THE ASSOCIATION BETWEEN HEALTH RELATED QUALITY OF LIFE AND SOME INDICATORS OF SEVERITY AND CONTROL IN DIABETIC TYPE 2 PATIENTS AT A CENTRE IN JOHANNESBURG.

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

Johannesburg, 2006

DECLARATION

I, Gerish Daya declare that this research report is my own work. It is being submitted in partial fulfilment for the degree of Master of Family Medicine to the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

…….

Gerish Daya

……day of …….. 2007

DEDICATION

In memory of my mother

Kamla C Daya

(1926-2003)

ABSTRACT

Diabetes mellitus type 2 is common and the prevalence is increasing exponentially. The long-term complications of diabetes can only be prevented by life long commitment to a challenging treatment regimen.

Health related quality of life might be an important determinant of whether patients will adhere to the prescribed treatment regimens. The purpose of this study was to determine whether there is an association between the health related quality of life and certain indicators of the severity and control of diabetes type 2 in a sample of patients at a diabetes centre in Johannesburg.

Data relating to the control and severity of diabetes type 2 was gathered from 97 patients attending at the Centre for Diabetes and Endocrinology, Johannesburg. Data related to their quality of life was gathered from a questionnaire. The data was captured and analysed using the Epi Info programme.

Insulin usage was found to be strongly associated with a **lower** health related quality of life. Surprisingly the other parameters studied viz. HbA1C, BMI, exercise, vascular complications and the use of oral hypoglycaemic, anti-hypertensive and lipid lowering agents were not found to be strongly associated with health related quality of life.

Clinicians prescribe insulin in order to maintain normal blood glucose levels. This is critical to prevent the long-term complications of diabetes. The findings of this study have important implications for the use of this essential medication.

ACKNOWLEDGEMENTS

1. To Professor Bruce Sparks for his guidance, encouragement and for supervising this research.
2. To J Gregory Boyer and Jo Anne L Earp for allowing me to use the Diabetes-39 questionnaire
3. To Professor Pieter Becker for help with the statistics.
4. To Dr L Distiller for allowing me to conduct the research at The Centre for Diabetes and Endocrinology.
5. To the staff at the Centre for Diabetes and Endocrinology who encouraged patients to participate in the study.
6. To the patients who participated by filling in the questionnaire and for allowing me to view their confidential medical files.

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PREFACE

The prevalence of diabetes type 2 is expected to increase exponentially as South Africa becomes more industrialized. Preventing the long-term complications of this disease requires life-long commitment to a rigorous treatment regimen.

The effects of the treatment regimens on the health related quality of life have not been extensively studied. These effects may have an important bearing on whether patients will adhere to the suggested treatment regimens.

This study determines the associations between health related quality of life and some indicators of the severity and control of diabetes.

1 INTRODUCTION AND LITERATURE REVIEW.

The World Health Organisation (WHO) has declared; "The world is facing a growing diabetes epidemic of potentially devastating proportions. Its impact will be felt most severely in developing countries".[1] The prevalence of diabetes worldwide is estimated to be at least 171 million people. This figure is likely to more than double by 2030.[1] It is estimated that 3.2 million people died from complications of diabetes in 2000.[1] The prevalence figures for South Africa are estimated to be about 8% of the overall population. The burden amongst the Asian section of the population is estimated to be >14%.[2] Indigenous people of African, Australasian and American origin are particularly susceptible to the disease. In developed countries it is predominantly the senior citizens who bear the brunt of this disease whereas in developing countries it is most prevalent in the 35 year to 64-year age group.[1] Increasing trends towards obesity, unhealthy diets, and sedentary lifestyle are major causes of the increase in prevalence of this disease.

