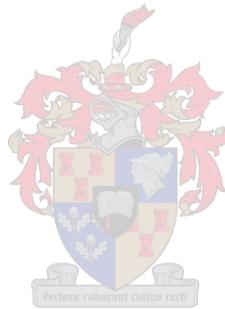


**ASSESSMENT OF THE PERCEIVED IMPACT OF
DIABETES ON QUALITY OF LIFE IN A GROUP OF
SOUTH AFRICAN DIABETIC PATIENTS**

LEANNE KATZENELLENBOGEN



Thesis presented in partial fulfillment of the requirements for the degree of
Master of Nutrition at Stellenbosch University

Project study leaders:

Dr Rene Blaauw
Dr Nelia Steyn

DECEMBER 2008

Declaration

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the owner of the copyright thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

Date: 21 November 2008

ACKNOWLEDGEMENTS

The author would like to thank all those patients at the diabetic clinic in Alberton who agreed to participate in this study. I would also like to thank the management of the Union hospital who gave their full support and allowed the opportunity to complete this study. Thanks also go to Dr Blaauw (study leader) and Dr Steyn (study co-leader) for all their help and support throughout this process; to Sr J Lubbe for her unquestioning participation and help in order to gather the data; to Dr A Kok for allowing us to engage her patients in this study and for allowing us full access to any medical information needed to make this data set complete. Finally I would like to thank my personal support system who supported and put up with me.

ABSTRACT

OBJECTIVES: To determine perceived Quality of Life (QOL) of the diabetic patient and to assess whether QOL is associated with diabetes-related markers.

DESIGN: This was a descriptive cross sectional study.

SETTING: A multiethnic group of type 1 and 2 diabetic patients (n= 68) attending a diabetic clinic in Alberton, South Africa, were evaluated.

SUBJECTS OUTCOME MEASURES: QOL was assessed by means of the Audit of Diabetes-Dependant Quality of Life (ADDQoL) questionnaire. Glycaemic control, duration of Diabetes Mellitus (DM), type of DM, diabetic complications, level of education and nutritional status were evaluated.

RESULTS: Ninety eight percent of diabetic patients perceived their DM to impact negatively on their QOL ($p=0.03$). QOL and glycaemic control were significantly ($p=0.03$) related. QOL and the duration ($p=0.80$) or type ($p=0.77$) of DM were not significantly related. QOL ratings were lower in participants who had hypertension and hyperlipidaemia, whereas this trend was not present in those with microvascular complications. There was a trend towards a negative relationship between QOL and weight ($p=0.10$), BMI ($p=0.10$) and WC ($p=0.41$). All 13 individual life domains were significantly related ($p < 0.05$) to QOL for the group as a whole. Rankings of individual life domains differed between type 1 and type 2 diabetics ($p<0.05$) as well as between black and white subjects ($p<0.05$).

CONCLUSIONS: These results show that DM impacts on various aspects of QOL and that various population sub-groups perceive their DM to impact differently on their QOL. QOL assessments should therefore form part of DM management and should be culturally sensitive.

OPSOMMING

INLEIDING: Om die bespeurde lewenskwaliteit van diabetiese pasiënte te bepaal en om te bepaal of dit geassosieer kan word met diabetes-verwante merkers.

ONTWERP: ‘n Beskrywende deursnee studie.

STUDIE OMGEWING: ‘n Multi-etniese groep tipe 1 en 2 diabetiese pasiënte ($n = 68$) wat ‘n diabetes kliniek in Alberton, Suid Afrika, besoek is bestudeer.

ONDERWERP UITKOMS MAATSTAWWE: Lewenskwaliteit is deur middel van die “Audit of Diabetes-Dependant quality of Life (ADDQoL)” vraelys evalueer. Glukemiese beheer, duurte van Diabetes Mellitus (DM), tipe DM, diabetes komplikasies, vlak van opvoeding en voedingstatus is ook evalueer.

RESULTATE: Agt en negentig persent van diabetiese pasiënte het gevoel dat DM ‘n negatiewe uitwerking het op lewenskwaliteit ($p = 0.03$). Lewenskwaliteit en glukemiese beheer was beduidend gekorreleerd ($p = 0.03$). Lewenskwaliteit en duurte van DM ($p = 0.8$) en tipe DM ($p = 0.77$) was nie betekenisvol verwant nie. Lewenskwaliteit skatting was laer in hipertensiewe pasiënte en dié met hiperlipidemie, terwyl hierdie neiging nie teenwoordig was in pasiënte met mikrovaskulêre komplikasies nie. Daar was ‘n neiging na ‘n negatiewe verwantskap tussen lewenskwaliteit en gewig ($p = 0.1$), liggaams-massa-indeks ($p=0,10$) en heupomtrek ($p=0.41$). Alle individuele lewensdomeine wat ondersoek is (13 in totaal) was betekenisvol verwant aan lewenskwaliteit vir die groep as geheel ($p < 0.05$). Skattings van individuele lewensdomeine het verskil tussen tipe 1 en 2 diabete ($p < 0.05$), sowel as tussen die swart en wit studiepersone ($p < 0.05$).

GEVOLGTREKKING: Hierdie resultate dui aan dat DM verskillende uitwerkings het op verskeie aspekte van lewenskwaliteit en dat die verskillende populasie sub-groepe voel dat DM verskillende uitwerkings het op hul lewenskwaliteit. Lewenskwaliteit bepaling moet dus ‘n roetine deel uitmaak in DM bestuur en moet kultuur-sensitief wees.

LIST OF TABLES

TABLES		Page
Table 4.1:	Demographic Characteristics	21
Table 4.2:	Glycaemic Control and Medical Information	23
Table 4.3:	Anthropometrical Data	24
Table 4.4:	Frequency Table demonstrating the Perceived Quality of Life of the Study Participants	25

LIST OF FIGURES

FIGURES

Figure 4.1:	Relationship between QOL and Glycaemic control	26
Figure 4.2:	Relationship between QOL and Hypertension	27
Figure 4.3	Relationship between QOL and Hyperlipidaemia	28
Figure 4.4	Relationship between QOL and Retinopathy	28
Figure 4.5	Relationship between QOL and Neuropathy	29
Figure 4.6:	Relationship between QOL and the various levels of Education	30
Figure 4.7	Relationship between QOL and Ethnicity	30
Figure 4.8	Relationship between QOL and Weight (kg)	31
Figure 4.9	Relationship between QOL and BMI (kg/m²)	32
Figure 4.10	Relationship between QOL and Waist Circumference	32
Figure 4.11	Life Domains ranked according to their Level of Importance for the group as a whole	33
Figure 4.12	Importance of Life Domains according to Type 1 Diabetics	35
Figure 4.13	Importance Ratings of Life Domains according to Type 2 Diabetics	36
Figure 4.14	The Importance Rating of the Life Domains according to Black Subjects	37
Figure 4.15	The Importance Rating of the Life Domains according to White Subjects	38

LIST OF APPENDICES

	Page
APPENDIX 1: Demographic Information forms that were completed by the participants in the study – English	63
APPENDIX 2: Format of the ADDQoL for use in study – English	64
APPENDIX 3: Informed consent in English	68
APPENDIX 4: Demographic Information forms that were completed by the participants in the study – Afrikaans	72
APPENDIX 5: ADDQoL format for use in the study – Afrikaans	73
APPENDIX 6: Informed Consent in Afrikaans	77
APPENDIX 7: The Medical Information form that was completed by the researchers	81

LIST OF ABBREVIATIONS

ADDQoL	Audit of diabetes-dependant quality of life
QOL	Quality of life
DM	Diabetes Mellitus
PAID	Problem Areas in Diabetes
DTSQ	Diabetes Treatment Satisfaction Questionnaire
DDRQOL	Diabetes Diet-Related Quality of Life
DHP	Diabetes Health Profile
HbA1c	Glycosylated haemoglobin
WC	Waist circumference
BMI	Body mass index
CODE-2	The Cost of Diabetes in Europe – Type 2 study
DAFNE	Dose Adjustment for Normal Eating
	Randomized Control Trial

TABLE OF CONTENTS

	Page
DECLARATION OF AUTHENTICITY	ii
ACKNOWLEDGEMENTS	iii
ABSTRACT	iv
OPSOMMING	v
LIST OF TABLES	vi
LIST OF FIGURES	vii
LIST OF APPENDICES	viii
LIST OF ABBREVIATIONS	ix
CHAPTER 1: STUDY INTRODUCTION AND PROBLEM STATEMENT...	1
1. 1 DIABETES MELLITUS AND QUALITY OF LIFE.....	2
1. 2 THE CONCEPT OF DIABETES QUALITY OF LIFE ASSESSMENT.....	2
1. 3 WHAT IS CURRENTLY KNOWN IN THE LITERATURE.....	3
1. 4 DIABETES QUALITY OF LIFE QUESTIONNAIRES.....	3
1. 5 RATIONALE FOR THIS STUDY.....	4
1. 6 SIGNIFICANCE OF THE STUDY.....	4
CHAPTER 2: LITERATURE OVERVIEW.....	5
2.1 BACKGROUND.....	6
2.2 QOL ASSESSMENT TOOLS.....	6
2.3 QOL IN THE DIABETIC PATIENT.....	8
2.3.1 Glycaemic Control.....	8
2.3.2 Duration of Diabetes.....	9
2.3.3 Anthropometry.....	10
2.3.4 Demographic Markers.....	10

2.4	CHOICE OF QUESTIONNAIRE.....	11
CHAPTER 3: METHODOLOGY.....		13
3.1	STUDY AIM.....	14
3.2	STUDY OBJECTIVES.....	14
3.3	HYPOTHESIS	14
3.4	STUDY DESIGN.....	14
3.5	STUDY POPULATION.....	15
3.5.1	SAMPLE SELECTION AND SAMPLE SIZE ESTIMATION.....	15
3.5.2	INCLUSION AND EXCLUSION CRITERIA.....	15
3.6	METHODS OR DATA COLLECTION.....	15
3.6.1	Procedure Followed	
3.6.2	Demographic Information	15
3.6.3	Glycaemic Control and Medical Information.....	16
3.6.4	Anthropometry	16
3.6.5	ADDQoL Questionnaire.....	16
3.6.6	Pilot Study.....	17
3.7	ANALYSIS OF DATA.....	18
3.7.1	Glycaemic Control.....	18
3.7.2	Anthropometry.....	18
3.7.3	ADDQoL Questionnaires.....	18
3.7.4	Statistical Analysis.....	19
3.8	ETHICS	20
3.8.1	Ethics Approval	20
3.8.2	Informed Consent.....	20
3.8.3	Anonymity.....	20
CHAPTER 4: RESULTS.....		21
4.1	SAMPLE CHARACTERISTICS.....	22
4.1.1	Demographic Characteristics of the Study Population.....	22
4.1.2	Glycaemic Control and Medical Information of the Study Population....	23

4.1.3	Anthropometry.....	24
4.2	PERCEIVED QOL.....	25
4.3	RELATIONSHIP OF QOL DIABETES ASSOCIATED MARKERS.....	26
4.3.1	QOL versus Glycaemic Control.....	26
4.3.2	QOL versus Duration and Type of Diabetes Mellitus.....	27
4.3.3	QOL versus Complications.....	27
4.3.4	QOL versus Demographic Markers	30
4.3.5	QOL versus Nutritional Status.....	32
4.4	CORRELATION ANALYSES FOR THE INDIVIDUAL QOL DOMAINS...34	
4.4.1	For the Group as a Whole.....	34
4.4.2	For Type 1 and Type 2 Diabetics.....	36
4.4.3	For the Ethnic Groups.....	38
	CHAPTER 5: DISCUSSION.....	40
5.1	DEMOGRAPHIC CHARACTERISTICS.....	41
5.2	GLYCAEMIC CONTROL AND MEDICAL CHARACTERISTICS.....	41
5.2.1	Glycaemic Control	41
5.2.2	Medical Characteristics.....	42
5.3	PERCEIVED QUALITY OF LIFE	43
5.4	QOL VERSUS GLYCAEMIC CONTROL.....	44
5.5	QOL VERSUS DURATION AND TYPE OF DIABETES MELLITUS.....	45
5.5.1	Duration of Diabetes.....	45
5.5.2	Type of Diabetes.....	45
5.6	QOL VERSUS COMPLICATIONS.....	46
5.7	QOL VERSUS DEMOGRAPHIC MARKERS.....	47
5.7.1	QOL versus Education Level, Age and Gender.....	47
5.7.2	QOL versus Ethnicity.....	48
5.8	QOL VERSUS NUTRITIONAL STATUS	49
5.9	INDIVIDUAL QOL DOMAINS.....	50
5.9.1	For the Group as a Whole.....	50
5.9.2	For Type 1 and Type 2 Diabetics.....	52
5.9.3	For the Ethnic Groups.....	53

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS	54
6.1 CONCLUSIONS	55
6. 2 RECOMMENDATIONS.....	57
6.3 LIMITATIONS.....	58
REFERENCES	60
APPENDICES	65

CHAPTER 1

STUDY INTRODUCTION AND PROBLEM STATEMENT

1.1 DIABETES MELLITUS AND QUALITY OF LIFE

Diabetes Mellitus (DM) and its related complications have grown exponentially in the last few years.¹ The increasing numbers of patients diagnosed with diabetes each year results in increased costs placed on health services to manage these patients. The treatment of DM is expensive and complex and requires constant education and vigil on the part of the practitioner and patient respectively. In addition, DM also plays a huge role in health-related quality of life (QOL) as it poses many lifestyle demands and debilitating complications and can sometimes be difficult to live with. Many patients find the demands of DM exasperating, taxing and overwhelming.²

1.2 THE CONCEPT OF DIABETES QUALITY OF LIFE ASSESSMENT

There is a growing interest in understanding and making use of the concept of a DM specific quality of life (QOL) assessment.³ This interest stems from the knowledge that health related QOL is an essential component in clinical care of health associated issues. In order to be successful, medical intervention should not only control overt symptoms, but should also aim to influence the patient's future well being. This necessitates that the medical care that is provided not only looks at clinical outcomes, but that the care becomes more patient-focused by incorporating the patient's own perspective on their health. In the efforts to prevent diabetic complications the impact of the condition and its impact on QOL are often overlooked.³

Health related QOL is known to impact on people living with both type 1 and type 2 DM. There are three main aspects which should be considered when assessing health related QOL. These include physical impact, psychosocial aspects and social functioning of the patient.¹

1.3 WHAT IS CURRENTLY KNOWN IN THE LITERATURE

Several studies have been undertaken to address these issues of QOL.^{1,4,2} Within these studies several health related questionnaires have been developed, looking at health related outcomes and several other outcomes such as depression, social functioning, marital relationships, physical functioning and other psychological variables thought to be associated with DM. The questionnaires that have been used in these studies do not necessarily focus on all these aspects but may have been designed to investigate one or more of these features. Some of these studies have found that DM impacts on health related QOL in several different ways. Rose et al⁴ found that those patients who believed in their self-efficacy and were optimistic about life had a higher QOL and in turn were better able to achieve their treatment goals.⁴ Researchers at the Institute for Behavioral Studies in Istanbul⁵ showed that coping with diabetes-related issues is an important factor, in both type 1 and type 2 DM, and that patients might benefit from programs that include coping strategies as part of their care. By the same token, West and McDowell⁶ recommend that health care professionals should be aware of factors influencing adaptation to living with diabetes since they impact on behavioral and emotional functioning.⁶

1.4 DIABETES QUALITY OF LIFE QUESTIONNAIRES

There are a considerable number of patient self-assessed measures of health outcome that are specific to DM. Due to the widespread availability of these DM related QOL questionnaires, several review articles were evaluated in order to determine which of those is most appropriate to use in this study based on their applicability, their reliability, validity and their relation to the question being asked.^{7; 8; 9} The audit of diabetes-dependant quality of life (ADDQoL) appeared to best meet these criteria. The researchers who designed the questionnaire, Bradley et al, gave consideration to the content and face validity, as well as to testing for construct validity.² The questionnaire was validated in a sample of 67 adult out-patients attending the diabetes clinic at Addenbrooke's Hospital in Cambridge. The audit of diabetes-dependant quality of life (ADDQoL) was chosen for use in this study and has been deemed one of the most promising instruments available for use, by several authors and several review articles.^{7; 8; 9}

1.5 RATIONALE FOR THIS STUDY

Due to the potential impact of DM on perceived QOL, this study was undertaken in order to assess this effect in a group of urban South African patients with DM. The current methods of care tend to exclusively consider the physical burdens of the disease while ignoring the personal, psychological and social aspects of the disease and how it impacts on the patient.¹⁰ The primary motivation and aim for this study was therefore to determine the psychosocial impact of DM in a group of South Africans with DM and to see if the disease impacts on their psychosocial functioning.

1.6 SIGNIFICANCE OF THE STUDY

The findings of the study would enable health care professionals to obtain a broader picture of the psychological impact of DM on the patients in this country. This knowledge will then offer further insight as how to care for these patients and thereby improve the overall care of patients. Currently the primary focus of DM management centres on the clinical management of the patients with respect to good blood glucose control and prevention of complications, with generally little attention being paid to the psychological impact of the disease. It therefore seemed prudent to assess the situation with a view to incorporating a psychosomatic aspect to patient care. The findings of this study will hopefully provide insight into the psychological impact of DM on diabetic patients living in an urban centre in this country. This knowledge may contribute to the overall care of diabetic patients in South Africa by enabling practitioners to implement interventions with the use of population specific data.

