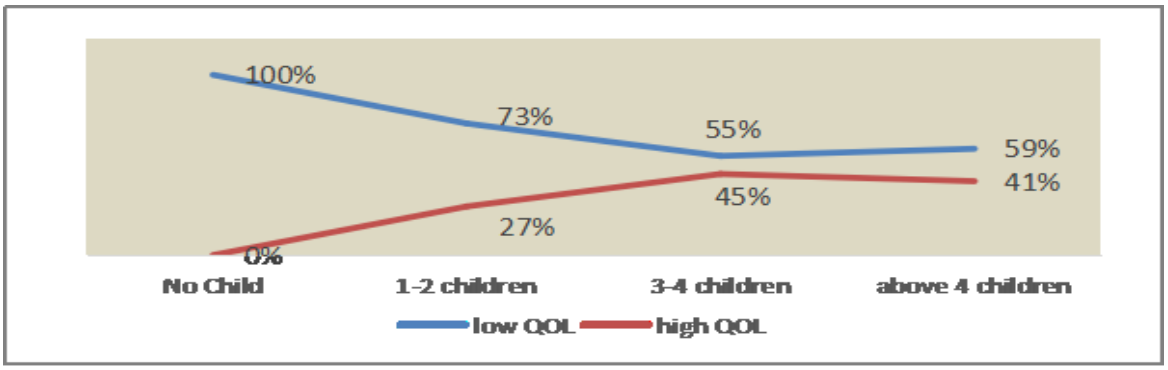


Person chi^2 (3)= 44.54, P= 0.000.

Figure 9: Physical component summary versus source of income.

Participants who were dependent on family members as their source of income were four times more likely to report low QOL when compared to those whose source of income was from employment only (OR= 3.81, P= 0.000, 95% CI= 2.07-6.99).

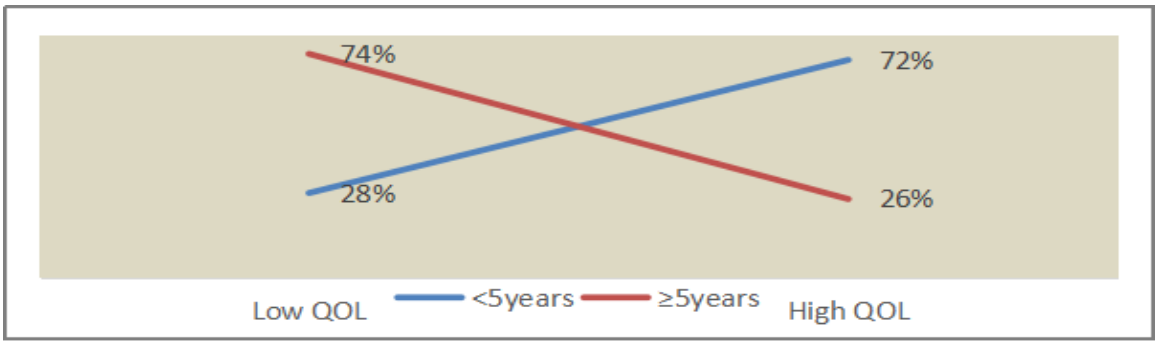
Participants who had more than one source of income were eight times more likely to report low QOL when compared to those whose source of income was from employment only (OR= 8.31, P= 0.000, 95% CI= 3.94-17.53).



Person chi^2 (3)=9.5563, P= 0.016.

Figure 10: Physical component summary versus dependents

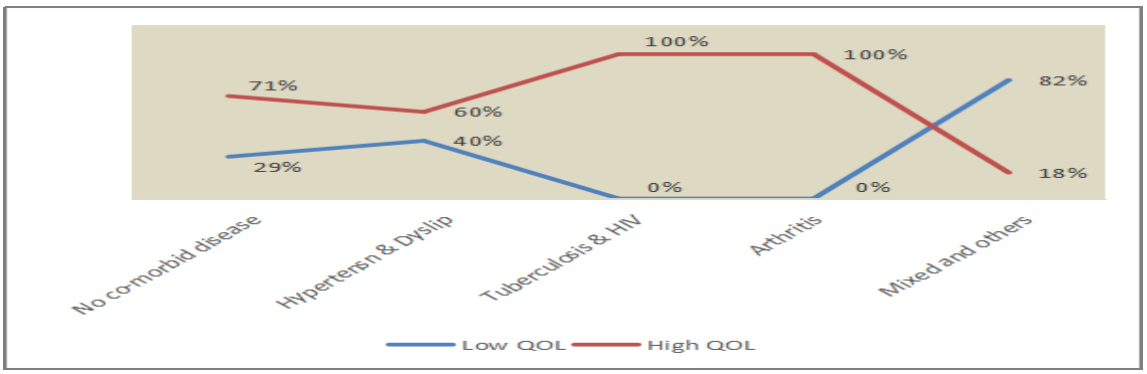
Participants with three or more dependents reported that they had low QOL when compared to participants who didn't have children, although logistic regression did not show any statistical significance.



Person chi^2 (1)=47.52, P= 0.000.

Figure 11: Physical component summary versus duration of diabetes

Participants who had five or more years duration of diabetes were seven times more likely to report low QOL when compared to those with durations of less than five years (OR= 7, P= 0.000, 95% CI= 4.03-13.58).

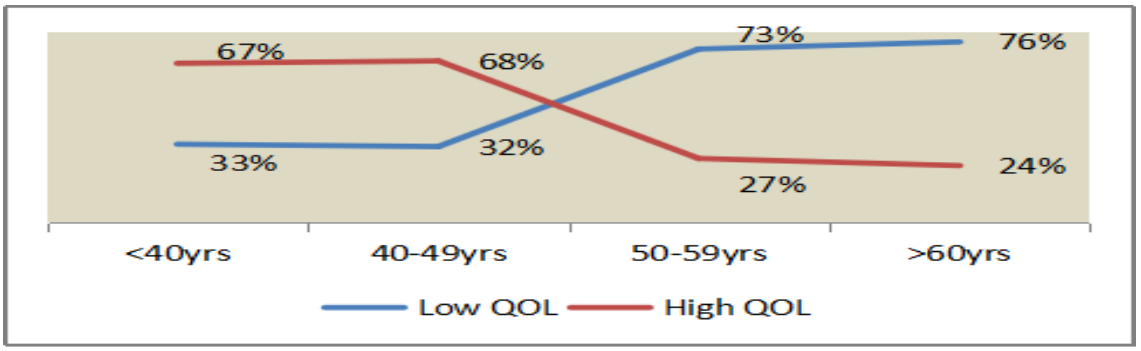


Person chi^2 (4)= 67.30, P= 0.000.