The health burden of HIV/AIDS has been highlighted globally. It is not common knowledge that the burden of premature death due to diabetes is on a par with HIV/AIDS.[1]

Diabetes consumes between 5% and 10% of the healthcare budget of many countries. More than 50% of the cost is on managing the complications of the disease.[1] Unlike in acute illness, successful management of chronic diseases is largely patient driven. Patients are responsible for more than 90% of diabetes care and clinicians have very little control over how patients manage themselves between office visits. The patient is the only person who will be able to determine what level of adherence is possible in his/her life.[3] There are numerous priorities in people's daily lives and

patients take cognisance of all these demands before deciding how much they can/will adhere to a particular treatment regimen. This becomes even more relevant when the treatment regimen is very rigorous and is life-long. The chronic complications of diabetes can only be prevented by life-long commitment to a rigorous treatment regimen. It is essential that patients perceive that the prescribed treatment is allowing them a good health related quality of life if an acceptable level of adherence is to be achieved. The prevention of chronic complications is the main object of the treatment regimens that are prescribed.

1.1 Health related quality of life.

The World Health Organisation defined health as "a state of complete physical, mental and social well-being and not merely absence of disease".[4] Health related quality of life (HRQoL) is a concept that tries to encompass the spirit of the WHO definition of health. It tries to assess the general health, cognitive function, mental health, emotional state, subjective well-being, life satisfaction and social support.[5]

Various instruments have been developed to measure health related quality of life. Amongst the most well known generic instruments are the SF-36 (this is the shortened version of the Rand Corporation's MOS Functioning and Well-being profile)[6], the Quality of Well-being (QWB) scale, its successor the Quality of Well-being Self-Administered Scale (QWB-SA)[7], the Euroqol 5D and the COOP/WONCA charts.

Disease specific questionnaires have been developed for many ailments. These attempt to measure aspects of ill health that are particularly salient to the disease group being studied and they should therefore be more sensitive to changes.[8] This has been supported in a number of studies where generic measures have

failed to indicate change as a consequence of treatment but disease-specific measures have done so.[9]

J. Gregory Boyer and Jo Anne L Earp developed the Diabetes-39 questionnaire.[10] It was developed to measure health related quality of life in both type 1 and type 2 diabetic patients. The reliability of the instrument is acceptable with a Cronbach's α of 0.81-0.93 for all the sub-scales. The construct validity was compared with the widely used SF-36 and found to be very satisfactory. The developers did not give express consideration to face/content validity but used extensive literature reviews, existing QoL questionnaires and interviews with health professionals and diabetic patients to develop the questionnaire.[11] The questionnaire has been validated in Dutch, French, German, Italian, UK English, Danish, Finnish, Norwegian and Swedish.[12,13]

A study in Netherlands concluded that diabetic patients without micro/macrovascular complications had an HRQoL only slightly lower than similar aged persons in the general population. Insulin therapy, obesity and diabetic complications were associated with a lower HRQoL. Higher HbA1C levels did not seem to materially affect the HRQoL.[14] A study from Michigan, USA found that HRQoL was lower in women and obese subjects and in those treated with oral hypoglycaemic, insulin, and antihypertensive drugs. Blindness, dialysis, symptomatic neuropathy, foot ulcers, amputation, stroke and congestive heart failure were associated with a markedly lower HRQoL.[15] Lau C, Qureshi AK and Scott SG found that there was a correlation between better HbA1C levels and improved mental, but not physical HRQoL.[16] D. Robb Holton, Sheri R. Colberg and Tanya Nunnold found no statistically significant difference in the QoL between exercising and non-exercising diabetic patients.[17] A French study found that age (>75years), female gender, loneliness, absence of professional or physical activity, management by a specialist, presence of two or more diabetes complications and

treatment with insulin were all factors reducing QoL.[18] The UKPDS study found that complications of diabetes affect QoL whereas therapeutic policies shown to reduce the risk of complications had no effect on QoL.[19] All these studies used generic HRQoL instruments.

Despite extensive search on Medline, the researcher could not find any reports of work done to determine the HRQoL of diabetics in South Africa.