CHAPTER 2

LITERATURE OVERVIEW

2.1 BACKGROUND

Diabetes is a worldwide epidemic that is affecting millions of people across the globe. The etiology of diabetes is multi-factorial and it is thought that several factors including genetics, immunology and lifestyle play a role in the pathophysiology of DM.¹¹ At diagnosis patients are classified as having either type 1 or type 2 diabetes. Type 1 diabetics are dependant on insulin, as they produce little or no insulin themselves and are often diagnosed before the age of 30.¹¹ Type 2 diabetics are often not dependant on insulin and lifestyle factors such as obesity, poor diet and inactivity usually play a role in the development of this type of diabetes.¹¹ The incidence of DM varies among different ethnic groups and across the different age groups. It is suggested that in America DM affects approximately 16 million people.¹¹ In South Africa studies suggest that DM is a non-communicable disease and can lead to other non-communicable diseases such as hypertension and coronary artery disease¹² and research has shown that the incidence of DM in rural areas may be as high as 12%.¹³ Diabetes contributes to an increase in morbidity and mortality and is associated with several microvascular as well as macrovascular complications, such as hyperlipidaemia, hypertension, retinopathy, neuropathy and nephropathy.¹¹ In our efforts to prevent these complications clinicians tend to concentrate on outcome and biochemical markers and often overlook the fact that diabetes may have an impact on the QOL of the person.^{3, 14}

Several studies have evaluated the impact that diabetes has on aspects of health-related QOL^{1, 3, 4} in order to see if DM does have an impact on perceived QOL. In addition, many studies have considered other variables such as time from diagnosis, type of diabetes, type of medication, complications, anthropometrical data as well as biochemical markers of diabetes control to be potentially important determinants in terms of QOL perceptions.^{1, 15, 16, 17}

2.2 QOL ASSESSMENT TOOLS

As it becomes more widely recognized that chronic conditions are associated with a decrease in quality of life, QOL assessments are being utilized alongside traditional

interventions in an attempt to uncover the reasons for this decline.² These QOL assessments are also being utilized as a tool to improve QOL of these patients.² It has been recognized that in developing these assessment tools that these tools need to be diseases specific, situation specific and population specific.² As a result of this several questionnaires have been designed, re-designed and improved upon as the knowledge of this field has grown.² It has also been recognized that QOL perceptions are multifactorial and are made up of many multidimensional components. For this reason, several researchers have attempted to design assessment tools that uncover these various aspects that make up the globally termed “quality of life”. Each of these questionnaires was carefully designed to uncover specific aspects of diabetes-related QOL. Several of these questionnaires are commonly used throughout the literature and serve as examples of the diversity within this area of research.

The Problem Areas in Diabetes (PAID) questionnaire was designed to look at the emotional distress experienced by the DM patient as a consequence of their diabetes.⁶ The Diabetes Treatment Satisfaction Questionnaire (DTSQ) assessment tool was developed to explore patients’ perceptions of their treatment and their satisfaction thereof, as well to find out how patients perceive the frequency of their hyperglycaemia and hypoglycaemic events.⁹ On a different note the Diabetes Diet-Related Quality of Life (DDRQOL) assessed the impact of diet on the type 2 diabetic patient’s QOL.¹⁸ The results of the study suggest that this assessment tool will enable researchers to determine the effectiveness of diet education from the point of view of QOL.¹⁸ On the other hand the Diabetes Health Profile (DHP)-1 and DHP-18 were specifically designed to look at QOL issues in the type 1 and type 2 diabetic patients, respectively.⁹ These are just a few examples of the multitude of questionnaires that are available and they highlight the complexities surrounding the QOL issues in these patients.

The ADDQoL looks at yet another aspect that makes up the very complex issue of diabetes-related QOL. The ADDQoL attempts to assess the perceived impact of DM on QOL measures. The ADDQoL measures this impact by assessing diabetes in terms of physical functioning, symptoms, psychological well-being, social well-being, role activities, and personal constructs.²

One common thread throughout all these assessment tools is the fact that DM is consistently associated with a decline in QOL measures. West and McDowell made use of the PAID questionnaire to investigate the distress experienced by people with type 2 DM.⁶ They found that worrying about the future, the possibility of complications and feelings of guilt and anxiety were significant sources of distress.⁶ They also found that the type of treatment, the length of diagnosis and age were significantly associated with the distress experienced by this population group.⁶ The DTSQ has demonstrated differences in satisfaction between patients who are treated with different insulin regimes.³ The Edinburgh Prospective Diabetes Study also made use of the DTSQ and showed that neuroticism, psychiatric distress and personality accounted for a large portion of the variation in diabetes QOL at 12 months after diagnosis.¹⁹

As the knowledge of this area of research is progressing researchers are realizing that there are intrinsic faults in many of these questionnaires.² Certain questionnaires have little relevance for people with DM because they are generic and certain instruments have focused on areas which have subsequently been identified to have less relevance and cause less concern for these patients.² The authors of the ADDQoL questionnaire acknowledged that although there are several questionnaires available that many of these questionnaires do not allow the patients to identify which aspects of life apply to them and in turn, which of these aspects are most important to them, thereby taking a more individualized approach.²

The ADDQoL questionnaire enabled researchers to investigate individual domains that are relevant to the diabetic patient and to uncover which of these impacts most on their perceived QOL.² The ADDQoL investigated domains such as enjoyment of food, worries about the future one self and one's family, the impact of their diabetes on sport and leisure activities as well as social life and travel.² The authors suggest that this approach enables the researchers to identify change over time and to look more closely at sub-groups of patients as opposed to a generic instrument that may not be as sensitive to these domains.² The study showed that diabetes has the greatest impact on enjoyment of food, worries about the future and travel and that social life, worries about friends and family had less impact on their perceived QOL.²

2.3 QOL IN THE DIABETIC PATIENT

2.3.1 Glycaemic Control

The primary goal in diabetes management is to ensure that levels of blood glucose control are as close to normal as possible in order to ensure desired metabolic outcomes and to prevent complications later on.¹¹ These goals are obtained by a combination of the correct medication dosage, diet and exercise. This long term glycaemic control is measured by the results of glycosylated haemoglobin tests. In diabetics, the glycosylated haemoglobin (HbA1c) levels are an average of the past three months' blood glucose levels. This value has been correlated to several of the diabetes-related QOL measures in order to see if the two are in fact related in any way.

A longitudinal study on glycaemic control and QOL in patients with type 2 diabetes showed that reductions in HbA1c after 2 years of treatment also improved QOL in this population group.²⁰ Similarly, the DIAB.&TE.S Project assessed a wide range of patients who were taking either insulin, oral agents or both and they found a correlation between QOL and metabolic control.²¹ These findings are supported by Ahlgren et al²² who also found significant correlations between glycaemic control and QOL in diabetic patients. In a Chinese population group, researchers showed that both fasting blood glucose levels as well as 2-hour post oral blood glucose levels were related to QOL measures.²³ In addition to these several other studies have found a relationship between the two^{14, 24} and although in the minority, others have not found this to be the case.^{16, 17}

2.3.2 Duration of Diabetes

The duration of DM as well as the type of DM and the complications brought about from the disease have also been thought to play a role in the patient's perceived QOL. The studies show that complications are almost universally associated with a negative impact on QOL.^{3, 25} Data is also available showing that those diabetics treated with insulin as well as those who are not insulin dependent felt that their DM impacted on their QOL.^{3,}

The correlation between DM duration and QOL scores is not as consistent as with glycaemic control. Wang et al²³ reported that in their population group the duration of the disease was significantly correlated with QOL scores. In contrast results of a Swedish based population study²⁶ as well as subjects in Kuwait²⁷ reported that disease duration was not related to QOL measures.

2.3.3 Anthropometry

Body mass index (BMI) and waist circumference (WC) are commonly used nutritional markers since they have been clearly established as independent predictors of cardiovascular disease as well as type 1 and type 2 DM. Both BMI and WC have been implicated by a large body of evidence in the pathogenesis of numerous metabolic risk factors, including DM. This observation has led to several recommendations that these two anthropometric measures be routinely used to identify those with increased health risk and be routinely monitored in those with DM.²⁸

As a result of this relationship these nutritional markers have been assessed by several researchers in terms of their relationship with QOL measures. These analyses generally found that obesity was associated with a lower health-related QOL.^{15, 16} The relationship between QOL and the other anthropometric measures are inconsistent. In a study looking at well-being and treatment satisfaction in adults with DM, researchers found that BMI and QOL sub-scales were not correlated.²⁶ In contrast to this researchers in Italy found that a lower BMI corresponds with a more satisfactory QOL score.²⁹ Similarly, in a study assessing the weight-related QOL in obese persons with type 2 diabetes, researchers reported a statistically significant correlation between weight-related QOL and BMI.³⁰ In terms of the relationship between WC and QOL there is a relative lack of information. The one study which does make reference to the correlation between QOL and WC is a study which looks at the relationship between QOL and weight loss in obese patients treated with a weight reducing agent.³¹ The study reported that those patients who received the weight reducing agent had significantly greater reduction in both BMI as well as WC and subsequently also showed a significant improvement in weight related QOL.³¹

2.3.4 Demographic Markers

Level of education may also have a role to play in terms of QOL. In a study in Greece³², researchers found that those patients with a lower level of education had a poorer knowledge regarding their DM and worsening of hypoglycaemic symptoms. In Iran³³ researchers showed that personal background characteristics such as the presence of medically educated people in the family, whether or not the patient was the breadwinner and unemployment account for a large amount of the variation in QOL. Based on the knowledge that several demographic variables and QOL seem to be inter-related it would therefore seem appropriate to assess the situation in our own country and to evaluate whether or not level of education impacts on QOL in the South African population.

Ethnic differences have also been identified as playing a role in reported QOL. Researchers identified that there are ethnic differences in QOL measures amongst Chinese, Malay and Indians residing in Singapore.³⁴ The Indian participants in the study reported higher psychological scores whereas the Chinese participants scored higher on physical as well as independence scores.³⁴ In a study looking at the perceived QOL in patients following renal transplant, researchers showed that there are ethnic differences in reported QOL.³⁶ The study investigated several dimensions of QOL, which included physical health, mental health and patient satisfaction.³⁵ The study demonstrated several differences in perceived QOL amongst the various ethnic groups within the study. QOL scores were significantly lower for Indio-Asians for both physical health as well as mental health scores compared to their white European counterparts.³⁵

Similarly, a systemic review of diabetes self-care interventions for adults with varying cultural backgrounds showed that cultural differences in these patients need to be identified in order for the interventions to be successful.³⁶ These studies highlight the need for interventions to be culturally acceptable and that when using a QOL questionnaire in different cultural groups that these questionnaires should be validated beforehand in order to ensure their cultural acceptability and appropriateness.

2.4 CHOICE OF QUESTIONNAIRE

In the above mentioned literature several different questionnaires were used by the different researchers. These instruments were designed with the aim of identifying health-related QOL and in particular the impact that DM has on health-related QOL issues.⁹ These instruments have however been criticized as many of them have intrinsic flaws or have failed to adequately measure the desired outcomes.⁹ When deciding on which instrument one would use there are several key criteria which should be filled. It is essential that the questionnaires be tested for reliability and validity (both internal and external). When commencing studies that involve both type 1 and type 2 diabetics it is essential that these questionnaires are disease specific and that they are applicable to both groups.⁹ These instruments have been assessed and reviewed and certain of them have been suggested for use as they have good reliability and validity, are disease specific and should the questionnaire be used again in the future, that the instrument has good responsiveness to change. Of these questionnaires the ADDQoL has been chosen for use in this study as it appears to best meet the criteria of this study.

CHAPTER 3

METHODOLOGY

3.1 STUDY AIM

The aim of the study was to evaluate the QOL of a multiethnic group of type 1 and 2 diabetic patients attending a diabetic clinic in Alberton, South Africa.

3.2 STUDY OBJECTIVES

- To determine the perceived QOL of the diabetic patient
- To assess whether or not the QOL measure is related to the diabetic patient's glycaemic control
- To assess whether or not the QOL measure is related to the duration of diabetes mellitus (DM)
- To assess whether or not the QOL measure is related to the type of diabetes mellitus
- To assess whether or not the QOL measure is related to diabetic complications
- To assess whether or not QOL is related to level of education
- To assess whether or not the QOL measure is related to nutritional status i.e. weight, body mass index and waist circumference
- To assess whether or not QOL is related to ethnicity of the diabetic patient

3.3 HYPOTHESIS

It was hypothesized that diabetes has no impact on the perceived QOL of the diabetic patient and therefore does not impact on glycaemic control. In addition the null hypothesis assumes that QOL in the diabetic patient is not related to duration of DM, to the type of DM, to diabetic complications, to level of education, to ethnicity, to nutritional status nor to morbidity indicators.

3.4 STUDY DESIGN

This study was designed as a descriptive cross sectional study

3.5 STUDY POPULATION

3.5.1 SAMPLE SELECTION AND SAMPLE SIZE ESTIMATION

The participants were selected for the study by means of non-random quota sampling. The data was collected over a period of eight months. In order to determine the size of the study population, the statistician calculated that the study should include 400 patients. This number was calculated based on the number of patients needed for this study to be ideally powered.

3.5.2 INCLUSION AND EXCLUSION CRITERIA

The study comprised of a multiethnic group of type 1 and 2 adult diabetic patients between the ages of 20 and 65 years that attended a private care diabetic clinic in Alberton, Gauteng and who live in urban communities. The study sample included male and female patients, at various stages of diagnosis e.g. newly diagnosed versus been diabetic for several years. Those patients with or without complications were included in the study.

Adolescents and elderly patients were not included in the study since their experiences would differ from that of an adult patient and would therefore have separate issues that may impact on quality of life e.g. school; family neglect etc. In addition the study protocol excluded those patients who were mentally incapacitated as the completion of the questionnaire requires a certain level of coherence in order to complete it, although when collecting data this situation was not encountered.

3.6 METHODS OF DATA COLLECTION

3.6.1 Procedure Followed

Patients arrived at the diabetic clinic for their regular visit with the diabetic educator or the dietitian. While waiting in the reception area for their appointment, the patient was asked whether or not they wanted to participate in the study. Once they agreed, the study

terms and procedures were explained and informed consent was obtained from all patients. While still sitting in the reception area, the patient completed the ADDQoL questionnaire as well as the demographic questionnaire. Once these forms were complete, each questionnaire was coded by assigning each patient with a number, in order to maintain their anonymity and for data capturing purposes. Anthropometric measurements such as weights, heights and WC were taken during the scheduled appointment. This was not unique to this study and formed a routine part of their appointment. Any blood samples taken also formed a routine part of the consultation for these patients e.g. HbA_{1c} values were routinely obtained for all patients at the clinic regardless of whether they were study participants or not. Once all the questionnaires had been completed and the anthropometric measurements had been recorded, the data was entered into the computer for future analysis.

3.6.2 Demographic Information

The demographic characteristics of the study group were obtained by means of a questionnaire. These questionnaires were available in both English (Appendix 1) and Afrikaans (Appendix 4). This information was completed by the participants at the same time as the ADDQoL questionnaire.

3.6.3 Glycaemic Control and Medical Information

In order to establish whether or not the perceived QOL is related to glycaemic control, HbA_{1c} (glycosylated haemoglobin) values were obtained for each patient. HbA_{1c} values were used as the target biochemical marker for the effectiveness of clinical management of diabetes.¹ These values are done routinely and were available for all patients either at the diabetic clinic or in the physician's patient files.

Any relevant medical history was also obtained from medical files. Information such as duration of DM, type of DM, complications and concomitant conditions were also obtained from medical files.

3.6.4 Anthropometry

Weight (kg) and height (cm) were obtained for each patient. These were performed by both the diabetes educator, as well as the dietitian at the time of consultation. Weights were measured on a scale and were taken with the patient wearing light clothing and without shoes and were taken to the nearest 0.1kg. An average of two measurements was taken for each patient. Height was measured using a wall-mounted height measure. Heights were measured to the nearest 0.5cm with the patient standing upright. Patients were asked to take their shoes off and to keep their heads upright in order that the most accurate measurement could be taken. An average of two measurements was taken for each patient. Body mass index (BMI) values were calculated using the equation $\text{weight (kg)}/\text{height}^2(\text{m})$.²⁸ Waist circumference (WC) was measured in all patients. WC was measured at the level of the last rib while subjects were in a standing position.²⁸ An average of two measurements was taken for each patient, to the nearest 0.1cm.²⁸ Patients were asked to take off as many layers of clothes as possible in order that the most accurate measurement could be taken.

3.6.5 ADDQoL Questionnaire

The test was in the form of a self administered questionnaire known as the Audit of Diabetes-Dependant Quality of Life (ADDQoL). This is a 15-item scale comprising of a list of 13 life domains that might affect: employment/career opportunities; social life; family relationships; friendships; sex life; recreational activities; ease of travel; personal worries about the future; worries about the futures of family and friends; motivation to achieve things; physical activities; potential loss of independence and eating enjoyment.² Patients were asked on a 7-point Likert scale to indicate to which extent each domain might affect their life if they did not have diabetes. Scores range from -3 to +3 indicating that their lives would be a great deal better or worse, respectively. Patients were then asked to rate each domain ranging from very important to not important at all.

The questionnaire was completed by the patients when they attended the diabetic clinic. The patients were asked to complete the questionnaire, in the reception area of the clinic, while waiting for their appointment with either the dietitian or the diabetic educator. The

patients were offered the questionnaires in either English (Appendix 2) or Afrikaans (Appendix 5), depending on which language they were more proficient in. Although there were also participants whose first language was neither English nor Afrikaans, there were no problems with the comprehension of the questionnaires. In addition help was available at all times if the need arose for clarification or if the patient needed help filling in the questionnaire.

3.6.6 Pilot Study

The questionnaire had been validated by Bradley et al ² and was validated for face validity in this study prior to its commencement in the form of a pilot study. Six questionnaires, 3 English and 3 Afrikaans, were utilized as part of this validation during the pilot study. The subjects who participated in the pilot study were recruited in the same manner as those who participated in the study. The pilot questionnaires were completed while sitting in the waiting room before their consultation. The pilot study was only done to test the ADDQOL questionnaire.

The questionnaire was well accepted. The participants felt that the questionnaire was easy to understand and they confirmed that the layout was acceptable. The overall response to the study was positive as the participants felt that the questionnaire was relevant and that they were happy to have an opportunity to bring these issues out into the open, as they are not usually discussed. The result of the pilot study was that the questionnaire could be used in the format that was proposed in the initial protocol without any changes. For this reason, those questionnaires completed during the pilot study, were included in the final analysis.