Figure 12: Physical component summary versus comorbid diseases

Participants who had mixed chronic diseases were eleven times more likely to report low QOL when compared to diabetic participants who had no comorbid disease (OR= 11, P= 0.000, 95% CI= 4.90-24.69).

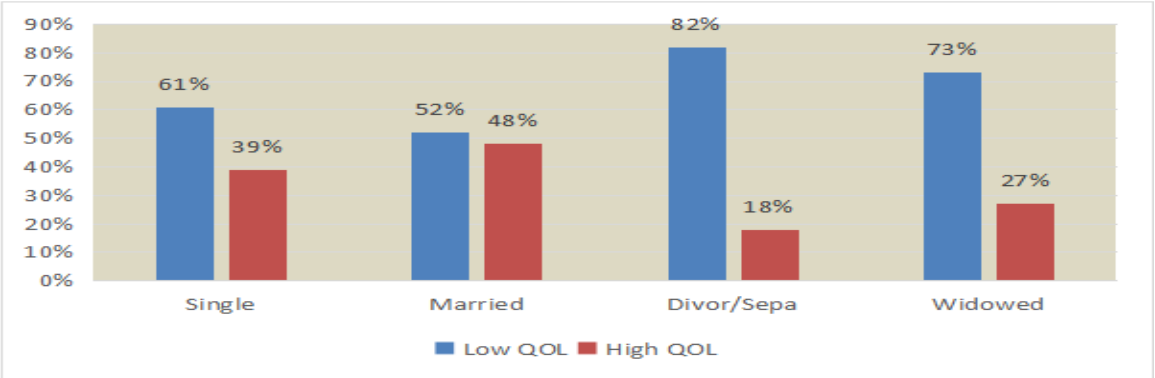
4.4.2 Association between sociodemographic characteristics of the participants and their quality of life in the mental health component summary



Person chi^2 (3)= 40.93, P= 0.000.

Figure 13: Mental health component summary versus age group

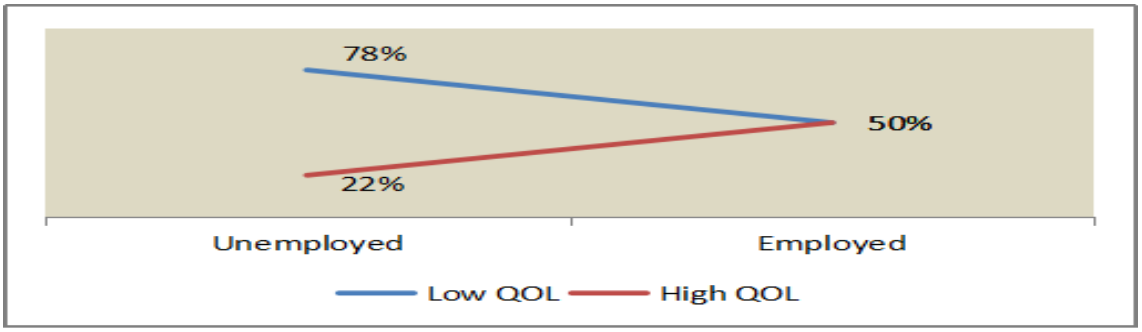
Participants of 50 years or more reported having low QOL when compared to their younger counterparts (participants in age group 50-59 years had OR= 5.48, P= 0.009, 95% CI= 1.54-19.50 and participants above 60 years had OR= 6.42, P= 0.005, 95% CI= 1.74-23.70).



Person chi^2 (3)= 19.09, P= 0.000.

Figure 14: Mental health component summary versus marital status

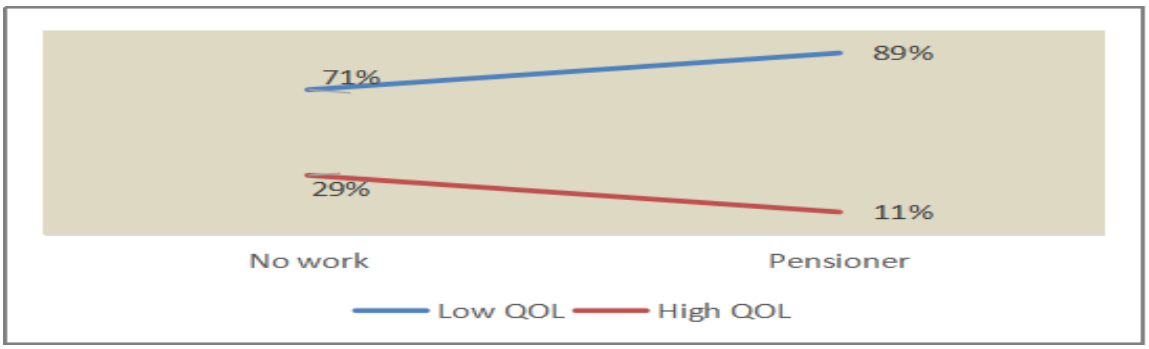
Participants who were divorced/separated were two times more likely to report low QOL when compared to those who were married (OR= 2.06, P= 0.030, 95% CI= 1.11-7.92).



Person chi^2 (1)= 22.45, P= 0.000.