1.2 Indicators of severity and control of diabetes.

Clinicians use various markers to determine severity and control of diabetes. These include:

- Glycosylated haemoglobin (HbA1C) levels. This is a measure of the blood glucose level over the previous 6-8 weeks. According to the Diabetes Care and Control Study data, HbA1C levels of less than 7% are desirable because they prevent or significantly delay complications of diabetes.[20]

- Body Mass Index (BMI). It is well known that obesity predisposes to diabetes type 2. Absolute weight is confounded by the different heights of people. Body Mass Index takes the height into consideration and standardizes the measurement for comparing people. The BMI is calculated by dividing the weight (in kilograms) by the height (in meters) squared. This measurement has become the standard in clinical practice where weight is being assessed.

- Diet, exercise and medication form the three pillars on which diabetes is managed. The medication can be divided into 4 categories viz. insulin sensitizors (eg metformin), insulin

secretagogues (eg.sulphonylureas), drugs delaying absorption of glucose (acarbose), and insulin. Clinicians prescribe various combinations of the above categories of medication. Various types and dosage regimens for insulin and oral hypoglycaemic are used. (This study did not distinguish between the different types or dosage regimens for insulin or oral hypoglycaemics.)

- Exercise. Regular exercise improves the utilization of glucose from the blood stream. Exercise is one of the pillars in the management of diabetes. The Centre has a gymnasium on site. Resident biokineticists advise on exercise regimens. Patients are not obliged to join the gymnasium.

The long-term complications of diabetes can be classified in terms of macrovascular and microvascular complications.

- Macrovascular complications manifest clinically as myocardial infarction, angina pectoris, coronary artery surgery/angioplasty, heart failure, stroke, transient ischaemic attacks, and peripheral vascular disease.[14]

- Microvascular complications manifest as foot ulcers, amputations, retinopathy, photocoagulation or vitrectomy, blindness, neuropathy, microalbuminuria, manifest nephropathy, dialysis and renal transplant.[14]

2 MOTIVATION FOR STUDY.

It is predicted that the burden of Diabetes Type 2 will increase exponentially as South Africa becomes more industrialized and the socio-economic profile changes amongst the various racial groups in our country. This increased burden will consume ever-increasing amounts from the already limited health care resources. Managing the complications of diabetes is extremely costly and difficult.[1] Preventing these complications is the object of the prescribed treatment regimens.

The management of diabetes (and other chronic diseases) is largely patient driven. Patients will ultimately decide which parts of the advice can and will be followed. The effects of the disease and its management on HRQoL will be an important determinant as to what advice can/will be heeded. Greater insight into HRQoL will be useful in managing chronic diseases. Clinicians need to realize that while they are experts in diabetes, the patient is an expert on his/her own life. Marriage of these two forms of expertise will lead to the best clinical outcome.[3]

In order to have a better understanding of the effects of diabetes on HRQoL, studies are needed to determine which parameters are having the greatest adverse effect. No such research has yet been published from South Africa.

The findings of this research will contribute to understanding and dealing with the complex issue of adherence to treatment regimens.

2.1 Aims and objectives.

AIM

To determine the association between the health related quality of life and certain indicators of the control and severity of disease in diabetic type 2 patients.

OBJECTIVES

1. To document the demographics of the population that is being studied.

2. To document co-existing diseases. (Hypertension and hyperlipidemia also cause vascular disease.)

3. To determine the health related quality of life of a sample of type 2 diabetic patients

4. To document the following parameters which are important in determining the control and severity of diabetes type 2.

    a) Glycosylated haemoglobin.
    b) Body Mass Index.
    c) Prescribed medication.
    d) Macrovascular complication.
    e) Microvascular complications.
    f) Exercise compliance.

5. To determine whether there is an association between any or all of the above parameters and the health related quality of life of these patients.

3 METHODOLOGY.

3.1 Definitions and abbreviations.

Health Related Quality of Life: (HRQoL). The Diabetes-39 questionnaire was used to determine the quality of life. "Quality of life"(QoL) was not defined to respondents during the development of the Diabetes-39 questionnaire.[10] No attempt was made to define quality of life to the subjects during this study; instead, patients were asked to indicate the effect of each item on their quality of life according to their own definition.