3.7 ANALYSIS OF DATA

Data was captured electronically using Microsoft Excel® spreadsheets and the researcher controlled for precision of data transfer with regular cross-referencing.

3.7.1 Glycaemic Control

The goal of therapy is a haemoglobin (HbA1c) within the normal range (<6.05%).³⁸ This HbA1c level corresponds to mean blood glucose levels of 5mmol/l. In diabetics, the glycosylated haemoglobin (HbA1c) levels are an average of the past three months' blood glucose levels and are used to indicate how well controlled the patient is in terms of their blood glucose levels.¹¹ A mean of these values was calculated for this study population in order to determine how well controlled the group was as a whole as well as for males and females within the group.

3.7.2 Anthropometry

Body mass index (BMI) was calculated for all patients using the formula weight (kg)/height²(m²). Subjects were then classified into groups on the basis of their BMI and WC status according to standard classification standards.²⁸

For BMI the cutoffs proposed by the World Health Organization were used: BMI 18.5 – 24.9 is normal; BMI 25.0 – 29.9 is overweight; BMI 30.0 – 34.9 is class I obesity and BMI \geq 35 is class II obesity.²⁸

The cut-offs proposed and adopted by the World Health Organization were used for WC: low risk = \leq 79cm in women and \leq 93cm in men; increased risk = 80 – 87cm in women and 94 – 101cm in men; substantially increased risk = \geq 88cm in women and \geq 102cm in men.²⁸

3.7.3 ADDQoL Questionnaires

A score (impact rating) was assigned to each response option. The scores range from -3 (a great deal better) to +3 (a great deal worse) for each domain. A corresponding importance rating was also assigned to each domain, which was then multiplied by the impact rating. In this way the scores for each domain were weighted according to their importance in the individual's life. There was also an available N/A option. If the

individual decided that the specific domain was not applicable then the domain was excluded from the scoring. The weighted scores were then summed and divided by the number of applicable domains. There were two overview items included in the questionnaire to provide single item indicators of QOL per se and impact of DM on QOL.

Weighted rating = unweighted rating (-3 to +3) x importance rating (0 – 3) for each domain. Unimportant domains score 0 regardless of the magnitude of the effect of diabetes. Domains unaffected by diabetes score 0 regardless of their importance for QOL.

ADDQoL score = \sum weighted rating / number of applicable domains

Scores could therefore vary from -9 (maximum negative impact of diabetes) to +9 (maximum positive impact of diabetes).²

Using this system, mean scores were obtained for each individual domain and a total QOL score was obtained. Individual life domains were ranked according to which were more or less important for the group as a whole and for sub-groups within the study e.g. black and white patients; type 1 and type 2 diabetics.

Once each questionnaire was completed each form was assigned a number and this “code” was used to represent the patient. In this way, anonymity of the patient was maintained at all times.

3.7.4 Statistical Analysis

The analyses were done by using StatSoft Inc. (2004) STATISTICA, version 7 (www.statsoft.com). Correlation analyses were used to determine the relationship between QOL and glycaemic control, as well as between QOL and the duration of diabetes. Due to the fact that many of the variables were not normally distributed, non-parametric testing was used in many cases. Mann-Whitney U tests were used to compare the relationship between QOL and type of DM, as well as ethnicity. The ANOVA test was used to test for homogeneity of variance between the various complications and QOL. In addition the Bonferroni multiple comparison test was used to detect differences

between the various complications and QOL. The non-parametric F-test was used to compare QOL and level of education; HbA_{1c} and gender. Spearman rank correlation tests were used to analyze the relationship between QOL and age; weight; BMI and WC. Lastly, correlation analyses were performed to rank the various life domains according to the perceived importance to QOL. These were performed for the group as a whole, as well as for the two ethnic groups and for type 1 and type 2 DM. An initial analysis was performed to look at the correlations between the various life domains and QOL as these variables are measured on a scale.²

3.8 ETHICS

3.8.1 Ethics Approval

The study was submitted to the Committee for Human Research, Faculty of Health Sciences, that is affiliated with the University of Stellenbosch as well as to the management of Union Hospital, in Alberton, Gauteng, for their approval. University of Stellenbosch project approval number: N05/02/033.

3.8.2 Informed Consent

Consent forms were given to each patient detailing the manner of the study and assuring them that participation is voluntary and that their refusals to participate will in no way affect their subsequent care. The questionnaires were available in both English (Appendix 3) and Afrikaans (Appendix 6), depending on the participants preferred language.

3.8.3 Anonymity

The self-administered questionnaires were completed by the participants. Once the questionnaires were complete they were only seen by the researcher. The patients were asked to write down their names on the demographic questionnaire so that the HbA_{1c} values and relevant medical information could be allocated to the relevant patient but the patient was assigned a code which was entered into the computer, in order that their

confidentiality was maintained. Confidentiality and non-disclosure of information was maintained at all times.

CHAPTER 4

RESULTS

4.1 SAMPLE CHARACTERISTICS

4.1.1 Demographic Characteristics of the Study Population

Seventy three people were recruited to participate in this study. Of the 73 participants, 5 refused to participate in the study and the overall response rate was therefore 93%. The data presented here includes that of the remaining 68 participants (Table 4.1).

Demographic information was collected at the time of recruitment via a demographic questionnaire (Table 4.2). A discrepancy exists between the calculated size of the sample ($n= 400$) and the final number ($n= 68$) used in this study. This discrepancy existed due to due to time constraints of the researchers of the study i.e. the number of participants recruited for the study was less than anticipated in the time allocated for data collection. Before the data collection was prematurely ended, a statistician was consulted to ensure that the study was sufficiently powered for the outcomes of the study. Therefore, although not ideal, the sample size ($n= 68$) in this study is statistically valid and representative of the population that was tested.

Table 4.1 The Demographic Characteristics of the Study Population (n= 68)

	% of participants	n
Marital status		
Single	4	3
Married	75	46
Divorced	11	7
Widowed	8	5
Education level		
< Matric	10	6
Matric	41	24
Degree/ diploma	49	29
Gender		
Male	54	37
Female	46	31
Ethnicity		
Black	21	13
White	75	45
Indian	1	1
Mixed race	3	2

The number of males participating in the study was 37 (54%) and the number of females was 31 (46%) (Table 4.1). The females were significantly older than the males with a mean age of 52.66 (9.75) years versus 47.16 (11.11) years for the males ($p = 0.03$). The majority of the study participants were married (75%), whereas 4%, 11% and 8% were either single, divorced or widowed, respectively. The level of education among the group varied. Of the participants, 10% completed school to either grade 10 or grade 11. The remaining portion of the participants, 90% of the group, had finished school. Forty one percent of the group had completed matric (grade 12) and 49% of the participants went on to complete diplomas and/or degrees (Table 4.1), with only two of those participants achieving an honours level degree.

The ethnic make-up of the group included 75% white subjects and 21% black subjects (Table 4.1). Only 4% of the group consisted of Indian or mixed race subjects. These participants were excluded from the statistical comparisons between the ethnic groups due to insufficient numbers.

4.1.2 Glycaemic Control and Medical Information of the Study Population

Of the 68 people, 11% ($n=8$) had type 1 DM and 89% ($n=60$) had type 2 diabetes mellitus. The time from diagnosis averaged 7.43 (6.96) years, ranging between 4 months and 14 years (Table 4.2).

The subjects that took part in the study were treated, based on their level of blood glucose control, by various different treatment regimes. Patients were treated with either insulin only (37%), with insulin and tablets (30%) or with tablets only (32%) (Table 4.2). The level of control as measured by the HbA1c value for the group averaged 8.05 (2.16), with no significant difference between males and females [8.17 (2.44) % and 7.67 (1.62) % ($p = 0.60$)] respectively.

Diabetes-related complications were recorded and the results show that 21% of the group had no complications, whereas 79% of the group had one or more complications (Table 4.2). Of the complications documented in the study, 39% of the participants had elevated blood pressure; 48% had hyperlipidaemia; 6% had evidence of retinopathy; 13% had

evidence of neuropathy and none of the participants in this study were recorded as having nephropathy. All of the study participants belonged to a medical aid.

Table 4.2 Glycaemic Control and Medical information of the study population (n = 68)

	% or mean (SD)	n
Treatment regime		
Insulin only	37	23
Insulin and tablets	30	18
Tablets only	32	20
HbA₁C		
Group average	8.05 (2.16)	59
Males	8.17 (2.44)	35
Females	7.67 (1.62)	31
Type of diabetes		
Type 1	11	8
Type 2	88	60
Complications		
> 1 complication	28	17
1 complication	51	31
No complications	21	13
Duration of diabetes (yr)		
	7.43 (6.96)	61

4.1.3 Anthropometry

Body mass index could be calculated for 61 of the 68 patients (Table 4.3). The results show that the mean BMI for the group was 31(6.57) kg/m² (obese). When looking at the genders individually, males had a mean body mass index of 29 (5.22) kg/m² and the females were significantly higher at 33 (7.59) kg/m² (p = 0.01). According to the WHO definition of obesity the males in this study group are classified as being overweight, whereas the female participants are categorized as having class I obesity.²⁸

The waist circumference was recorded for 60 of the 68 subjects. The mean waist circumference for the female subjects was significantly higher at 112cm versus 102cm

for the males ($p = 0.02$) (Table 4.3). According to the cut offs proposed by the WHO these values indicate that both the males and females in this study population are at a substantially increased risk ($\geq 88\text{cm}$ in women and $\geq 102\text{cm}$ in men²⁸).

Table 4.3 Anthropometrical Data of the Study Population (n= 61)

	Mean (SD)	n
BMI (kg/m²)		
Average	31 (6.57)	61
Males	29 (5.22)	37
Females	33 (7.59)	29
Waist circumference (cm)		
Male	101.72 (12.06)	33
Female	111.92 (21.18)	27

4.2 PERCEIVED QOL

The total QOL values in Table 4.4 depict the QOL scores that were obtained by totaling the 13 life domains to reach a single score. The values in row 1 show the number of patients who rated their perceived QOL most negatively through to those in row 10 who felt that their DM had a positive impact on their QOL. Row 1 in this table shows that 3 participants (4.41% of the population) felt that their diabetes had the maximum negative impact on their lives, as they scored the questionnaires with the most negative ratings available. The results also show that the majority of the patients (98%) perceived DM to impact negatively on their QOL. Only two people (1 in row 8 and 1 in row 10) felt that DM had a positive impact on their QOL.

Table 4.4 Frequency Table Demonstrating the Perceived Quality of Life of the Study Participants (n=68)

Rating *	Total QOL From to	Count	Cumulative count	Percent	Cumulative percent
1	-9.00 to -7.95	3	3	4.41	4.4
2	-7.94 to -6.65	1	4	1.47	5.88
3	-6.64 to -5.45	4	8	5.88	11.76
4	-5.44 to -4.15	7	15	10.29	22.06
5	-4.14 to -2.95	7	22	10.29	32.35
6	-2.94 to -1.65	14	36	20.59	52.94
7	-1.64 to -0.45	21	57	30.88	83.82
8	-0.44 to 0.84	10	67	14.71	98.52
9	0.85 to 2.04	0	67	0	98.52
10	2.05 to 3.00	1	68	1.47	100.00

* 1 indicates most negative and 10 most positive

4.3 RELATIONSHIP OF QOL DIABETES ASSOCIATED MARKERS

4.3.1 QOL versus Glycaemic Control

The correlation analysis between QOL and glycaemic control (Figure 4.1) demonstrated that QOL in the diabetic patient is negatively ($r=0.259$) and significantly ($p=0.04$) related to their HbA1c results. Therefore their perceived QOL is negatively impacted if their blood sugar is not well controlled.

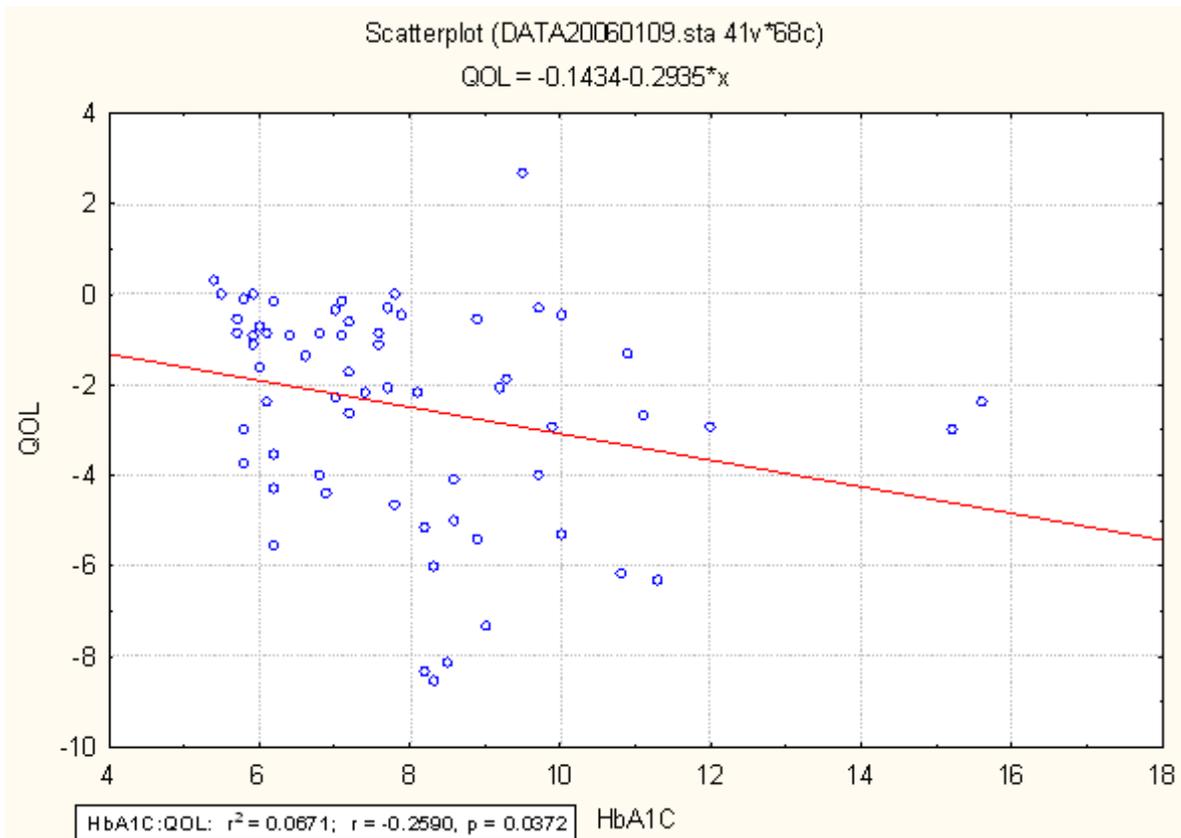


Figure 4.1: Relationship between QOL and Glycaemic control (n=65)

4.3.2 QOL versus Duration and Type of Diabetes Mellitus

A correlation analysis showed that QOL and the duration of DM are not significantly related ($r=0.03$; $p = 0.80$) in this population. In addition a Mann-Whitney analysis proved the hypothesis that total QOL is not significantly related to either type 1 or type 2 DM ($p = 0.77$) in this study group.

4.3.3 QOL versus Complications

Analyses were performed to elucidate relationships between QOL and the various diabetes-related complications (Figure 4.2 to Figure 4.5). This study looked at relationships between hypertension (n= 24) (complication 1; Figure 4.2), hyperlipidaemia (n=33) (complication 2; Figure 4.3.), retinopathy (n= 4) (complication 3; Figure 4.4), neuropathy (n=9) (complication 4; Figure 4.5) and nephropathy (n = 0) (complication 5)

and QOL. The number and type of complications were documented for all study participants (n=68). The analyses showed that QOL in this group of subjects was not significantly affected by any of the above mentioned complications. Although the study looked at five diabetes-related complications, only four complications are depicted in the graphs as none of the participants were documented to have nephropathy. When assessing these relationships, Figures 4.2 and 4.3 show that although these relationships were not significant, that there were still lower QOL ratings in those participants who had hypertension and hyperlipidaemia, whereas this trend was not present in those with microvascular complications.