Figure 15: Mental health component summary versus employment status

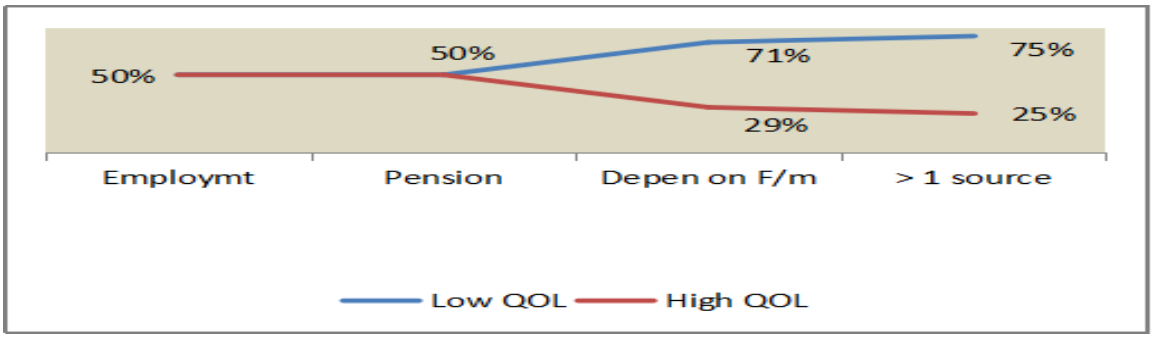
Participants who had employment were less likely to report low QOL when compared to unemployed participants (OR= 0.29, P= 0.000, 95% CI= 0.17-0.49).



Person chi^2 (1)= 5.13, P= 0.024, Fisher's exact= 0.027.

Figure 16: Mental health component summary versus unemployment category

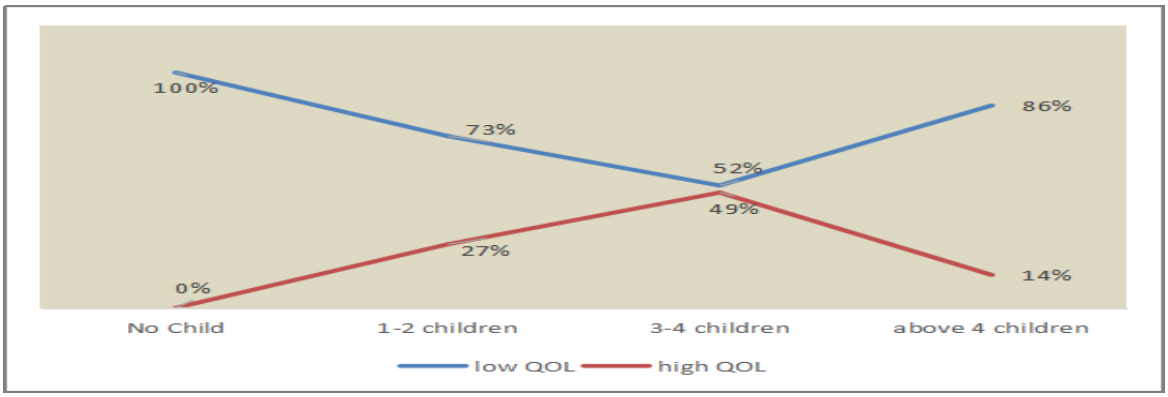
Pensioner participants were three times more likely to report low QOL when compared to those who didn't work (OR= 3.2, P= 0.029, 95% CI = 1.13-9.08).



Person chi^2 (3)= 15.59, P= 0.001.

Figure 17: Mental health component summary versus source of income

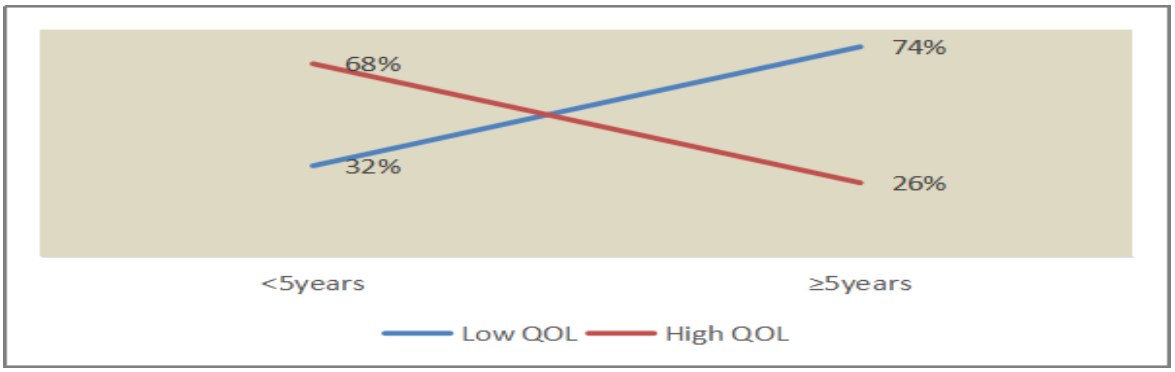
Chi^2 shows that half of the participants whose source of income was from their employment had low QOL as well as those who depended on pension as their source of income.



Person chi^2 (3)= 21.40, P= 0.000, Fisher's exact= 0.000.

Figure 18: Mental health component summary versus dependents

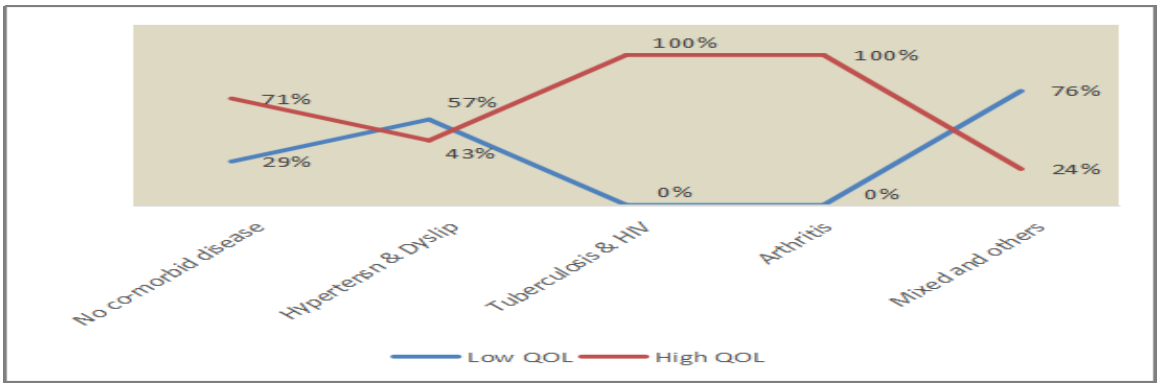
Participants who had three or more dependents were less likely to report low QOL when compared to those without dependents (OR= 0.16, P= 0.001, 95% CI= 0.05-0.50).