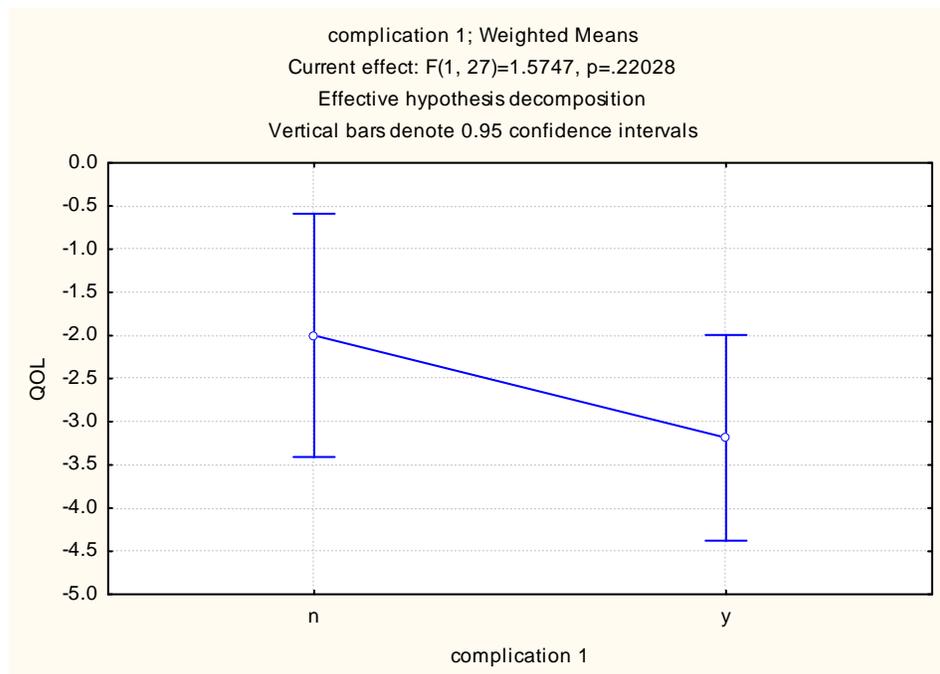


Figure 4.2: Relationship between QOL and Hypertension (n= 68)

n = hypertension was not present; y = hypertension was present

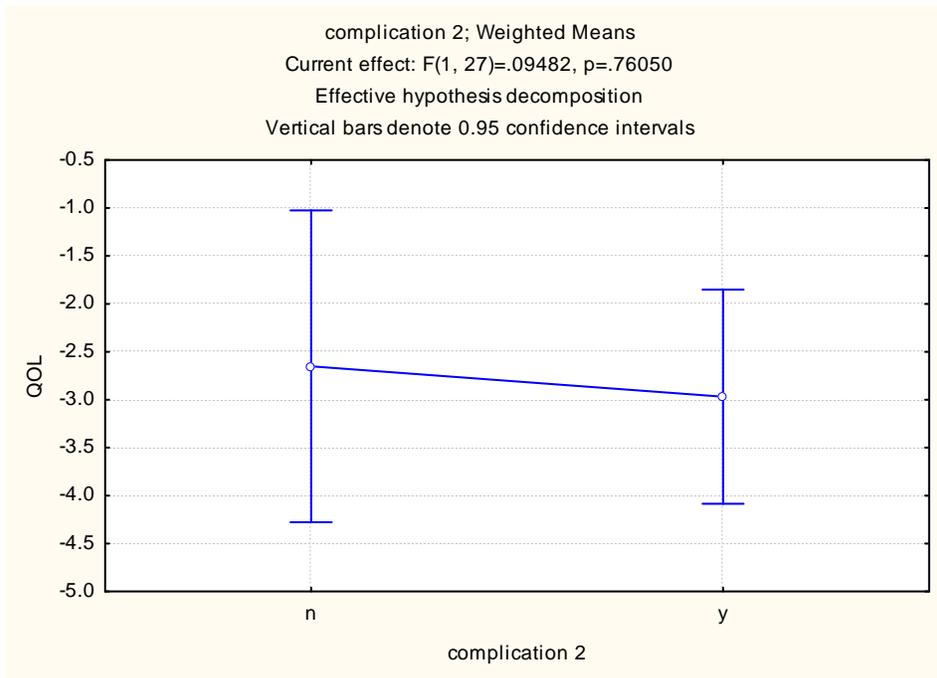


Figure 4.3: Relationship between QOL and Hyperlipidaemia (n= 68)

n = hyperlipidaemia was not present; y = hyperlipidaemia was present

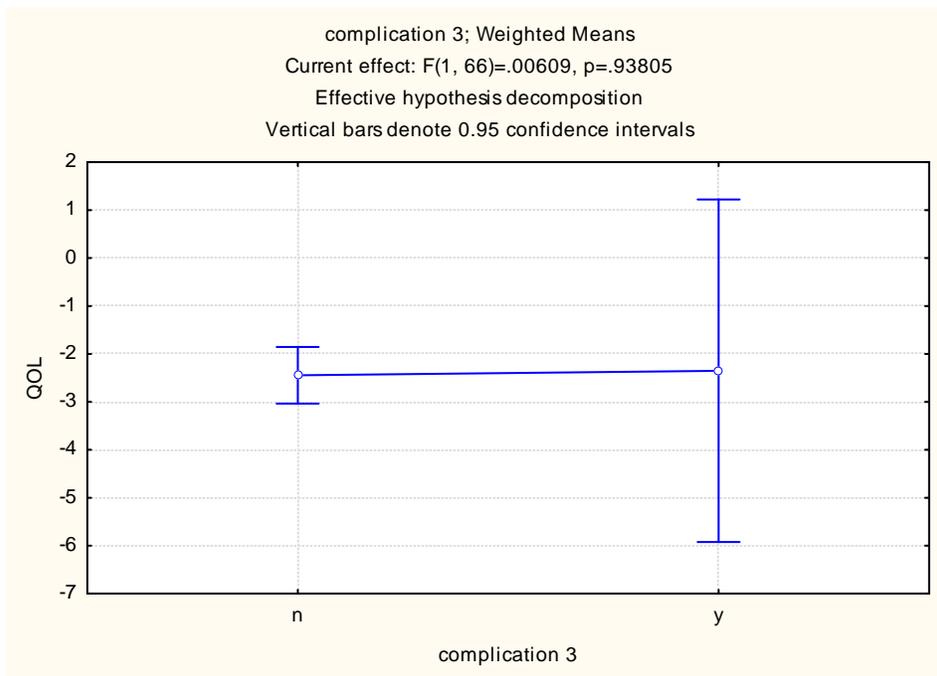


Figure 4.4: Relationship between QOL and Retinopathy (n= 68)

n = retinopathy was not present; y = retinopathy was present

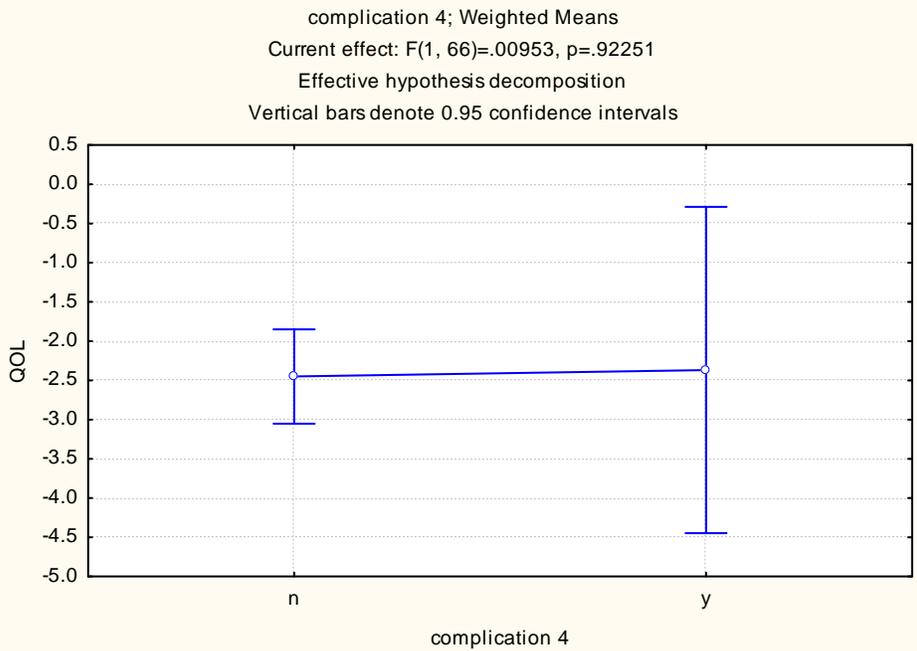


Figure 4.5: Relationship between QOL and Neuropathy (n=68)

n = neuropathy was not present; y = neuropathy was present

4.3.4 QOL versus Demographic Markers

The data was analyzed to assess the relationship between education level and QOL. Data was available for 66 of the 68 participants. In response to the question “what level of education was completed?”, seven different responses were given by the participants: grade 10 (n=5); grade 11 (n=3); grade 12 (n=26); college (n=5); diploma (n=10); degree (n= 15) and honors degree (n= 2). Statistical analyses revealed that QOL is not significantly related to any level of education level ($p = 0.35$) (Figure 4.6).

Age ($p = 0.59$) and gender ($p=0.44$) were also not significantly related to QOL. When compared to ethnicity however, the Mann-Whitney U test showed that total QOL and ethnicity are significantly related ($p = 0.03$). The results showed that both ethnic groups (black and white subjects) perceived their QOL to be negatively associated by their DM. Figure 4.7 also shows that black subjects perceive their QOL more negatively than do white subjects. Further results will also show that although QOL is negatively impacted in both groups that these associations differ between the groups (Figure 4.7).

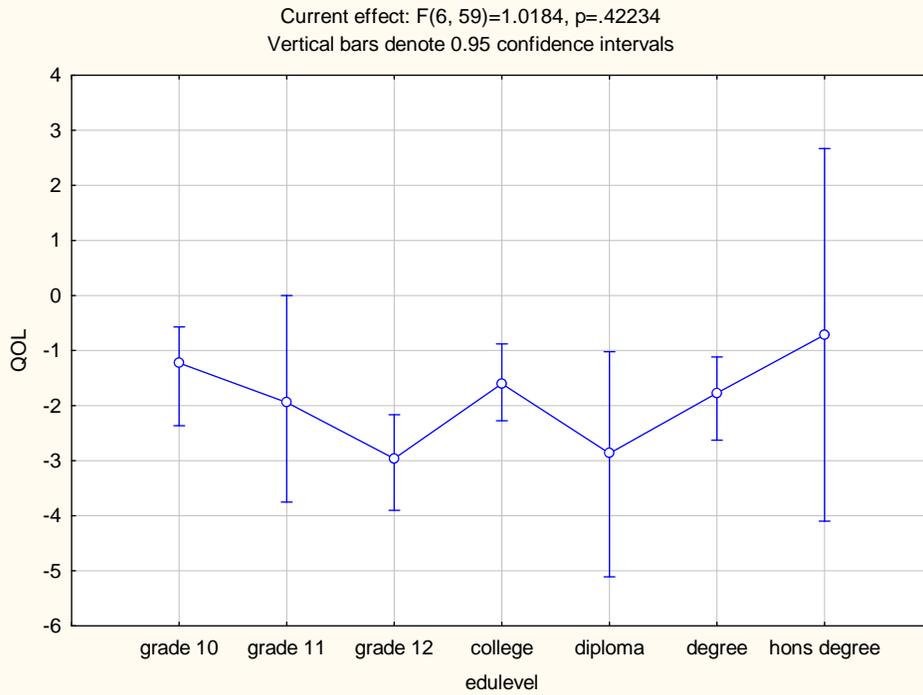


Figure 4.6: Relationship between QOL and the various Levels of Education (n=66)

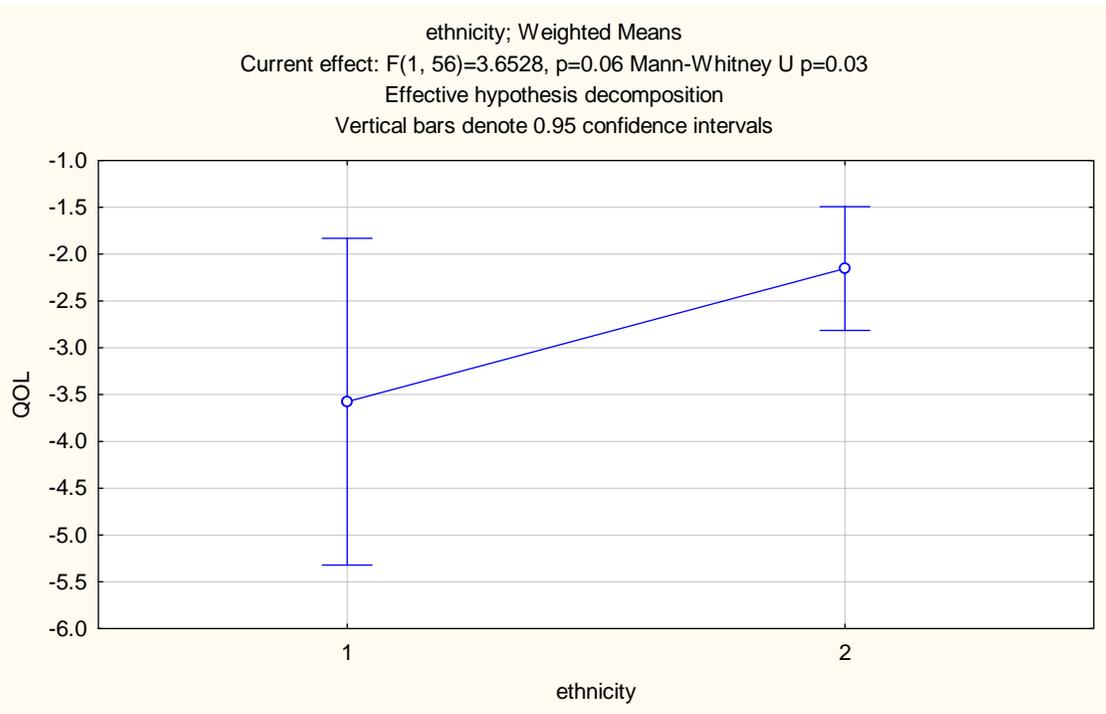


Figure 4.7: Relationship between QOL and Ethnicity (n=65)
 1= black subjects: 2 = white subjects

4.3.5 QOL versus Nutritional Status

Spearman rank correlation analyses revealed that neither weight ($p = 0.10$; $r = -0.19$) (Figure 4.8.); BMI ($p = 0.10$; $r = -0.19$) (Figure 4.9) nor WC ($p = 0.41$; $r = -0.12$) (Figure 4.10) were significantly related to perceived QOL in this study population. However, amongst all these analyses there was a trend towards a negative relationship between QOL and increasing weight, BMI and WC.

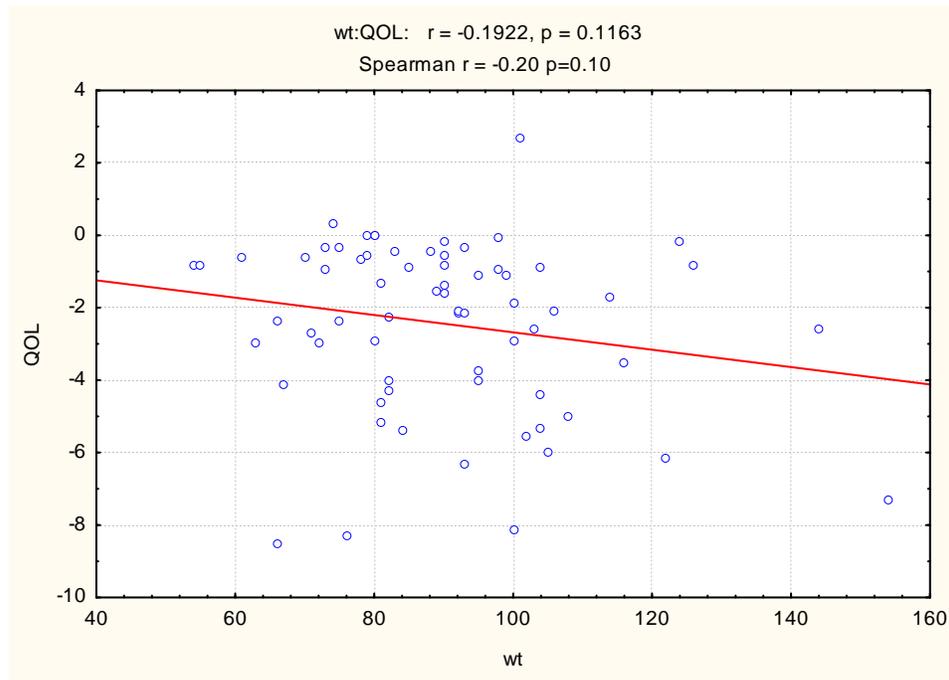


Figure 4.8: Relationship between QOL and Weight (kg) (n= 68)

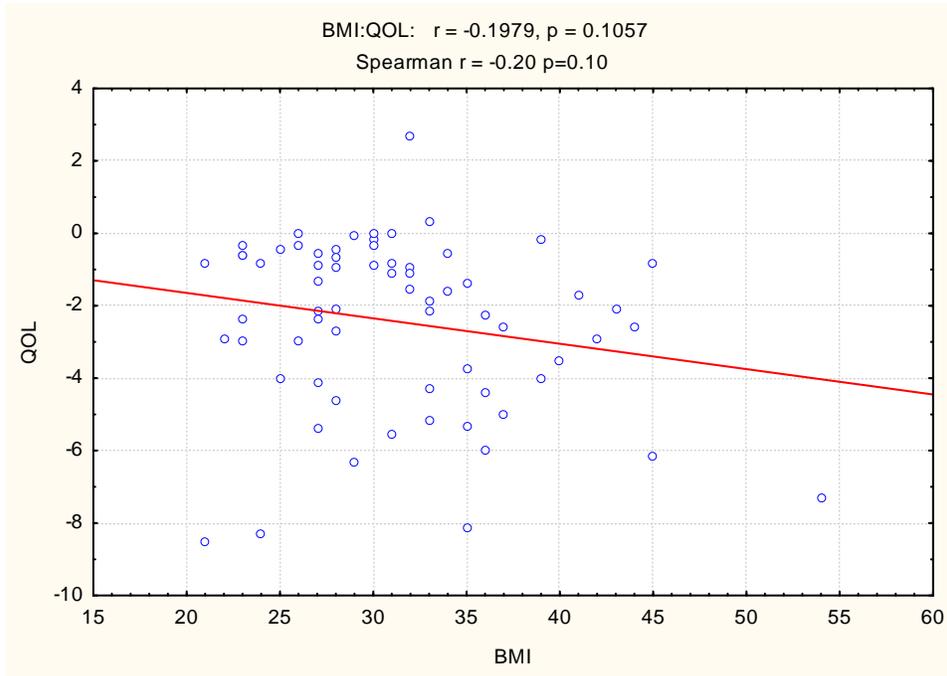


Figure 4.9: Relationship between QOL and BMI (kg/m^2) (n= 68)

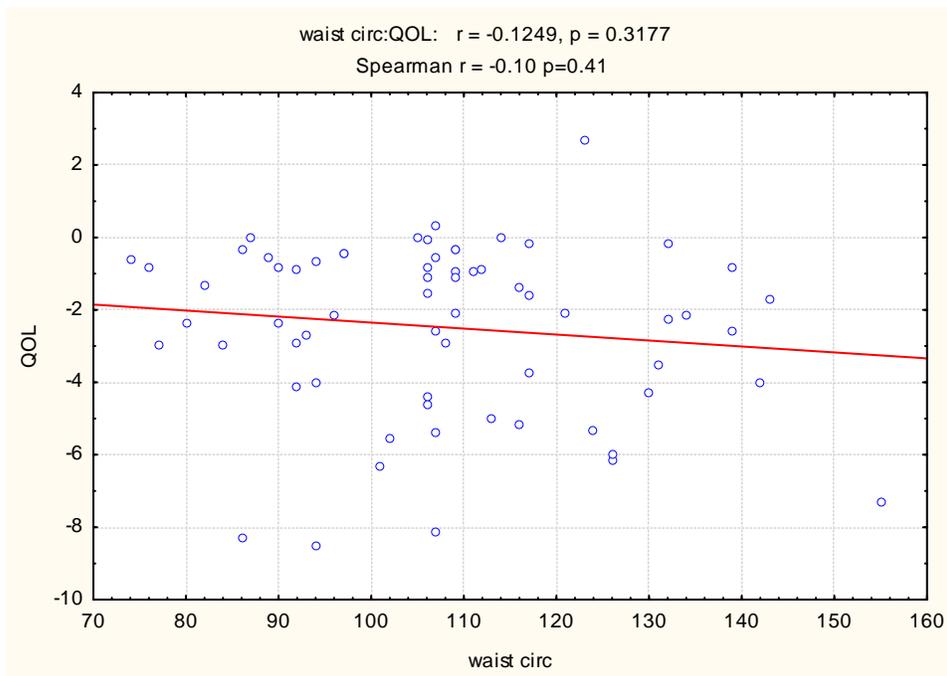


Figure 4.10: Relationship between QOL and Waist Circumference (n= 66)

4.4 CORRELATION ANALYSES FOR THE INDIVIDUAL QOL DOMAINS

4.4.1 For the Group as a Whole

Pearson correlation analyses were performed in order to assess whether or not the individual life domains were rated/ ranked differently and if so to assess whether or not these domains had more or less impact on the QOL of the study subjects. This analysis shows that, for the group as a whole (Figure 4.11) the various life domains impact differently on the subject's perceived QOL. The analysis shows that the subjects felt that if they did not have DM that the ease with which they can travel would be better than it is currently. The results also show that the second and third most important domains were worries about the future of their families and leisure activities. Interestingly, these subjects rated their "enjoyment of food" and "the extent to which people would fuss" as having the least impact on their perceived QOL. All 13 individual life domains were significantly related ($p < 0.05$ for all domains) to QOL for the group as a whole.

4.4.2 For Type 1 and Type 2 Diabetics

Pearson correlation analyses were also performed to assess the importance ratings of the 13 individual life domains in type 1 and type 2 diabetics. The individual life domains were ranked from the life domain that had the largest perceived impact to the lowest perceived impact. Type 1 diabetics (Figure 4.12) felt that the three domains that impacted on their perceived QOL the greatest were "my social life"; "my family relationships" and "the ease with which I can travel". In contrast to this, these subjects felt that their DM had the least impact on "career aspects" as this domain causes them the least concern. The last 8 life domains were not significantly related ($p > 0.05$) to QOL in these subjects (Figure 4.12).

The results for the subjects with type 2 DM showed a different picture (Figure 4.13). Their QOL was seemingly affected the most by "worries about the future of my family"; "the ease with which I can travel" and "my sporting, holiday and leisure opportunities".

These subjects were least concerned about people “fussing over” them. All the life domains were significantly related to QOL in these subjects ($p < 0.05$ for all domains) (Figure 4.13).

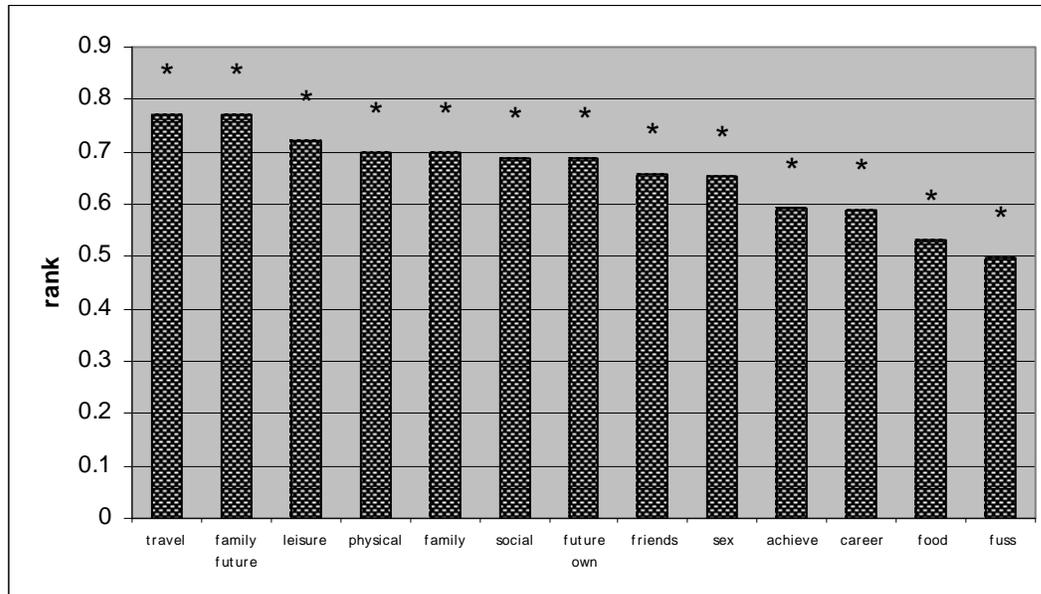


Figure 4.11: Life Domains ranked according to their Level of Importance for the Group as a Whole (n=68)

* = significant

travel = “the ease with which I can travel”; family future = “worries about the future of my family and close friends”; leisure = ‘sporting, holiday or leisure opportunities’; physical = ‘things I could do physically’; family = “family relationships”; social = “my social life”; future own = “worries about my future”; friends = “my friendships”; sex = “my sex life”; achieve = “my motivation to achieve things”; career = “my employment/ career opportunities”; food = “my enjoyment of food”; fuss = “the extent to which people would fuss”

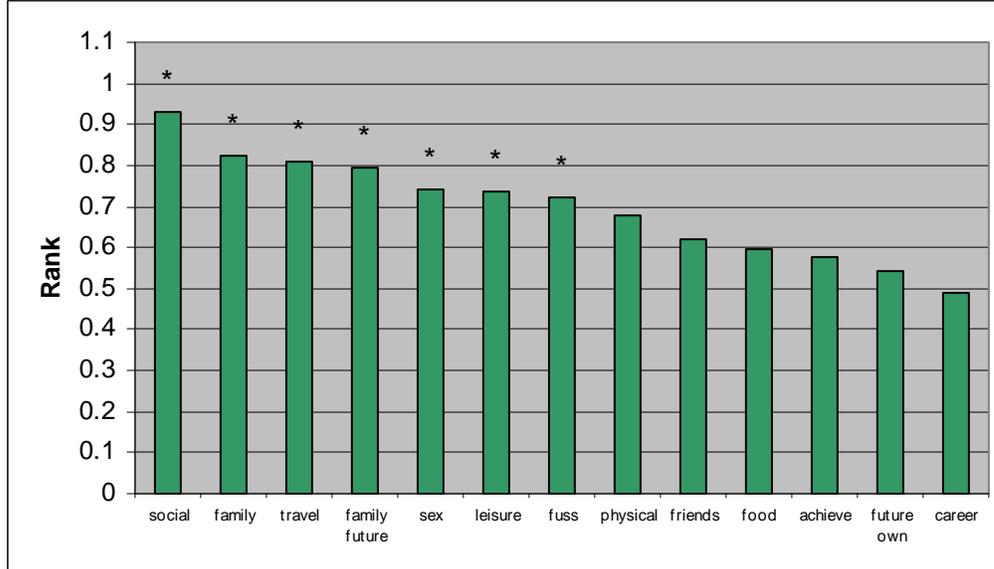


Figure 4.12: Importance of Life Domains according to Type 1 Diabetics (n=8)

* = significant

social = “my social life”; family = “family relationships”; travel = “the ease with which I can travel”; family future = “worries about the future of my family and close friends”; sex = “my sex life”; leisure = ‘sporting, holiday or leisure opportunities’; fuss = “ the extent to which people would fuss”; physical = ‘things I could do physically’; friends = “my friendships”; food = “my enjoyment of food”; achieve = “my motivation to achieve things”; future own = “worries about my future”; career = “my employment/ career opportunities”

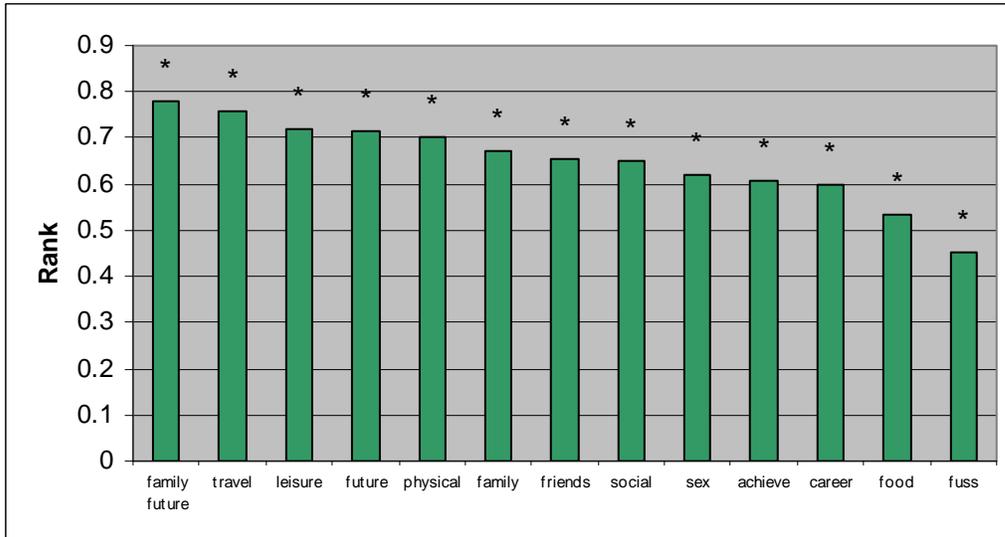


Figure 4.13: Importance Ratings of Life Domains according to Type 2 Diabetics (n= 60)

* = significant

family future = “worries about the future of my family and close friends”; travel = “the ease with which I can travel”; leisure = ‘sporting, holiday or leisure opportunities’; future = “worries about my future”; physical = ‘things I could do physically’; family = “family relationships”; social = “my social life; sex = “my sex life”; achieve = “my motivation to achieve things”; career = “my employment/ career opportunities”; food = “my enjoyment of food”; fuss = “ the extent to which people would fuss”; friends = “my friendships”;

4.4.3 For the Ethnic Groups

Spearman rank correlations were performed to assess which life domains ranked as most or least important in the two ethnic groups. The results show that the most important worries for the black subjects were “worries about the future of my family”; “sporting, holiday or leisure activities” and “my sex life”. The life domain that ranked as least important was “the extent to which people would fuss about me”. The life domains “my employment/ career opportunities”; “my friendships” and “the extent to which people would fuss about me” were not significantly related to QOL ($p > 0.05$). (Figure 4.14).

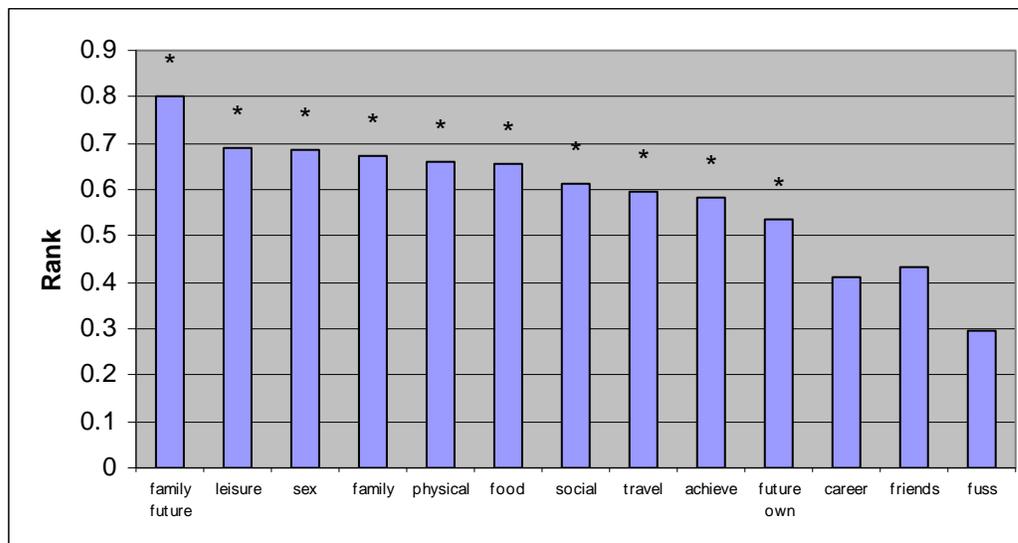


Figure 4.14: The Importance Rating of the Life Domains according to Black Subjects (n=15)

* = significant

family future = “worries about the future of my family and close friends”; leisure = “sporting, holiday or leisure opportunities”; sex = “my sex life”; family = “family relationships”; physical = “things I could do physically”; food = “my enjoyment of food”; social = “my social life”; travel = “the ease with which I can travel”; achieve = “my motivation to achieve things”; future own = “worries about my future”; career = “my employment/ career opportunities”; friends = “my friendships”; fuss = “the extent to which people would fuss”

The white subjects ranked the impact of the life domains in a different order (figure 4.15). They felt that “the ease with which I can travel”; “my social life” and “worries about the future of my family” were their biggest worries and had the biggest impact on their QOL. Surprisingly, “my enjoyment of food” was the least of their concerns. All the life domains were significantly related to QOL in this group of subjects ($p < 0,05$).

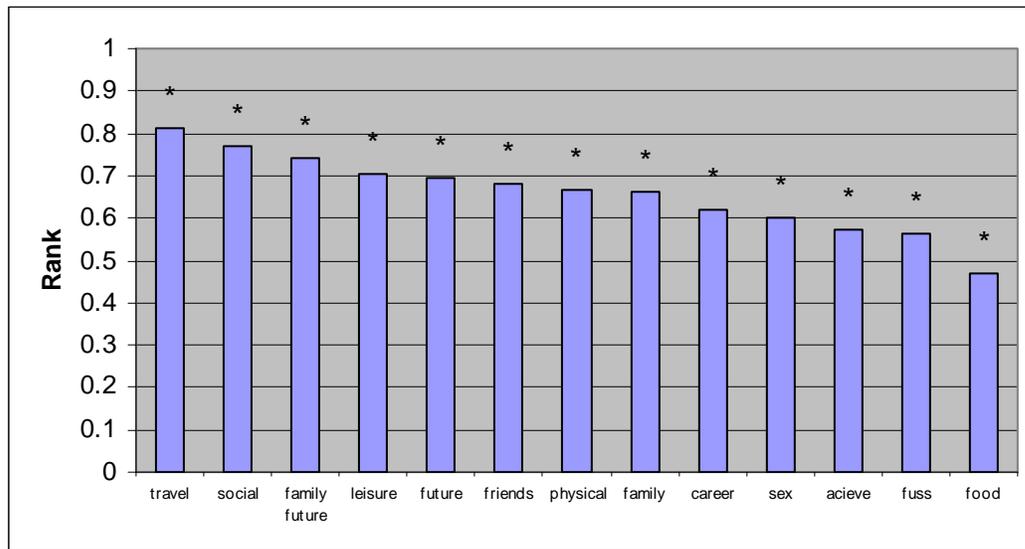


Figure 4.15: The Importance Rating of the Life Domains according to White Subjects (n= 53)

* = significant

travel = “the ease with which I can travel”; social = “my social life; family future = “worries about the future of my family and close friends”; leisure = “sporting, holiday or leisure opportunities”; future = “worries about my future”; friends = “my friendships”; physical = “things I could do physically”; family = “family relationships”; career = “my employment/ career opportunities”; sex = “my sex life”; achieve = “my motivation to achieve things”; fuss = “the extent to which people would fuss”; food = “my enjoyment of food”

CHAPTER 5

DISCUSSION

5.1 DEMOGRAPHIC CHARACTERISTICS

The patients that participated in this study represent a variety of patients within the population. The study population was representative of both type 1 and type 2 DM at various stages of their diagnosis. The study included both male and female subjects and therefore QOL assessment was possible for both male and female subjects. The level of education of the patients was varied. Ninety percent of the patients had finished school and no subject that participated in the study had achieved an education level below grade 10. This study population group was therefore well educated. The majority of the patients who participated were white subjects, with a smaller proportion of the group being made up of black subjects. This did however allow for comparisons between these groups in order to ascertain whether or not their perceptions differ in terms of QOL issues. This is important because in a culturally diverse country such as South Africa, in the development of programs to educate patients the use of culturally sensitive and appropriate data would be of importance. A potential shortcoming of the study may have included the fact that the questionnaires were not available in all 11 South African languages. Due to the fact that the study leaders spoke either English or Afrikaans, should the subjects require an explanation it could only be done in English or Afrikaans and not necessarily in their mother tongue. Although all the subjects involved in the study spoke either English or Afrikaans, this may have impacted on the understanding of the questionnaire and possibly on the explanation given should the subject have required assistance.