Person chi^2 (3)= 38.60, P= 0.000, Fisher's exact= 0.000.

Figure 19: Mental health component summary versus duration of diabetes

Participants who had five or more years' duration of diabetes were six times more likely to report low QOL when compared to those with duration of less than five years (OR= 5.9, P= 0.000, 95% CI= 3.27-10.63).



Person chi^2 (4)= 41.94, P= 0.000.

Figure 20: Mental health component summary versus comorbid diseases

Participants who had hypertension and dyslipidaemia were three times more likely to report low QOL when compared to those with no comorbid disease (OR= 3.22, P= 0.007, 95% CI= 1.37-7.54). Also, participants who had mixed chronic diseases were eight times more likely to report low QOL when compared to those with no comorbid disease (OR= 7.82, P= 0.000, 95% CI= 3.55-17.22).

Race, gender and country of birth of the participants did not show any statistically significant relationship to either the physical or mental health components of QOL. Furthermore, participants' educational status and income had no relationship to the mental health component of QOL (P= 0.211 and 0.711 respectively).

Table 3: Multivariate logistic regression of the participants

Variables for PCS	**Odds ratio**	**P value**	**95% CI**
40-49	0.50	0.37	0.11-2.25
50-59	3.13	0.22	0.51-19.50
>60	24.10	0.006	2.47-235.23
Primary	0.21	0.05	0.04-1.02
High school and above	0.78	0.76	0.15-3.97
Married	0.30	0.05	0.10-0.99
Divorced	1.72	0.48	0.38-7.70
Widowed	0.09	0.04	0.01-0.91
More than one source of income	0.67	0.53	0.19-2.36
≥ 5 years	1.45	0.52	0.46-4.52
No comorbid disease	0.34	0.01	0.14-0.80
Variables for MCS	**Odds ratio**	**P value**	**95% CI**
50-59yrs	0.78	0.74	0.18-3.42
Married	2.56	0.22	0.56-11.57

Divorced	1.60	0.48	0.43-6.04
≥ 5 years	1.72	0.61	0.21-14.09
No comorbid disease	0.58	0.43	0.15-2.25

In the multivariate logistic analysis model, participants aged above 60 years were 24 times more likely to report low QOL in the physical component when compared to participants of less than 40 years. Also in this model, participants with primary school education who were married or widowed and had no comorbid disease, were less likely to report low QOL in the physical component. There were no statistically significant associations in the mental health component of QOL in the multivariate model.

CHAPTER 5

DISCUSSION

Chapter 5 discusses the results of this study in relation to other studies.

5.1 Methodology

A cross-sectional study was used here to have a snapshot of the QOL of the participants as there had been no study done in this district. This report will help further studies on this matter. The researcher was happy with the sample size for the completion of this study.

5.2 Sociodemographic characteristics

The sociodemographic characteristics are discussed below under the following sub-headings: Age, Gender, Country of birth, Race, Level of education, Marital status, Employment status and Category of unemployment status, Income and source of income and Number of dependents.

5.2.1 Age

The age range of the participants was 29 to 73 years with a mean age of 55.1 years and the commonest age group being 50-59 years. The mean age in this study was slightly lower than the Kenyan study[21] (56.4 years), but a little higher than those of the Iranian[6] and Brazilian studies[22] (52.3 years for both studies). This current study's findings were very low when compared to studies from developed countries.[24,25,26] This might be a reflection that patients with diabetes have better care and live longer in developed nations. The most common age group in this study was similar to the Pretoria[10] and Iran studies[6]. This shows that either diabetes is more common in middle aged populations than

the younger populations or that patients in the middle-aged group seek more medical help than other age groups.

5.2.2 Gender

Females (161/270, 60%) predominated in this study, as was the case with most of the studies done in Africa[3,10,21] other than the study conducted in a private care diabetic clinic in Alberton, Johannesburg,[7] which reported more male than female subjects. This was also the case of studies done in Canada[27] (less than half of the subjects were females), the Netherlands,[24] and Spain[23] (equal gender distribution). This revealed that females in Africa might either be more prone to DM or that females with diabetes seek medical attention more frequently than their male counterparts.

5.2.3 Country of birth

Ninety-two percent of the participants were South African-born. Similarly, a Swedish study[28] revealed that the majority of participants were Swedish-born. Findings reflect the place where studies are conducted.

5.2.4 Race

Black subjects were higher in number than any other race in this study (184/270, 68%). However, the aforementioned South African study done in Alberton, Johannesburg[7] found that white participants made up the majority of the study sample. The present study was done in a public sector that caters for all types of patients (coming from informal, rural, semi-urban and urban areas), while the Alberton study was done in a private sector that caters for an urban community.

5.2.5 Levels of education

This study revealed that half of the participants (135/270, 50%) had a primary level of education, followed by 36% who had high school level education and above. The participants' educational levels in the current study was slightly higher than in the Kenyan,[21] Ugandan,[3] and US[29] studies, but were inconsistent with the Alberton[7] and Catalonian[23] studies, where the majority of participants had secondary school levels of education and above. The current study findings reflected the educational background of the society involved.

5.2.6 Marital status

Fifty-three percent of the participants were married/cohabiting, 10% were single, 25% were separated/divorced and 12% were widowed. Similarly, studies in Pretoria,[1] Alberton,[7] Kenya,[21] and other parts of the world[23,25,26,27] revealed that married subjects had made up majority of their samples. This might reflect that married participants with diabetes tend to seek more medical help than their counterparts.

5.2.7 Employment status and category of unemployment status

Almost half of the participants (129/270, 48%) were unemployed. The unemployment proportion was lower by far than in the Pretoria study,[10] which reflected the community this hospital was serving. The Kenyan study[21] revealed 40% unemployed respondents, which was lower than the present study. Of the unemployed participants in the current study, 65% had no work and 35% were pensioners. No study that discussed the different categories of unemployment status could be found.