5.2 GLYCAEMIC CONTROL AND MEDICAL CHARACTERISTICS

5.2.1 Glycaemic Control

The aim of treatment in this population group, within the clinic, was to achieve blood glucose levels as close to the target levels as possible. At the time of this study the targets were set HbA1c < 7%, that were recommendations brought about by the results of the UKPDS study.¹⁴ The treatment regimes included either insulin on its own, insulin together with oral hypoglycaemic agents or with tablets alone. The level of control as

measured by the HbA1c value for the group averaged 8.05 (2.16) %. These HbA1c levels are to be expected as goals below 7% are generally only achieved in large intervention studies.¹⁴ This is highlighted by a study in a peri-urban black community in South Africa that achieved these targets in only 20.1% of patients.¹² In addition, a cohort study in the USA reported mean HbA1c values of 8.5%¹³. The HbA1c levels achieved in this population group are in accordance with levels expected in a setting that is not as tightly controlled as an intervention study. This result serves to highlight just how difficult it is to achieve target glycaemic control in practice. It also makes the results of this study all that more relevant because it just serves to reiterate that any avenues that we can utilize to improve this control should be explored and that if a negative QOL is linked to a poorer HbA1c then perhaps improving QOL could have the reverse effect. It also shows that there are still new avenues to explore that can be incorporated into the care of these patients to hopefully improve not only their control but their QOL as well.

5.2.2 Medical Characteristics

Diabetes-related complications were recorded and the results show that a small proportion of the group had no complications, whereas the majority of the group had one or more complications. Of the complications documented in the study, elevated blood pressure, hyperlipidaemia, retinopathy and neuropathy were present whereas none of the participants in this study were recorded as having nephropathy. Comparisons of these incidences to the results of other studies are difficult to make. This study population included a variety of patients at various states of disease progression. Several studies have reported that the incidence of complications will vary according to the duration of disease. For example, the UKPDS study showed that in the intensively treated group the incidence of microalbuminuria was 11.8% at the start of the trial and had progressed to 27.1% after 15 years.¹⁴ This incidence may also vary between type 1 and type 2 diabetic patients. In a study looking at the microvascular complications in South African patients with long-duration DM the presence of retinopathy was 53.2% in type 1 diabetic patients, whereas the incidence in type 2 subjects was 64.5%.¹⁵ Therefore in terms of conclusions of this study, it is possible to say that microvascular as well as macrovascular complications are associated with a worse outcome for the patient¹⁴ and therefore every effort should be made to minimize these complications not only for the obvious medical

reasons but also because it negatively impacts on, the previously highly under-estimated, QOL of these patients

All of the study participants belonged to a medical aid. Medical aid cover in South Africa is costly and in order to be able to afford medical aid cover, the subject would need to be earning a salary that is reasonable. The study is therefore unlikely to have included any subjects who were extremely socio-economically disadvantaged. This is a potential shortcoming of this study and would require further research in order to understand the impact that DM has on the related QOL in this particular part of the population.

Body mass index was recorded for 61 of the 68 patients. The results show that the average BMI for the group was 31kg/m^2 which according to the WHO classification identifies this group as having class 1 obesity. When looking at the genders individually, males are classified as being overweight, whereas the female participants are defined as having class I obesity.²⁸ The WC was recorded for 60 of the 68 subjects. According to the WHO classification this group of subjects is at substantially increased risk for cardiovascular outcomes.²⁸ When comparing these results to other studies it would appear that obesity is still rife in diabetic patients. The results of the UKPDS study showed that the average BMI for the population group was 27kg/m^2 .¹⁴ In a study in a rural South African diabetic population the results showed that severe obesity was present in 36.5% of the group.¹⁶ Similarly, a study in black hypertensive women with the metabolic syndrome, attending an urban primary health care centre in South Africa, revealed that the mean BMI for these women was 34.1kg/m^2 .¹⁷ A recent review article²⁴ highlighting the global increase in obesity showed that the figures for obesity in women were 57% and for men, 29%. The relevance of the data can not be ignored as it highlights the growing incidence of obesity worldwide and that the South African population has not been spared.²⁴ This stresses the issue that further research into how best to manage this obesity is still necessary and that intervention programs need to be implemented in order to curb this growing epidemic. These results also show that as BMI increases, that QOL of the patient tends to decrease. This adds yet another dimension to this very complex disease and really just serves to reinforce how important it is to manage this disease aggressively. It is crucial though to not only consider the medical implications but also the psychological impact that all these factors have on the patient.

5.3 PERCEIVED QUALITY OF LIFE

There is a growing interest in understanding and making use of the concept of a DM specific QOL assessment.³ In the efforts to prevent diabetic complications the impact of the condition on QOL are often overlooked.³ Health-related QOL is known to impact on people living with both type 1 and type 2 diabetes.¹¹ The results of this study show that the majority of the patients (98%) perceived DM to impact negatively on their QOL. Only two people felt that diabetes had a positive impact on their QOL. Within this study group, 3 subjects felt that diabetes had no role to play in their QOL and that their QOL would be the same, with or without diabetes.

These results are in line with several other international studies that have viewed DM management from a patient's perspective. The Cost of Diabetes in Europe – Type 2 study (CODE-2)²⁵ showed that the overall average score for assessing QOL was lower in the diabetic patient than that for the healthy population. A review on patients perceptions of DM and DM therapy revealed that diabetes has an almost universally negative impact on diabetes-related QOL.³ In South Africa the situation seems to follow a similar trend. A study conducted in a different area in South Africa and using a different assessment tool to that used in this study, showed that diabetes has a significant impact on QOL in the black diabetic patient.³⁷ Researchers showed that these patients were more likely to report worse scores for functioning and general health than the controls.³⁷

The Diabetes Control and complications trial (DCCT) showed that the goal of achieving as near to normal blood glucose levels as possible does not worsen a patient's QOL.¹ These results show that intensive blood glucose control should still be the main aim of clinical practice in preventing diabetes-related complications and that it is possible to do so without adversely affecting QOL issues. Therefore both tight blood glucose control and well as QOL issues should be addressed in a holistic management of the diabetic patient. This opinion is shared by other researchers who have concluded that in order to enhance the QOL of patients, attention needs to be paid to the psychological treatment of patients.²³ This study further adds to this body of information by showing that patients in South Africa are not exempt from the deleterious effect that DM has on health-related QOL and that from now on this should be factored into the care of these patients.

5.4 QOL VERSUS GLYCAEMIC CONTROL

The results of this study demonstrate that QOL and HbA1c are inversely related in the diabetic patient. Therefore, as the glycaemic control deteriorates the perceived QOL is reported as being significantly worse. Similar results were seen in a sub-study of the CODE-2 study that showed that HbA1c levels were negatively associated with health-related QOL issues.³³ Likewise, a longitudinal study on the glycaemic control and QOL of the type 2 diabetic patient showed that QOL improved in patients who achieved a better glycaemic control.²⁰ Finally, the DIAB.&TE.S Project study group found a correlation between metabolic control and QOL outcomes.²¹ These results are however not consistent across the board. A Swedish population based study showed no significant relationship between HbA1c and QOL.²⁶

The DAFNE study³⁸ evaluated whether a course in intensive training of patients with relation to their medication and diet would impact on their glycaemic control and QOL. The study found improvements in both HbA1c levels and well as QOL measures in the study group that received a 5 day training course compared to those who received their usual care.³⁸ This highlights the need for patient interventions that empower the patients and of the fact that such strategies can improve not only glycaemic control, but QOL as well.

5.5 QOL VERSUS DURATION AND TYPE OF DIABETES MELLITUS

5.5.1 Duration of Diabetes

The patients enrolled in this study had been diabetic for varying lengths of time. Some of the study participants were newly diagnosed whereas this range extended up to 16 years after diagnosis. The results of the study did not show any significant relationship between DM duration and QOL assessment in these patients. These results are in accordance with a large Swedish population based study that found no relationship between any of the QOL scales and duration of DM.²⁶ Similarly, in a subjective assessment of QOL of diabetic outpatients, researchers found that illness duration was not significant.²⁷

Although similar findings have been reported elsewhere, this lack of significance may also be due to the fact that the sample size was small and QOL assessments should be made regardless of the duration of the patients' DM.

5.5.2 Type of Diabetes

Evaluation of the impact of DM on QOL assessments in both type 1 and type 2 diabetics has suggested an almost universally negative impact of DM on patients perceptions on QOL.³ This relationship was however not evident in this population group. We found that neither type 1 nor type 2 DM has a significant relationship to QOL measures. The absence of any significant relationship is likely to be due to the fact that that the population group in this study was small. The results of the correlation analyses showed a negative trend for both groups, although not significant, may have been significant in a larger study sample. This theory is supported by the CODE-2 study that showed that type 2 diabetics reported QOL scores that were lower than that of a healthy population and that treatment with insulin is associated with a reduced QOL.²⁵ Poorer health-related QOL scores have also been reported in South African type 2 diabetic patients, when compared to a control group.³⁷ Type 1 diabetic patients in Kuwait also report a significantly lower QOL when compared to the general population.²⁷ Lastly, it has also been shown that scores differ between patients who are taking various kinds of treatment for their DM. For example patients taking oral therapies achieved higher QOL scores than those on insulin.^{21, 39} The issue is complex though as patients using advanced insulin devices scored higher than those using conventional insulin.²¹ These results serve to highlight the complexity of the subject surrounding QOL issues in diabetic patients and the need for further investigation and well as implementation of policies surrounding these complex issues.

5.6 QOL VERSUS COMPLICATIONS

When assessing these relationships between QOL and diabetes-related complications this study found that although these relationships were not significantly related, that QOL ratings in participants who had hypertension and hyperlipidaemia tended to be lower. Therefore QOL seemed to be adversely affected in patients who had macrovascular

complications. This trend was however not present in those with microvascular complications. The likely explanation for this is that the sample size was not large enough to detect these differences. The relationship between both macrovascular as well as microvascular complications and QOL has been described in other studies.^{25, 40} The CODE-2 study showed a significant relationship between QOL and both macro as well as microvascular complications.²⁵ The study showed that the onset of either type of complication reduced the QOL score and the presence of both types of complications reduced this score even further.²⁵ This body of evidence is also supported by the results of the UKPDS trial that showed that patients who had a macrovascular complication within the last year, scored more negatively on the general health questionnaire, than those without complications.⁴⁰ The UKPDS group also reported that microvascular complications negatively impacted on QOL scores when compared to those subjects without complications.⁴⁰ These results serve to highlight, once again, that the management of diabetes is multi-factorial as each stage of the disease impacts on other areas of life and management. Therefore, when managing this disease, practitioners should not only focus on the obvious medical management of the patient but should consider the psychosocial impact that the disease has, and ensure that these very important issues are dealt with as aggressively.

5.7 QOL VERSUS DEMOGRAPHIC MARKERS

5.7.1 QOL versus Education Level, Age and Gender

The results of this study show that there are no significant relationships between QOL scores age or gender in this particular population group. The lack of a relationship between education level and QOL was also evident. This lack of significance between QOL and education level held true regardless of whether patients had not completed school or whether they had a post graduate degree. Once again the small sample size in this study may account for the lack of any significant relationships between QOL and demographic variables. Although this lack of association does not seem to be the majority finding, a German based study also found that profession and education play a minor role in their influence on health-related QOL issues.⁴¹

In contrast to these findings, a Swedish based population study showed that females were more likely to report a more negative impact on their daily life than were males.²⁶ Younger patients in Kuwait also reported a poorer QOL.²⁷ Similarly, age was found to influence health-related QOL in German patients where an increase in age resulted in a decrease in QOL.⁴¹ The CODE-2 study showed that many demographic variables are associated with QOL measures.²⁵ Their analysis showed that several factors independently predict a poorer QOL score.²⁵ The results of the CODE-2 study showed that the following factors, in order of importance, predict a poorer QOL: gender; complications; treatment type; age; obesity and hyperglycaemia.²⁵ These results are also supported by other researchers who showed significant correlations with age and gender and health related QOL measures.^{22, 41} Gender differences in psychological adjustment to DM have been assessed by Enzlin et al⁴² who found that women tend to have more depressive symptoms when adjusting to DM and that there were significant gender differences found in terms of psychological adjustment to DM. The DCCT also found significant associations between sex and age and DM related QOL.¹ There seems to be a universal association between QOL measures and demographic variables and perhaps a larger study would find relationships in this population group.

5.7.2 QOL versus Ethnicity

The results of this study showed that both black and white subjects, independently, perceived their QOL to be negatively affected by their DM. We also found that black subjects perceive their diabetes-related QOL more negatively than do white subjects. Discussions later on in this paper will also reveal that the individual importance ratings of life domains differ between the groups. Only black and white patients were included in this analysis as the numbers of patients that participated in the study from other ethnic groups, e.g. Indian and Colored subjects, were too low to include in the analysis. The difference of perceived impact of DM on QOL between various ethnic groups has not been widely investigated. These results are of great relevance as it indicates that when treating patients and considering the impact that DM has on QOL measures, that the different ethnicities and cultures need to be taken into account. This subject matter would also need to be taken into account when policies are being formulated and when education programs are being designed.

This opinion seems to be true for other studies that have investigated ethnic differences in QOL between groups of subjects. A study comparing ethnic differences in QOL between Chinese, Malay and Indian subjects in Singapore found that there were several differences in ethnic QOL domains between the groups.³⁴ The study also found that these differences persisted even after adjusting for socioeconomic and health status.³⁴ Similarly a study comparing differences in QOL between Asian and white European patients with kidney disease showed that there differences between the two ethnic groups.³⁵ In addition, a systemic review designed to assess diabetes self-care interventions in African American or Latino adults concluded that large clinical trials that are designed with cultural and age specific criteria in mind are necessary in order to gain more insight as to how to address this growing health problem.³⁶ Lastly, when developing health-related QOL instruments for use in Asia the authors uncovered several important issues. They reported that evidence is limited and mixed as to whether health-related QOL is the same between Asia and North America or Europe.⁴³ They also mention that there are cultural differences in terms of which questions are appropriate to ask and which are not.⁴³ They also have an additional predicament in that there are many different regional languages which would necessitate translation as well as adaptation of the questionnaires.⁴³ The authors conclude by saying that the health-related QOL instruments in those areas tend to reflect socio-economic development rather than their disease burden.⁴³ These results together with the results from our study serve to highlight the need for studies and programs that take heed of the ethnic differences between population groups in order that the studies are designed appropriately and that any intervention designed are culturally acceptable and appropriate.

5.8 QOL VERSUS NUTRITIONAL STATUS

This study investigated the potential relationships between perceived QOL measures and various indicators of nutritional status. The literature suggests that several indicators may be related to QOL, some of which include weight, BMI and WC. This study found that neither weight, BMI nor WC were significantly related to perceived QOL in this study population. However, there was a trend towards a negative relationship between all the

nutritional variables and QOL. The results in the literature regarding the relationship between these nutritional variables and QOL issues are conflicting.

The CODE-2 study showed that obesity plays a negative role in determining QOL in type 2 diabetic patients.²⁵ The study showed that although obesity is not the most important determinant of QOL, that it is still nonetheless an independently related factor.²⁵ In contrast to this, studies in Swedish diabetic patients showed no relationship between any of the QOL sub-scales BMI.²⁶ These results, together with a similar trend in our study suggest that when implementing intervention strategies, various factors need to be taken into account, and should include tools with which patients can manage their weight and once again that the management of this disease is multi-factorial and that none of these factors should be managed in isolation.

5.9 INDIVIDUAL QOL DOMAINS

5.9.1 For the Group as a Whole

In general reports assessing the impact of DM on health-related QOL issues have shown consistently negative relationships between the two variables.^{2, 32, 33, 40} However, when assessing QOL in the diabetic patient, one cannot simply assess QOL as a whole, but rather the various domains that make up this broad subject matter. Perceived QOL in these patients is multifactorial and is made up of various subdivisions, which together contribute to the broadly termed ‘quality of life’. This is evident within the results of this study as we see that the various groups perceive their DM to impact differently on their lives to their counterparts. For the group as a whole this analysis shows that the various life domains impact differently on the subject’s perceived QOL. The domains which were ranked as having the most significant impact on QOL for the group as a whole included, “the ease with which they can travel”; “worries about the future of their family and close friends”; and ‘sporting, holiday or leisure opportunities’ were the most important domains that impacted on their perceived QOL. Interestingly, these subjects rated their “enjoyment of food” and “the extent to which people would fuss “as having the least impact on their perceived QOL. All 13 individual life domains were negatively related to QOL for the group as a whole. Studies looking at patients in Canada and Brazil found

that health satisfaction, enough money, meaning in life and opportunities for leisure activities played a significant role in QOL in these patients.⁴⁴ They also found that satisfaction with personal relationships was not significant for patients in either country.⁴⁴ In a different study using the ADDQoL questionnaire, researchers found that patients reported a greater impact on domains such as enjoyment of food and domains including work, social life and family and friends rated less important.² In a separate study, researchers found that the greatest negative impact on perceived QOL was for the domain “freedom as I wish to eat”.²⁵ These differences in results may reflect differences in the cultures, social background or geographical differences between the population groups. These results once again highlight the need to identify specific needs within various population groups when considering intervention schemes. The results from this study as well as other studies clearly show that there are differences in patients’ perceptions of QOL issues that would need to be addressed specifically and individually within various population groups.

Although this study was not designed to determine the effect of intervention strategies on health-related QOL issues it seems appropriate to discuss it here as future research might include the implementation of such strategies based on the results of this study. There are several studies that have used health-related QOL questionnaires longitudinally. These studies have aimed to look at the benefits of interventions for tighter blood glucose control long term whereas others have looked at the use of the questionnaires in dietary modification programs and how they impact on QOL over time. The UKPDS trial compared QOL at the beginning of the trial and from 6 months to 6 years after randomization. The results showed that no improvement in QOL domains in patients in either the conventional or intensively controlled groups over time.⁴⁰ The authors concluded that policies to reduce complications had no affect on QOL in these patients.⁴⁰ In contrast to this the CODE-2 study concluded that the goal of policy makers should be to reduce or prevent complications associated with DM based on the fact that health-related QOL is an important issue in type 2 DM and that this QOL decreases as the disease progresses.²⁵ Similarly the DAFNE trial showed significant improvements in QOL measures in those patients who were assigned to an intensive training course immediately as opposed to those who received the usual care.³⁸ The study showed that these improvements remained significantly improved over time and in fact continued to

improve as time went on.³⁸ This improvement in QOL was reported for several domains such as dietary freedom, present quality of life, psychological wellbeing and treatment satisfaction.³⁸ The DCCT showed no improvements in QOL over time.¹ They do however conclude by saying that the special circumstances of the study may have led to the QOL results.¹ They emphasize that in situations where there is less support by family members or health care professionals or when access to these facilities are inadequate, that the demands of treatment may cause more problems with QOL issues.¹ These longitudinal results together with the results of our study serve to highlight the need for very carefully designed intervention policies that include multi-disciplinary teams and for careful consideration of the population group that is involved.

5.9.2 For Type 1 and Type 2 Diabetics

This study aimed to elucidate differences between perceptions on QOL measures between type 1 and type 2 diabetics. This study found no significant relationship between type 1 and type 2 DM and QOL as a whole. However when comparing the individual life domains within the groups differences between the groups are apparent. Similar results have been reported in a study designed to develop a diabetes-related QOL scale. Researchers found almost no correlations among the QOL related to diet therapy and suggested that the different domains within the diet-related QOL be considered as independent concepts.¹⁸

When looking at the groups separately these differences in perceived QOL are evident. Type 1 diabetics felt that the three domains that impacted on their perceived QOL to a greater extent were “my social life”; “my family relationships” and “the ease with which I can travel”. In contrast to this, these subjects felt that their DM had the least impact on “career aspects” as this domain caused them the least concern. This study also found that not all the domains were significantly related. Similar finding were reported by C Bradley et al who found that insulin users reported a negative impact of their DM on most domains.²

The results for the subjects with type 2 DM showed a different picture. Their QOL is seemingly affected the most by “worries about the future of my family”; “the ease with

which I can travel” and “my sporting, holiday and leisure opportunities”. These subjects were least concerned about people “fussing over” them. All the life domains were significantly related to QOL in these subjects.

As discussed earlier, there seem to be differences in perceived QOL in type 1 and type 2 diabetics. These results serve as further substantiation of these findings. Not only are there differences in perceived QOL between the two groups, but they also rate the various life domains in different orders of importance. These results suggest that the type of DM that a patient has impacts on their life differently to that of their counterparts. Similar differences in ratings have been reported elsewhere. In a study comparing QOL in patients with DM and impaired glucose tolerance showed that diabetic patients rated QOL measures such as physical functioning, general health perception and vitality lower than that of their glucose intolerant counterparts.²³ The Fremantle Diabetes Study showed similar results. They found that insulin users within the study group had more negative scores on their satisfaction, worry and impact scores on the modified diabetes quality of life questionnaire (DQOL) than those who did not use insulin.³⁹ It is therefore important that when designing questionnaires and QOL assessment and intervention programs that the programs are applicable for both types of patients, as is the ADDQoL.

5.9.3 For the Ethnic Groups

The results show that the most important worries for the black subjects were “worries about the future of my family”; “sporting, holiday or leisure activities” and “my sex life”. The life domain that ranked as least important was “the extent to which people would fuss about me”. The life domains “my employment/ career opportunities”; “my friendships” and “the extent to which people would fuss about me” were not significantly related to QOL in these subjects. The white subjects ranked the impact of the life domains in a different order. They felt that “the ease with which I can travel”; “my social life” and “worries about the future of my family” were their biggest worries and had the biggest impact on their QOL. Surprisingly, “my enjoyment of food” was the least of their concerns. All the life domains were significantly related to QOL in this group of subjects. These results once again highlight the differences in perceived QOL between the ethnic groups is evident. The results also show that the groups differ according to their

perceptions of how DM impacts on their QOL, within the specific domains. These results together with other studies looking at ethnic differences in perceived QOL issues serve to highlight the need for culturally sensitive intervention strategies. When developing policies and when dealing with patients on a one-to-one basis these ethnic differences need to be taken into account.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSIONS

Diabetes and its complications is a growing epidemic worldwide.¹ An integral part of this epidemic is the impact that DM has on the health-related QOL of these patients.² There is a growing understanding that in order to manage health issues successfully, that symptom control as well as health-related QOL issues should be dealt with.³ It has been well documented that both type 1 DM and type 2 DM impact, in various different ways, on the perceived QOL of these patients.^{1,2,4} The primary motivation for this study was therefore to determine the psychosocial impact of DM in a group of South Africans with DM and to see if the disease impacts on their psychosocial functioning, in order that this knowledge may contribute to the overall care of diabetic patients in South Africa. QOL was assessed in these patients and analyses done to determine whether or not QOL is related to duration of DM, to the type of DM, to diabetic complications, to level of education, to ethnicity, to nutritional status or to morbidity indicators in a multiethnic group of type 1 and type 2 diabetic patients living in urban communities in South Africa.

The results show that the vast majority (98%) of patients perceive DM to impact negatively on their perceived QOL. Only two people felt that diabetes has a positive impact on their health related QOL. When the life domains were assessed individually, the group as a whole felt that “the ease with which I can travel” had the largest impact on their perceived QOL. The results also show that the second and third most important domains were worries about the future of their families and leisure activities. These subjects rated their “enjoyment of food” and “the extent to which people would fuss “as having the least impact on their perceived QOL.

The correlation analysis between QOL and glycaemic control demonstrated that QOL in the diabetic patient is negatively and significantly related to their HbA1c results. Therefore the perceived QOL of these patients is negatively impacted if their blood sugar is not well controlled. The correlation analysis between QOL and type or duration of DM was not significant, indicating that the type of DM and the duration of DM do not significantly impact on the perceived QOL in this population group. This however could be due to the fact that the sample size in this study was small. A similar result was found

for the relationship between QOL and diabetes related complications. Although not statistically significant, there was a trend towards lower QOL ratings for patients with hyperlipidaemia and hypertension. This trend was not evident for microvascular complications such as neuropathy and retinopathy.

QOL scores were also not shown to be related to any level of education or age. When compared to ethnicity however, QOL was shown to be significantly related. The results showed that both ethnic groups (black and white subjects) perceived their QOL to be negatively affected by their diabetes. The results also showed that black subjects perceive their QOL more negatively than do white subjects. Interestingly, although QOL is negatively impacted in both groups these associations differ between the groups. It seems that different domains rank as more or less important when looking at the ethnic groups separately. For example, the most important worries for the black subjects were “worries about the future of my family”; “sporting, holiday or leisure activities” and “my sex life”. The life domain that ranked as least important was “the extent to which people would fuss about me”. Whereas for white subjects, “the ease with which I can travel”; “my social life” and “worries about the future of my family” had the biggest impact on their QOL and “my enjoyment of food” was the least of their concerns.

When comparing QOL to the various anthropometrical indicators, there was a trend towards a negative relationship between QOL and increasing weight, BMI and WC. Therefore patients felt that their diabetes had a larger impact on their perceived QOL if they weighed more, had a higher BMI or WC. The lack of significance was likely do to the fact that the sample size was small.

To assess whether type 1 and type 2 diabetics perceive their DM to impact on their QOL differently, the individual life domains were assessed for these two groups independently. Type 1 diabetics felt that the three domains that impacted on their perceived QOL the greatest were “my social life”; “my family relationships” and “the ease with which I can travel” whereas “career aspects” had the least impact on their perceived QOL. For type 2 diabetics “worries about the future of my family”; “the ease with which I can travel” and “my sporting, holiday and leisure opportunities” ranked as having the largest impact on their perceived QOL and they were least concerned about people “fussing over” them.

These results show that DM impacts on various aspects of QOL in this population group. The results also show that the various domains that make up the globally termed “QOL” impact to a greater or lesser extent on the overall perception of health related QOL in these subjects. Perceived QOL differs between ethnic groups and it was also shown to be different between type 1 and type 2 diabetics. In addition, the worse the glycaemic control, the worse the perceived QOL and the presence of macrovascular complications as well as higher anthropometrical measurements also impacted negatively on QOL ratings.

These results serve to highlight several issues. Firstly the assessment of QOL in the diabetic patient should form part of management in the overall care of the diabetic patient as it impacts on so many aspects of their lives. Secondly, an effort should be made to make these assessment tools culturally sensitive as the perceived QOL differs significantly between the ethnic groups. Health care practitioners should also not assume that QOL issues are the same for type 1 and type 2 diabetics as these results have shown that there are differences in perceived QOL between the two groups. These results also serve to reiterate the fact that that tight glycaemic control and the appropriate lifestyle management not only impact on diabetes-related complications but also on the health related QOL of these patients. Lastly, this study evaluated the impact of DM on the QOL of the patient in the private care sector. Since QOL impacts so significantly on the health-related QOL of these patients, an effort should be made to do a similar assessment within the public sector in order to ascertain whether or not these issues are similar.

6.2 RECOMMENDATIONS

- The need for a multidisciplinary team approach is evident. Teams including diabetes educators, social worker/ psychologist, physicians etc should be accessible to educate and empower the patient and to ensure that not only diabetes control is dealt with but that the impact of DM on QOL is addressed when managing these patients
- Given the diverse nature of cultures and backgrounds in South Africa, all these factors should be taken into account when considering the impact that DM has on

the QOL of the patient because different life domains are affected differently within each ethnic group and therefore an effort should be made to use assessment tools that are culturally sensitive. Therefore, before implementing an assessment tool it should first be piloted in that group of patients to ensure that it is culturally appropriate.

- QOL evaluation should form part of the integral management and assessment of patients as a means to sustaining improvements in glycaemic control. The ADDQoL is one such tool that may be used to assess diabetes-related QOL
- Patients should be identified and assessed at the outset of their diagnosis so that the health related QOL issues can be identified and monitored regularly and intervention can be provided to the patient at the appropriate time, to avoid deterioration in health-related QOL of the patient.
- Psychological services should be made available to patients as part of standard care.
- Reducing and preventing complications as well as maintaining good blood glucose control can not be overemphasized as it not only impacts on the macro and microvascular complications of the patient but on the QOL of the patient. Therefore each diabetes care facility should work towards a set of goals or guidelines in order to achieve these outcomes.
- Learning to understand the patient and to gain insight into the patient's perspective will help the health professionals to communicate more effectively with the patients and will also enable them to tailor treatment education programs that address these issues specifically and to tailor these to the individual. Therefore time should be spent in each call getting to know the patients and the diabetes-related issues that affect their daily living
- Further research into the monitoring of patients psychological well being as well as the frequency with which this should be done is warranted. It would be of value to broaden the results of this study and to further research this area of knowledge in a larger patient group and over a wider geographical area in order to get a better picture of the situation as it stands in South Africa.

6.3 LIMITATIONS

- The small sample size was the primary limitation of the study.
- The study included mainly white and black subjects whereas Indian and Colored patients are not represented by this study due to the small numbers of participants.
- The study depended on a convenience sample and may therefore not represent the wider population of adults.
- Because the study was a convenience sample, the study group probably represented patients who attended the clinic more frequently and according to the schedule set out for them by the physician as opposed to those patients who attended the clinic less frequently.
- The study included one questionnaire for all participants. Although the questionnaire was pilot tested and deemed appropriate for all the individuals involved, the results of this study suggest that perhaps more culturally specific questionnaires should be used in future studies

REFERENCES

1. The diabetes control and complication trial research group. Influence of intensive diabetes treatment on quality-of-life outcomes in the diabetes control and complications trial. *Diabetes Care* 1996; **19** (3): 195 – 203.
2. Bradley C, Gorton T, Symonds E, Martin A, Plowright R. The development of an individualized questionnaire measure of perceived impact of diabetes quality of life: the ADDQoL. *Qual Life Res* 1999; **8** (1 -2): 79 – 91.
3. Bradley C, Speight J. Patient perceptions of diabetes and diabetes therapy: assessing quality of life. *Diabetes Metab Rev* 2002; **18** (suppl 3): S64 – 69.
4. Rose M, Fliege H, Hildebrandt M, Schirop T, Klapp BF. The network of psychological variables in patients with diabetes and their perceptions for quality of life and metabolic control. *Diabetes Care* 2002; **25** (1): 35 – 42.
5. Turan B, Osar Z, Molzan Turan J, Damci T, Ilkova H. The role of coping with disease in adherence to treatment regimen and disease control in type 1 and insulin treated type diabetes mellitus. *Diabetes Metab* 2002; **28** (3): 186 – 193.
6. West C, McDowell J. The distress experienced by people with type 2 diabetes. *Br J Community Nurs* 2002; **7** (12): 606 – 613.
7. Gentili P, Maldonado A, Grieco R, Santini A. Influence of patient's representations and beliefs about diabetes and its treatment of their adherence to therapy. *Diabetes Nutr Metab* 2002; **14** (3): 140 – 152 (abstract).
8. Raiford Wildes K, Greisinger A, O'Malley K. Measurement in practice: review of quality of life measures for patients with diabetes (Online). Available http://www1.va.gov/hsrd/for_researchers/measurement/practice/tf-diabetes.cfm. Accessed: 11 August 2007
9. Garratt AM, Schmidt L, Fitzpatrick R. Patient assessed health outcome measures for diabetes: a structured review. *Diabetic Med* 2002; **19** (1): 1 – 11.
10. Pouwer F, Snoek FJ, Van der Ploeg HM, Ader HJ, Heine RJ. Monitoring psychological well-being in outpatients with diabetes: effects on mood, HbA1c, and the patients evaluation of the quality of diabetes care: a randomized controlled trial. *Diabetes Care* 2001; **24** (11): 1929 – 1935.
11. Franz, MJ . Medical nutrition therapy of diabetes mellitus and hypoglycemia of nondiabetic origin. In Escott-Stump S, Mahan LK. *Krause's Food, nutrition and diet therapy*. WB Saunders, 1996: 742 - 780.

12. Erasmus RT, Blanco Blanco E, Okesina AB, Gqweta Z, Matsha T. Assessment of glycaemic control in stable type 2 black South African diabetics attending a peri-urban clinic. *Postgrad Med J* 1999; **75** (888): 603 – 606.
13. Hayward RA, Manning WG, Kaplan SH, Wagner EH, Greenfield S. Starting insulin therapy in patients with type 2 diabetes: effectiveness, complications and resource utilization. *JAMA* 1997; **278** (10): 1663 – 1669.
14. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998; **352** (9131): 837 – 853.
15. Motala AA, Pirie FJ, Gouws E, Amod A, Omar MA. Microvascular complications in South African patients with long-duration diabetes mellitus. *S Afr Med J* 2001; **91** (11): 987 – 992.
16. Rotchford AP, Rotchford KM. Diabetes in rural South Africa – an assessment of care and complications. *S Afr Med J* 2002; **92** (7): 536 – 541.
17. Rheeder P, Stolk RP, Veenhouwer JF, Grobbee DE. The metabolic syndrome in black hypertensive women – waist circumference more strongly related than body mass index. *S Afr Med J* 2002; **92** (8): 637 – 41.
18. Sato E, Miyashita M, Suzukamo Y, Kazuma K. Development of a diabetes-related quality of life scale. *Diabetes Care* 2004; **27**(6):1271 – 1275.
19. Taylor MD, Frier BM, Gold AE, Deary IJ. Psychosocial factors and diabetes-related outcomes following diagnosis of type 1 diabetes in adults: the Edinburgh Prospective Diabetes Study. *Diabet Med* 2003; **20** (2): 135 – 146.
20. Goddijn PP, Bilo HJ, Feskens EJ, Groeniert KH, Van der Zee KI, Meyboom-de Jong B. Longitudinal study on glycaemic control and quality of life in patients with type 2 diabetes mellitus referred for intensified control. *Diabet Med* 1999; **16** (1): 23 – 30.
21. Marra G: DIAB.& TE.S Project Study Group. The DIA.&TE.S Project: How patients perceive diabetes and diabetes therapy. *Acta Biomed Ateneo Parmense* 2004; **75** (3): 164 – 170.
22. Ahlgren SS, Schultz JA, Massey LK, Hicks BC, Wysham C. Development of a preliminary diabetes satisfaction and outcomes measure for patients with type 2 diabetes. *Qual Life Res* 2004; **13** (4):819 – 832.

23. Wang W, Shi L, Wang K. Assessment of quality of life in patients with diabetes mellitus and impaired glucose tolerance. *Zhonghua Yu Fang Yi Xue Za Zhi* 2001; **35** (1):26 – 29 (abstract).
24. Van der Merwe MT, Pepper MS. Obesity in South Africa. *Obes Rev* 2006; **7** (4): 315 – 322.
25. Koopmanschap M: CODE-2 Advisory Board. Coping with type 11 diabetes: the patients perspective. *Diabetologia* 2003; **46** (2): 302 – 303.
26. Wredling R, Stalhammar J, Adamson U, Berne C, Larsson Y, Ostman J. Well-being and treatment satisfaction in adults with diabetes: a Swedish population-based study. *Qual Life Res* 1995; **4** (6): 515 – 522.
27. Awadall AW, Ohaeri JU, Tawfiq AM, Al-Awadi SA. Subjective quality of life of outpatients with diabetes: comparison with family caregivers' impressions and control group. *J Natl Med Assoc* 2006; **98** (5): 737 – 745 (abstract).
28. Janssen I, Heymsfield SB, Allsion DB, Kotler DP, Ross R. Body Mass Index and waist circumference independently contribute to the prediction of non-abdominal abdominal subcutaneous and visceral fat. *Am J Clin Nutr* 2002; **75** (4): 683 – 688.
29. Baiardi F, Puglia MG, Valpiani et al. Relationship between body weight, quality of life and cardiovascular risk factors: a general population based Italian experience. *Eat Weight Disord* 2005; **10** (1): 19 – 24.
30. Kolotkin RL, Crosby RD, Williams GR. Assessing weight-related quality of life in obese persons with type 2 diabetes. *Diabetes Res Clin Pract* 2003; **61** (2): 125 – 132.
31. Di Francesco V, Sacco T, Zamboni M et al. Weight loss and quality of life improvement in obese subjects with sibutramine: a double-blind randomized multicenter study. *Ann Nutr Metab* 2007; **51** (1): 75 – 81.
32. Sotiropoulos A, Skliros EA, Tountas C, Apostolou U, Peppas TA, Pappas, SI. Risk factors for severe hypoglycaemia in type 2 diabetic patients admitted to hospital in Piraeus, Greece. *East Meditter J* 2005; **11** (3):485 - 489.
33. Ghanbari A, Yekta ZP, Roushan ZA, Lakeh NM. Assessment of factors affecting quality of life in diabetic patients in Iran. *Public Health Nurs* 2005; **22** (4): 311 – 322.