5.2.8 Income and source of income

Fifty-five percent of the participants had monthly incomes of < R5,000. No study on this factor could be found, and further research might be required.

5.2.9 Dependents

The current study showed that a majority of participants (171/270, 63%) had three or more dependents, which was more than in the Iranian study[6]. The increase in the present study might be due to the fact that participants take care of their children and grandchildren.

5.2.10 Duration of diabetes

Seventy-four percent (199/270) of the study population had diabetes for five or more years. This was similar to the Alberton study,[7] in which participants averaged a duration of seven years. Meanwhile, the UK study,[25] reported that the majority of their subjects had been diabetic for two to five years. This suggests that patients in developed countries are healthier than those in developing countries, and that they tend to get diabetes in the later stages of life.

5.2.11 Comorbid diseases

Eighty-six percent (232/270) of the participants had comorbid diseases. The Alberton study[7] showed that 87% of the subjects had hypertension or hyperlipidaemia while this study showed 25% had these diseases. The difference might be due to the type of study population (the latter catered for unemployed black participants in informal, rural, semi-urban and urban areas, while the former catered for urban employed white participants). In the present study, more than half the participants (59%) had more than two comorbid diseases. This shows that the study population was unhealthy. One needs to consider this factor during the management of patients, and to see if preventative measures through health education can make a difference.

5.3 Physical and mental health component summaries of the quality of life of the participants

Although the majority of the participants in this study reported low QOL, their mean scores for the physical and mental health components of QOL were 50.44±12.3 and 51.38±11.53 respectively.
Four out of eight items in the SF-36 tool scored high, and these had an effect on the mean score.

Mean score in the physical component of QOL (50.44) was higher than the Australian[30] and American[29] studies, where mean scores were 43 and 46.06 respectively. In the current study, the physical functioning (PF) item of the physical component was scored and reported high. Physical functioning in this study proved that the diabetic participants were able to carry out basic activities such as carrying groceries, sweeping, climbing a few stairs and walking 100 meters. Body pain (BP), role limitations due to physical problems (RP) and general health (GH), were reported to have affected them, and their scores were low. In the Pretoria study,[10] black South African diabetic patients tended to have poorer general health and more body pain than the healthy black patients, and this agreed with the present study findings. This means that symptom distress might be a primary factor for low scores in the physical component of QOL. This finding also agreed with the American study findings,[29] where it was reported that there was a strong association between greater symptom distress and low HRQOL among low-income older African-Americans. Camacho et al.[32] in 2002, and Gulliford et al.[33] in1999, found that symptom distress was a major determinant of HRQOL in patients with type 2 diabetes.

Maddigan et al.[34] reported in 2005 that multiple chronic medical conditions caused a significant decrease in the HRQOL. In 2001, Wensing et al.[35] found that comorbid conditions had a negative effect on RP and BP in primary care patients. A similar finding was reported in the American study.[12] In the present study, participants with mixed chronic diseases reported in the physical component of QOL that they were 11 times more likely a have low QOL when compared to diabetic patients who had no comorbid

disease. This finding concurs with the Wensing et al. report,[35] where the majority of patients had functional limitations and symptoms that distressed them.

The current study showed that participants who had equal to or more than five years duration of diabetes were seven times more likely to have low QOL in the physical component. This concurs with the Kenyan study[21] but contradicts the Alberton study[7]. However, all the studies used different measuring tools. A systematic review of QOL in diabetic patients in a primary care setting in Nordic countries[5] stated that the duration of diabetes is one of the predicting factors of impaired HRQOL. This current study also found that duration of diabetes was an important factor.

The mean score in the mental health component of QOL (51.38) was lower than the Australian[30] and American[29] studies where their mean scores were 53.4 and 58.52 respectively. In the current study, the social functioning (SF) item of the mental health component was scored and reported high by over 50% of the participants, showing that they could engage in normal social activities with family, friends and neighbours, or groups. This contradicted the Pretoria study,[10] which suggested that social functioning reflected the residential area of the participants and that insecurity or lack of facilities limited their social activities. The other items of the mental health component (role limitations due to emotional problems [RE], vitality [VT] and mental health [MH]) of this study were scored and reported low by most of the patients.

In the American study,[29] religion showed as an effect on the high scores. Though religion showed as a positive effect on the physical and mental well-being of the health outcomes of the individuals in the American study[29], this current study did not examine the relationship as it was not part of the objectives.

It has been proven that diabetic patients are more likely to have clinical depression, [35] and poor QOL was reported in the American study[29]. Poor HRQOL with depression in diabetics was also found in the Blaum et al. studies,[36] The current study did not look at depression with diabetes. Depression might have affected these participants as a majority

of them (63%) scored low in the mental health component of QOL. As such, further studies on the effects of depression and religion need to be undertaken.

Symptom stressors, mixed comorbid diseases, duration of diabetes, functional limitation due to emotional and physical problems and depression, might be associated with low QOL in the current study.

5.4 Association between sociodemographic characteristics and physical and mental health component summaries of the quality of life

5.4.1 Age

This study reported statistical significant changes in both the physical and mental health components of QOL with age (P= 0.000). The physical component of QOL findings was similar to other studies[10,21,24,25] but contradicted the Alberton study,[7] where no significant association was found. The Pretoria study[10] showed significantly poorer physical, role functioning and general health (three of the four scales of physical component of QOL) in the older respondents than their younger counterparts. This is a common finding seen in older age groups, and it is difficult to specify diabetes as the cause of these changes. There was no study found that reported on MCS.

5.4.2 Gender

Though studies have shown worse QOL among females, [7,10,24,25,26] we could not prove it (physical component P= 0.964 and mental health component P= 0.262). These findings in other studies might have reflected the different survey tools that were used. The Pretoria study[10] showed that female participants had significantly poorer functioning (p= 0.05) and more body pain than their male counterparts (p< 0.01). The present study did not investigate an association with individual items of physical components of QOL, hence further studies are advised.