34. Ng TP, Lim LC, Jin A, Shinfuku N. Ethnic differences in quality of life in adolescents among Chinese, Malay and Indians in Singapore. *Qual Life Res* 2005; **14** (7):1755 – 1768.
35. Bakewell AB, Higgins RM, Edmunds ME. Does ethnicity influence perceived quality of life of patients on dialysis and following renal transplant?. *Nephrol Dial Transplant* 2001; **16** (7):1395 – 1401 (abstract).
36. Sarkisian CA, Brown AF, Norris KC, Wintz RL, Mangione CM. A systemic review of diabetes self-care interventions for older African-American or Latino adults. *Diabetes Educ* 2003; **29** (3):467 – 479.
37. Westaway MS, Rheeder P, Gumede T. The effect of type 2 diabetes mellitus on health-related quality of life (HRQOL). *Curationis* 2001; **24** (1): 74 – 78.
38. DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomized controlled trial. *BMJ* 2002; **325** (7367):746 – 765.
39. Davis TM, Clifford RM, Davis WA. Effect of insulin therapy on quality of life in type 2 diabetes mellitus: the Fremantle Diabetes Study. *Diabetes Res Clin Pract* 2001; **52** (1):63 – 71.
40. UK Prospective Diabetes Study Group. Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). *Diabetes Care* 1999; **22** (7): 1125 – 1136.
41. Prause W, Saletu B, Tribl GG, et al. Effects of socio-demographic variables on health related quality of life determined by the quality of life index – German version. *Hum Psychopharmacol* 2005; **20** (5):359 – 365.
42. Enzlin P, Mathieu C, Demyttenaere K. Gender differences in the psychological adjustment to type 1 diabetes mellitus: an explorative study. *Patient Educ Couns* 2002; **48** (2):139 – 145.
43. Cheung YB, Thumboo J. Developing health-related quality-of-life instruments for use in Asia: the issues. *Pharmacoeconomics* 2006; **24** (7):643 – 650.
44. Paskulin LM, Molzahn A. Quality of life of older adults in Canada and Brazil. *Pharmacoeconomics* 2007; **29** (1): 10 – 26.

APPENDICES

APPENDIX 1: demographic information forms that were completed by the participants in the study - English

Demographic information

Please complete the following form which contains your personal details

Please note that the square blocks are for office use only

Name:.....

Date of birth:.....

Age:.....

Marital status: single/ married/ divorced/ widowed/ separated/ other.....

Level of education completed:.....

Gender: Male / Female

Ethnic group: black/ white/Indian/ other.....

Are you part of the CDE program? YES/ NO

Have you attended the diabetic clinic previously? YES/ NO

What medication do you take for your diabetes? Insulin/ tablets/ both/ none

Do you have any other medical conditions that are bothering you at the moment?

YES/ NO If yes what is the condition

.....

.....

.....

Do you belong to a medical aid scheme? YES/ NO

APPENDIX 2: format of the ADDQoL for use in study - English

This questionnaire forms the basis of this study and will be used to assess whether or not your diabetes impacts on your quality of life. Please answer the question by circling the comment that best represents how you feel e.g. if I did not have diabetes my employment /career opportunities would be..

A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
---------------------	--------------------	-----------------	----------	----------------	-------------------	--------------------

N/A

Section A: English**1. if I did not have diabetes my employment/ career opportunities would be...**

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is...						
very important	important	quite important	not important at all			

N/A

2. if I did not have diabetes my social life would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is...						
very important	important	quite important	not important at all			

N/A

3. if I did not have diabetes my family relationships would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is...						
very important	important	quite important	not important at all			

N/A

4. if I did not have diabetes my friendships would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is...						
Very important	important	quite important	not important at all			

N/A

5. if I did not have diabetes my sex life would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is..						
Very important	important	quite important	not important at all			

N/A

6. if I did not have diabetes my sporting, holiday or leisure opportunities would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is..						
very important	important	quite important	not important at all			

N/A

7. if I did not have diabetes the ease with which I can travel would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is..						
very important	important	quite important	not important at all			

N/A

8. if I did not have diabetes my worries about my future (e.g. health, independence, income) would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is..						
very important	important	quite important	not important at all			

N/A

9. if I did not have diabetes my worries about the future of my family and close friends (e.g. their health, independence, income) would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is..						
very important	important	quite important	not important at all			

N/A

10. if I did not have diabetes my motivation to achieve things would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is..						
very important	important	quite important	not important at all			

11. if I did not have diabetes the things I could do physically would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is..						
very important	important	quite important	not important at all			

12. if I did not have diabetes the extent to which people would fuss too much about me would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is..						
very important	important	quite important	not important at all			

N/A

13. if I did not have diabetes my enjoyment of the food I would eat would be...

Choose the most appropriate answer						
A great deal better	Quite a lot better	A little better	The same	A little worse	Quite a lot worse	A great deal worse
This aspect of my life is..						
very important	important	quite important	not important at all			

APPENDIX 3: Informed consent in English

Informed consent

Title of the research study: The measurement of the perceived impact of diabetes on quality of life of the diabetic patient

Reference number:.....

Principal investigators: Leanne Katzenellenbogen and Sister Jaqueline Lubbe

Address: 50 Clinton Rd, Alberton, Johannesburg

DECLARATION BY THE PATIENT/ PARTICIPANT:

I the undersigned, (name) [ID

no:.....] the patient of

.....

.....

(address)

A .Hereby confirm as follows:

1. I/ the patient was invited to participate in the abovementioned research project which is being undertaken by the Department of Human Nutrition, Faculty of health Sciences, Stellenbosch University.

2. The following aspects have been explained to me/ the patient:

2.1 **Aim:** To assess the perceived impact of diabetes on quality of life in diabetic patients

2.2 **Procedures:** Each patient will be asked to complete a standard questionnaire that determines the perceived impact of diabetes on quality of life. I will only be asked to complete the questionnaire once. We are expecting 460 patients to be involved in the study, that will be ongoing from March – October.

2.3 **Benefits:** The study hopes to identify if diabetes impacts on the quality of life of the diabetic patient and if it does to try and incorporate this knowledge to the overall care of diabetic patients in South Africa

2.4 **Confidentiality:** When you have completed the questionnaire please place the form into a sealable envelope, which will be provided to you, to ensure that your response

remains confidential. Once we have those results we would also like to see if the quality of life assessment is in any way related to long term blood glucose control and we will therefore be comparing the questionnaire results to your HbA1C values. The HbA1C values are performed automatically by either Sister Jaqueline Lubbe or by Dr AJ Kok. We might therefore be required to contact the doctor's office for your HbA1C values if we are not already in possession of those. The results will be kept strictly confidential and the only person that will see the results is Leanne Katzenellenbogen. Once the envelopes (with your forms in) are opened you will be assigned a numerical code and your name will therefore not be published. Neither the sister nor the doctor will see the results of the questionnaire that you completed.

2.5 Access to the findings: Once the study is complete and the results have been analyzed the results will be submitted to peer reviewed journals so that other practitioners are aware of the results. The clinic will also produce a pamphlet that will be available for you to see. The results will be published for the group as a whole and not individually.

2.6 Voluntary participation/ refusal: Please remember that you participation in this study is voluntary and you are in no way obliged to participate. Should you refuse to participate in the study your future treatment at the diabetic clinic or at the doctor will not prejudice for future treatment.

3. The information above was explained to me/ the patient by

.....

..... (*name of the person*) in Afrikaans/ English and I am in command of this language. I/ the patient was given the opportunity to ask questions and all these questions were answered satisfactorily.

4. No pressure was exerted on me/ the patient to consent to participation and I/ the patient understand that I may withdraw at any stage without any penalization.

5. Participation in this study will not result in any additional costs to myself/ the patient.

B. I HEREBY CONSENT VOLUNTARILY TO PARTICIPATE IN THE ABOVE-MENTIONED PROJECT

Signed/ confirmed aton.....200.....

(Place)

(date)

.....

*Signature or right thumb print
of the patient*

signature of witness

STATEMENT BY OR ON BEHALF OF INVESTIGATORS:

I,, declare that

- I explained the information given in this document to
(name of the patient)
- He/ she was encouraged and given ample time to ask me any questions;
- This conversation was conducted in Afrikaans/ English and no translator was used.

Signed at

(Place)

on.....20....

(date)

.....

.....

Signature of investigator

signature of witness

I understand the information above and I am in command of the English/ Afrikaans information that has been provided to me by(name of researcher). I/ the patient was given the opportunity to ask questions and all these were answered satisfactorily. No pressure was exerted on me to consent to participate and I understand that I may withdraw at any stage without penalization. Participation in this research will not result in any additional costs to myself.

I hereby consent to voluntarily participate in the abovementioned study

Signed at.....on.....20.....

(place)

(date)

.....

Signature or right thumb print of the patient

.....

signature of witness

IMPORTANT MESSAGE TO THE PATIENT:

Dear patient:

Thank you for your participation in this study. Should, at any time during the study, you require any further information with regard to the study kindly contact Leanne Katzenellenbogen at 724-2133, 50 Clinton Rd Alberton. In case of emergencies I may be contacted at 0832308101.

APPENDIX 4: demographic information forms that were completed by the participants in the study – Afrikaans

Voltooi asseblief die volgende vorm wat u persoonlike inligting bevat:

Blokkies is slegs vir kantoorgebruik

Naam:

Geboortedatum:.....

Ouderdom:

Huwelikstatus: Enkel/Getroud/Geskei/Weduwee/Wewenaar/Vervreemd/Ander.....

Vlak van opleiding:.....

Geslag: Manlik/Vroulik

Etniese groep: Blank/Nie-blank/Indiër/Gekleurd/Ander.....

Is jy deel van die CDE-program? JA / NEE

Het jy al voorheen die diabetiese kliniek besoek? JA / NEE

Watter metode gebruik U om U diabetes te beheer? Insulien/Tablette/Beide/Geen

Het U huidiglik enige ander mediese toestand wat u ongerief verskaf? JA / NEE:

Indien JA op bg.

Spesifiseer:.....
.....

Behoort U aan enig mediese skema? JA / NEE

LET WEL Blokkies is slegs vir kantoorgebruik

APPENDIX 5: ADDQoL format for use in the study - Afrikaans

Die vraelys vorm die basis van die studie en sal help om u kwaliteit van lewe te bepaal, as a diabeet. Antwoord asseblief die kommentaar wat u beste beskryf b.v. as ek ni 'n diabeet was nie sou my beroep geleentheid as volg wees...

Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
---------------	------------	--------------	-----------	----------------	--------------	--------------------

N/A

1. sonder diabetes sou my loopbaan/ beroepsgeleentheid as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

2. sonder diabetes sou my sosiale lewe moontlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

3. sonder diabetes sou my gesins-verhoudinge waarskynlik as volg daarna uitsien...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter

N/A

Hierdie aspek van my lewe is:			
Baie belangrik	belangrik	Nogal belangrik	onbelangrik

4. sonder diabetes sou my verhoudings met my vriende moontlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

5. sonder diabetes sou my intieme lewe moontlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

6. sonder diabetes sou my vakansie of ontspannings geleentede waarskynlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

7. sonder diabetes sou die gemak en spontaniteit waarmee ek rondreis waarskynlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

8. sonder diabetes sou my bekommernisse rakende my toekoms (gesondheid, loopbaan, onafhanklikheid en ideale) waarskynlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

9. sonder diabetes sou die besorgheid oor my gesin en vriende (se gesondheid, onafhanklikheid, inkomste) waarskynlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

10. sonder diabetes sou my dryfkrag/ motivering om te presteer waarskynlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

11. sonder diabetes sou my fisiese vermoëns waarskynlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

12. sonder diabetes sou die graad en ophef wat mense oor my maak as diabeet waarskynlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

13. sonder diabetes sou die smaak van voedsel en hoe ek dit genit waarskynlik as volg wees...

kies die mees korrekte antwoord						
Heelwat beter	Baie beter	Effens beter	dieselfde	Effens slegter	Baie slegter	aansienlik slegter
Hierdie aspek van my lewe is:						
Baie belangrik	belangrik	Nogal belangrik	onbelangrik			

N/A

APPENDIX 6: informed consent in Afrikaans

Ingeligte toestemming

Doelstelling van die navorsings-projek: Die meting van die verwagte impak van diabetes op die “kwaliteit van lewe” op die pasiënt

Verwysingsnommer:

Hoof-navorsers: Leanne Katzenellenbogen (Dieetkundige) and Jacqueline Lubbe (Geregistreerde Verpleegkundige)

Adres: Clintonweg no.50, Alberton, Johannesburg

Verklaring van pasiënt/deelnemende party:

Ek, die ondergetekende,.....(Volle name)

[ID.no.....]; pasiënt van

.....(adres).

A.Hiermee verklaar ek as volg:

1.Ek die pasiënt is gevra om deel te neem aan hierdie navorsings-projek, geloods deur Departement van Menslike Voeding, Fakulteit van Gesondheidswetenskappe en Universiteit van Stellenbosch.

2.Die volgende aspekte is aan my/pasiënt verduidelik:

2.1 Doel: Om die impak te meet van diabetes op die kwaliteit van lewe in diabetiese pasiënte.

2.2 Presedure: Elke pasiënt sal gevra word (op vrywillige vlak) om ‘n gestandaardiseerde vraelys te voltooi wat ten doel het om die impak van diabetes te help bepaal op die kwaliteit van lewe. Die vraelys word eenmalig voltooi. Ons beraam ‘n deelname van gemiddeld 460 pasiënte, vanaf Maart 2005 tot Oktober 2005.

2.3 Voordele: Die oogmerk van hierdie projek is om probleme te identifiseer m.b.t. impak van diabetes op “kwaliteit van lewe” in die diabetiese pasiënte; ten einde ‘n beter gewaarwording/ bewustheid te kweek in die behandeling van hierdie persone in Suid-Afrika.

2.4 Vertroulikheid: Dit sal noodsaaklik wees dat langtermyn-bloeduitslae (HbA1C) geneem word deur dr.J.A.Kok of plaaslike laboratorium (o.l.v. Sr.J.Lubbe); sodat die impak van die die

kwaliteit van lewe ook gemeet word tussen die uitkoms van die vraelys en die bloeduitslae. Sodoende sal daar dus 'n indirekte instrument wees om die "kwaliteit van lewe" te meet. Daar sal dus navrae gerig word aan u dokter of die suster om die resultate te kry, as u nie self oor die inligting beskik nie.

Nadat u die vraelys voltooi het, moet u asseblief dit onmiddelik in die beskikbare koevert plaas en verseël. Op hierdie wyse verseker dit die vertroulikheid van u inligting, aangesien slegs Leanne Katzenellenbogen, hierdie inligting verwerk. Sodra die koevert geopen word, word daar onmiddelik 'n rekenaarnommer toegeken en daarom sal u persoonlike inligting nie gepubliseer word nie. Beide Dr. J.A. Kok en Sr. J. Lubbe het geen toegang tot hierdie dokumente sodra dit verseël is nie.

2.5 Toegang tot resultate: Sodra al die inligting ingevoer en verwerk is, sal dit bekend gemaak word in plaaslike mediese tydskrifte, sowel as 'n plaaslike pamflet by die kliniek. Hierdie inligting sal op "groeps-basis" hanteer word; sodat dit die plaaslike mediese multidissiplinêre spanne kan help met bewustheid van die "kwaliteit van lewe" en die impak van diabetes daarop. Geen individuele verslae sal beskikbaar wees nie.

2.6 Vrywillige deelname en of weiering van deelname: Neem asseblief kennis, dat die deelname aan hierdie projek, absoluut vrywilliglik is en dat u onder geen omstandighede verplig hoef te voel om deel te neem nie. Dit sal geensins u toekomstige versorging/behandeling beïnvloed nie.

3. Die inligting van bogenoemde projek is aan my verduidelik deur
(naam van persoon) in Afrikaans/Engels. Ek is totaal en al vertrouwd met die taal. Ek/pasiënt is die geleentheid gegun vir die stel van vrae (oor die projek) en my vrae is begroet met deeglike antwoorde, wat my tevrede stel.

4. Hoegenaamd geen druk van enige aard is op my/pasiënt geplaas om deel te neem aan die projek/studie nie. Ek is ook bewus dat ek ter eniger tyd myself mag onttrek aan deelname, sonder enige pennalisering daarvoor.

5. Deelname aan hierdie projek/studie sal geensins enige finansiële vergoeding of uitgawe vir myself/pasiënt inhou nie

B. HIERMEE VERLEEN EK OP VRYWILLIGE GRONDSLAG, TOESTEMMING TOT DEELNAME AAN BOVERMELDE PROJEK:

Geteken/verklaar te op 200

(Plek)

(Datum)

Geteken te.....op.....200.....

*(Plek)**(Datum)*

.....

(Handetening van pasiënt)

.....

*(Handtekening van getuie)***BELANGRIKE BOODSKAP AAN PASIËNT:**

Geagte Pasiënt:

Baie dankie vir U deelname aan bogenoemde projek. Sou u enigsens (tydens verloop van die studie/ projek) inligting daaromtrent verlang, kontak asseblief Leanne Katzenellenbogen @ Clintonweg no. 50, New Redruth, Alberton, 724-2133. In geval van nood kan el getontak word op volgende nommer 08323081801.

APPENDIX 7: the medical information form that was completed by the researchers

This section of the demographic questionnaire is to be completed by researcher as obtained in medical file:

Most recent HbA1c

Type of DM

Duration of DM (years)

Complications related to DM: BP/ hyperlipidaemia/ retinopathy/ neuropathy/ nephropathy

Concomitant conditions

Weight (kg)

Height (cm)

BMI

Waist circumference (cm)

Comments (if relevant)

.....

.....

.....

.....