5.4.3 Country of birth

There was no significant statistical difference between the South African-born participants and their foreign-born counterparts in both the physical and mental health components of QOL (P= 0.333 and P=0.714 respectively). In the Swedish study,[28] HRQOL decreased on nine of the 13 scales in the foreign-born, and eight in the Swedish-born. Though both studies were cross-sectional and in public health sector, the difference in the results might have been due to the type of survey conducted (SF-36v2 vs SWED-QUAL).

5.4.4 Race

Though the European[25] and USA[29] studies reported that race showed significant changes in HRQOL, the present study could not prove this association (Physical component P= 0.761 and mental health component P= 0.179).

5.4.5 Education

A systematic review[5] proved that lower educational levels were a predictive factor to impaired HRQOL. The study showed that education was a protective factor in the physical component (p= 0.004), but was not significant in the mental health component of QOL (p= 0.239).

5.4.6 Marital status

The study showed that separated/divorced participants had low QOL when compared to their single counterparts in the physical and mental health components (P= 0.007 and 0.030 respectively). This is similar to the UK study[25] in which significantly worse QOL was reported in divorced subjects compared to their single counterparts. The Pretoria study[10] showed that widows had significantly poor physical and role functioning, and more body pain than married or single respondents. However, being married or widowed was a protective factor in the physical component of QOL in multivariate analysis model

in this study (p= 0.05 and 0.04 respectively). These factors should be considered during the management of these diabetic patients.

5.4.7 Employment status

Employment was a protective factor in both physical and mental health components of QOL (P= 0.000) when using logistic regression. This correlates with other studies where there was significant association between employment and high QOL score. [6,10,21,26] The Pretoria study[10] showed that employed respondents had significantly better physical and role functioning, mental and general health and less body pain than unemployed respondents (p< 0.01). The present study concurred with it.

5.4.8 Income of the participants

Studies have shown that the lower the income, the lower the QOL score.[5,21,26] This study did not show any statistically significant associations between income of the participants and the physical and mental health component summaries of QOL.

5.4.9 Dependents

Having three or four children was reported to be a protective factor in the mental health component of QOL (P= 0.001). There was no significant association between dependents and the physical component of QOL. No study was found with which to compare this result.

5.4.10 Duration of diabetes

Various studies have been done looking at the duration of diabetes and QOL.[5,7,21,25,26] The Alberton study[7] did not find any significant relationship, but the Kenyan study[21] reported the physical domain to be significantly related with the duration of diabetes, using the WHO-QOL BREF tool. The present study showed that the duration of five or more years of diabetes was related to low QOL in both the physical and mental health components of QOL, using logistic regression (p = 0.000). This relates to the findings of the Kenyan study.[21] The longer the duration of diabetes, the poorer the QOL, which is a

non-modifying factor. In order to improve their QOL, multidisciplinary interventions must take place to prevent patients from getting diabetes.

5.4.11 Comorbid diseases

Various studies have looked at the relationship between comorbid diseases and the QOL,[3,7,26,27] but no significant correlation was found. The present study found that patients with chronic diseases and diabetes had low QOL in both the physical and mental health components of QOL, using logistic regression (p= 0.000). Having no comorbid disease was a protective factor in the physical component of QOL when using the multivariate logistic regression (p= 0.01). This finding did not concur with findings in the above studies, but it is an important factor to consider when managing diabetic patients. This factor needs intervention from other allied health care workers to prevent further complications in diabetic patients.

5.12 Limitations of the study

- A cross-sectional survey was used to explore the prevalence of QOL in diabetic patients, it could have weakened the strength of the study.
- A qualitative study would have given a better understanding of QOL among these participants, but due to time constraints, the researcher decided to use the SF-36v2 tool, which looked at the perceptions of the participants in a quantitative manner. A qualitative method is recommended for future studies.
- This study did not investigate the association between QOL, religion and depression as they were not part of the objectives of the study.
- Reporting bias cannot be fully excluded as convenient sampling method was used and the results were dependent on the participants' self-reporting on QOL. This might have affected the mean score of the items in the SF-36v2.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

Quality of life in diabetic patients has been assessed worldwide by using various measuring tools, which were cited in the literature section of this study. Demographic factors were also studied in relation to the QOL, using individual items of the different tools. Few studies of this nature have been done in Africa. Overall, very few studies have used the SF-36v2 tool to report on the physical and mental health component summaries of the QOL of diabetic patients. Furthermore, no studies were found that associated sociodemographic factors with these component summaries of QOL. Factors like sociodemographic characteristics can be used in the implementation of a holistic approach in the management of diabetic patients.

In the research, the mean scores for QOL using the SF-36v2 tool were 50.44, and 51.38 for the physical component summary (PCS) and mental health component summary (MCS) respectively, but a majority of participants reported that they had low QOL in both component summaries. Regression analysis showed that being married, having education and not having comorbid diseases were protective factors associated with the physical component of QOL. Those participants above 60 years who had low incomes, a duration of diabetes for five or more years with mixed chronic conditions, and were separated or divorced, were risk factors for low scores in the physical component of QOL. There were no significant findings in the mental health component of QOL. Therefore, the following recommendations are made:

- This researcher suggests that health workers should consider symptom stressors, functional status, emotional/mental well-being and multiple chronic diseases during clinical assessment of a diabetic patient.
- Further studies should examine the effects of depression and diabetes on QOL.
- If the monthly income of the diabetic patients under study was increased to more than R5,000 to afford better diet and lifestyle and enhance better social well-being, their QOL would improve.

- Allied health care workers play a major role in the holistic management of diabetes and hence diabetic patients must be referred to these workers e.g. occupational therapists, physiotherapists, social workers, psychologists, dieticians.
- Diabetic patients should be encouraged to have regular social gatherings (support groups) to improve their mental health status.
- This study did not look at the body mass index of the participants as it was not part of the objectives. Further studies would be advised.
- The study can be generalized to a similar setting as the researcher has calculated the sample size of the diabetic patients.

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ANNEXURE 1: QUALITY OF LIFE QUESTIONNAIRE.

PERCEIVED QUALITY OF LIFE OF PATIENTS WITH DIABETES ATTENDING OUT-PATIENT DEPARTMENT OF DR YUSUF DADOO HOSPITAL

WHO defines Quality of Life as individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.

Instruction

Please answer questions 1-17 in part 1 and 1-11 in part 2 of this questionnaire. Tick one box in the required questions.

PART 1: BASIC CHARACTERISTICS

1. Code number for the patient? ……

2. What is your age in Years? ……...

3. What is your gender?
☐ Male ☐ Female

4. What is your country of birth? .....

5. What race do you belong to?
☐ White ☐ Black
☐ Coloured ☐ Asian ☐ others. If others, please specify .....

6. What is your educational level?
☐No schooling ☐ Pre-school ☐ Primary School ☐ High School ☐ Diploma
☐Post Higher Diploma ☐ Bachelors Degree ☐ Honours Degree
☐Higher Degree (Masters/PhD) ☐Others. If others, please specify .....

7. What is your marital status?
☐ Single ☐ Married
☐ Co-habiting ☐ Divorcee/separated ☐ Widowed

8 a. What is your employment Status?
☐ Unemployed ☐ Employed

8 b. If unemployed, what is your status

☐ No work ☐ Student ☐ Pensioner

9. What is your monthly income?

☐ No monthly income ☐ <R1000/Month ☐ R1000-R5000/Month
☐ R5000-R10000/Month ☐ >R10000/Month

10. Where do you receive this income from? (*you can tick more than one*).

☐ Employment income ☐ Child support grant ☐ Disability grant
☐ Pensioner ☐ Depend on family member ☐ Others. If others, please specify .....

11. How many dependents do you have? .....

12. Have you been admitted in the hospital? ☐ Yes ☐ No

13. If yes, for what health problem? .....

14. If yes to question number 13, for how long? .....

15. When were you diagnosed with diabetes by a health care practitioner? .....

16. Do you have any other health problem? ☐ Yes ☐ No

17. If yes, please specify.....

SF-36v2™ Health Survey Scoring Demonstration

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.
Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Tick on the box that best describes your answer.)

Excellent	**Very Good**	**Good**	**Fair**	**Poor**
☐	☐	☐	☐	☐

2. *Compared to one year ago*, how would you rate your health in general now?

Much better now than one year ago	**Somewhat better now than one year ago**	**About the same as one year ago**	**Somewhat worse now than one year ago**	**Much worse now than one year ago**
☐	☐	☐	☐	☐

3. The following questions are about activities you might do during a typical day. *Does your health now limit* you in these activities? If so, how much? (Tick on a box on each line.)

		Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a.	*Vigorous Activities,* such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b.	*Moderate Activities,* such as moving a	☐	☐	☐

	table, sweeping			
c.	Lifting or carrying groceries	☐	☐	☐
d.	Climbing 10 steps of stairs or walking 10 steps upwards on a steep road	☐	☐	☐
e.	Climbing more than 10 steps of stairs or walking more than 10 steps upwards on a steep road	☐	☐	☐
f.	Bending, or kneeling	☐	☐	☐
g.	Walking *more than 1.6 km*	☐	☐	☐
h.	Walking *several hundred meters*	☐	☐	☐
i.	Walking *one hundred meters*	☐	☐	☐
j.	Bathing or dressing yourself	☐	☐	☐

4. During the *past 4 weeks,* how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of your physical health?*

		All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	Cut down on the *amount of time* you spent on work or other activities	☐	☐	☐	☐	☐
b.	*Accomplished* less than you would like	☐	☐	☐	☐	☐
c.	Were limited in the *kind* of work or other activities	☐	☐	☐	☐	☐
d.	Had *difficulty* performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

5. During the *past 4 weeks,* how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

		All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	Cut down on the *amount of time* you spent on work or other activities	☐	☐	☐	☐	☐
b.	*Accomplished less* than you would like	☐	☐	☐	☐	☐
c.	Did work or activities *less carefully than usual*	☐	☐	☐	☐	☐

6. During the *past 4 weeks,* to what *extent* has your *physical health or emotional problems* interfered with your normal social activities with family, friends, neighbours, or groups?

Not at all	**Slightly**	**Moderately**	**Quite a bit**	**Extremely**
☐	☐	☐	☐	☐

7. How much *bodily* pain have you had during the *past 4 weeks*?

None	**Very Mild**	**Mild**	**Moderate**	**Severe**	**Very Severe**
☐	☐	☐	☐	☐	☐

8. During the *past 4 weeks,* how much did *pain* interfere with your normal work (including both work outside the home and housework)?

Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**

☐	☐	☐	☐	☐

9. These questions are about how you feel and how things have been with you *during the past 4 weeks*. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks*...

		All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	Did you feel full of life?	☐	☐	☐	☐	☐
b.	Have you been very nervous?	☐	☐	☐	☐	☐
c.	Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
d.	Have you felt calm and peaceful?	☐	☐	☐	☐	☐
e.	Did you have a lot of energy?	☐	☐	☐	☐	☐
f.	Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
g.	Did you feel worn out?	☐	☐	☐	☐	☐
h	Have you been happy?	☐	☐	☐	☐	☐
i.	Did you feel tired?	☐	☐	☐	☐	☐

10. During the *past 4 weeks,* how much of the time has your *physical health or emotional problems* interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
☐	☐	☐	☐	☐

11. How TRUE or FALSE is *each* of the following statements for you?

		Definitely true	**Mostly true**	**Don't Know**	**Mostly false**	**Definitely false**
a.	I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
b.	I am as healthy as anybody I know	☐	☐	☐	☐	☐
c.	I expect my health to get worse	☐	☐	☐	☐	☐
d.	My health is excellent	☐	☐	☐	☐	☐

ANNEXURE 2: INFORMATION DOCUMENT

INFORMATION DOCUMENT

Title of Study: Perceived quality of life of patients with diabetes attending Out-Patient Department at Dr Yusuf Dadoo Hospital".

Good day,

Introduction: I am Dr Uwakata Ejiroghene Bishop, a fourth-year registrar in Department of Family Medicine at University of the Witwatersrand and allocated at West Rand District. The study is on **"Perceived quality of life of patients with diabetes attending Out-Patient Department at Dr Yusuf Dadoo Hospital".** Research is just the process of learning the answer to a question. In this study, the researcher wants to learn about the quality of life in patients with diabetes and the researcher will treat the participants of the study during this consultation according to the 2012 Hospital Level Standard Treatment Guidelines and Essential Medicines List.

Invitation to participate: I invite you to participate in the study aimed at assessing the perceived quality of life of patients with diabetes attending Out-Patient Department at Dr Yusuf Dadoo Hospital.

What is involved in the study: This is prospective study. It entails completing questionnaire that requires you filling out personal information that will not identify you as well as answering questions about your quality of life. The questionnaire will take about 20 minutes to complete.

Risks: There is no risk in participating in this study.

Benefits: There is no direct benefit for you to participate in this study.

Alternative procedures: There is no alternative procedure in this study.

Participation is voluntary and you may withdraw from this study at any time without any effect on your treatment.

Confidentiality: The findings and recommendations of the study will be reported to the staff working in the Out-Patient Department and the authorities of the hospital in order to improve the quality of life of the patients with diabetes. Also, it may be published in the

peer-reviewed journal for academic purpose, In both cases, confidentiality of your personal details will be strictly observed and protected.

Contact details of researcher: Should you wish to contact the researcher at any stage regarding any information, contact Dr Yusuf Dadoo Hospital at 011 951 6290. – for further information / reporting of study related adverse events.

Contact details of HREC administrator: For direct queries, concerns or complaints regarding the ethical activities surrounding the study, contact the Administrative Officer of Human Research Ethics Committee of University of the Witwatersrand at 011 717 2700/1234/1252.

Thank you for taking the time to read this information document.

ANNEXURE 3: CONSENT FORM

Consent form: Use of Clinical Information

Dear Patient,

You are currently attending Dr Yusuf Dadoo Hospital to seek health care service. This hospital not only renders health care services but is 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 patients' records from which information is extracted and answers of questionnaires. The use of such information is subject to:

1. Approval from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. HREC protocol approval number: M160215
2. Anonymity i.e. the identity of the patient from whose file information is extracted and who answered the questionnaire is never revealed to anyone but the researcher unless specific consent is obtained to do so. The information gathered does not contain the name of the patient but only a coded number so as to maintain anonymity.

The researcher would like to obtain your consent to use information from your file and answers of questionnaire for the purpose of this research: **"Perceived quality of life of patients with diabetes attending Out-Patient Department at Dr Yusuf Dadoo Hospital".** If you choose not to give consent, this will not compromise your treatment in any way. If at any time you choose to withdraw consent, you are 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 Yusuf Dadoo Hospital at 011 951 6290.

A. Consent Given

I_____ hereby give consent for my records to be used as per the above mentioned conditions for the purposes of research.

PATIENT: _____DATE: _____

B. Consent Not Given

I _____ do not give consent for my records to be used.

PATIENT: _____DATE: _____

ANNEXURE 4: HUMAN RESEARCH ETHICS COMMITTEE CLEARANCE CERTIFICATE

R14/49 Dr Ejiroghene Bishop Uwakata

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160215

NAME: (Principal Investigator)	Dr Ejiroghene Bishop Uwakata
DEPARTMENT:	Family Medicine Dr Yusuf Dadoo Hospital, Krugersorp, West Rand District
PROJECT TITLE:	Perceived Quality of Life of Diabetic Patients Attending the Out-Patient Department at Dr Yusuf Dadoo Hospital
DATE CONSIDERED:	26/02/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Elizabeth Reji
APPROVED BY:	Professor P. Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	23/03/2016

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 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, 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**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

ANNEXURE 5: LETTER OF PERMISSION TO CONDUCT RESEARCH FROM THE CHIEF EXECUTIVE OFFICER OF DR YUSUF DADOO HOSPITAL

Department of Health

OFFICE OF THE CHIEF EXECUTIVE OFFICER
DR. YUSUF DADOO HOSPITAL

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

ENQUIRIES : P.M. Sofohlo
TELEPHONE : (011) 951-6161
FAX : (011) 953-5952
REF NO : 1/7/2/1
E mail: : SofohloP@gpg.gov.za

Date : 16.03.2016

Attention Dr. E. B. Uwakata

The Registrar
West rand District
Krugersdorp
1740

RE: PERMISSION TO CONDUCT RESEARCH AT DR. YUSUF DADOO HOSPITAL

Research Title: Perceived Quality of Life of Diabetic Patients attending the Out Patient Department at Dr. Yusuf Dadoo Hospital

Permission is hereby given to you Dr. E. B. Uwakata to conduct research on the above mentioned topic at Dr. Yusuf Dadoo Hospital.

You are therefore expected to adhere and comply with the Ethics of research as stipulated in the research policy.

Regards

P.M. Sofohlo
CEO (Dr. Yusuf Dadoo Hospital)
Date: 2016/03/16

Dr. YUSUF DADOO HOSPITAL PRIVATE BAG X2006 2016 -03- 16 KRUGERSDORP 1740 CHIEF EXECUTIVE OFFICER

ANNEXURE 6: LICENCE AGREEMENT TO USE SF-36V2 QUESTIONNAIRE

APPENDIX B

OPTUM™

LICENSE AGREEMENT - DETAILS

Licensee: University of the Witwatersrand
Bishop Uwakata
PO Box 2013
Bertsham, Gauteng 2013

License Number: QM038405
Amendment to: N/A
Study Term: 12/15/16 to 12/14/17

Approved Purpose
Perceived quality of life of patients with diabetes attending the Out Patient Department at Dr Yusuf Dadoo Hospital.

Licensed Surveys (Modes) and Services:

Item	Description	Mode of Admin	Quantity
PROJ01	License Fee		1
ADMINS	Administrations		400
ES0220	SF-36v2, Standard Recall	Paper	1

Approved Languages:
South Africa (English)

SS100	Scoring Software v5		1
SS108	SS v5 Key: SF-36v2		400
EM125	SF-36v2 User's Manual 3rd Ed.		1

Approved Languages:
United States (English)

TOTAL FEES: **0.00 USD**