Diabetes: The study was confined to patients with diabetes mellitus type 2. Patients with diabetes type 1 were asked not to participate in the study. Unless otherwise proven, it was assumed that patients diagnosed after the age of 30 years were type 2. Other workers have used 30 years as a cut-off point.[14] Patients under the age of 18 years were asked not to participate in the study.

Exercise. Participants were deemed to be exercising if they attended a gymnasium at least 3 times per week or if they reported self- exercising for at least 30 minutes three times per week. This regimen must have been followed for at least 1 month.

Centre. The Centre for Diabetes and Endocrinology, Houghton, Johannesburg

3.2 Study design.

This is a descriptive study.

A sample of patients, attending for routine consultation at the Centre, was asked to fill in the Diabetes-39 questionnaire. Certain parameters, which are important in the management of diabetes, were documented from patient files. The results were computed in the Epi info programme and associations were determined using statistical analysis.

3.3 Site of study.

The study was conducted at The Centre for Diabetes and Endocrinology, Houghton, Johannesburg. This is a private institution specializing in the care of diabetes (all types) and other endocrine diseases. A team consisting of clinicians, diabetes educators, biokineticists, psychologists, podiatrists, nutritionists, pharmacists and other role players manage the care.

Patients have to pay for the medication and services they receive. The funding comes from health insurance (medical aid funds) or payment from personal funds. This excludes patients who cannot afford the fees. This implies that patients from the lower economic bands of the population were excluded from the study.

3.4 Study population.

The study population was a sample of patients consulting routinely at the Centre. The practice manager and the receptionists were requested to ask consecutive patients to participate in the study.

3.4.1 Statistical consideration.

The presence or absence of co-existing diseases viz. hypertension, and/or hyperlipidemia was expected to be the largest confounding factor in this study. The sample size needed to be large enough to address this issue. Hypertension and hyperlipidemia are treated very aggressively when they co-exist with diabetes. An estimate of at least 50% prevalence of these diseases was made.

3.4.1.1 Sample size.

The sample size was determined with the help of a biostatistician from the Medical Research Council (Prof. P.Becker). The sample size was calculated using the Epi Info programme.

- The sample size was based on objective number (2). A conservative scenario of a 50% prevalence of co-existing disease was considered. It was calculated that a 95% two-sided confidence interval based on a sample size of 97 patients would estimate the assumed prevalence of 50% to an accuracy of 10%.

This sample size would have adequate power to address the other objectives of the study.

3.5 Measuring instruments.

3.5.1 Demographic features and co-existing diseases.

This was ascertained from the questionnaire. (Appendix 11.2/Page75). This included details of age, sex and co-existing diseases. Questions (1) and (2) asked participants whether they

were on medication for hypertension and high cholesterol respectively. Participants who were not on medication for hypertension and/or high cholesterol were assumed not to have these diseases for the purposes of this study. The answer to the question on 'other diseases' was correlated with the notes in the patient files for accuracy. The medication prescribed for the various illnesses was ascertained from patient files.

3.5.2 Health related quality of life.

Participants were asked to complete the Diabetes-39 questionnaire. (Appendix 11.3/Page 76).

The questionnaire measures five scales: Energy and Mobility; Sexual Functioning; Social Burden; Anxiety and Worry; and Diabetes control. The questionnaire and scoring instructions were obtained from the developers of the questionnaire.

3.5.2.1 Energy and Mobility.

Fifteen of the questions in the Diabetes-39 questionnaire quantify how much the diabetes is affecting the participant's energy and mobility. The developers of the questionnaire maintain that at least 12 of the questions need to be answered for the result to be meaningful.

3.5.2.2 Sexual Functioning.

Three of the 39 questions are related to this aspect of quality of life. The developers of the questionnaire maintain that all 3 questions need to be answered for the result to be meaningful.

3.5.2.3 Social Burden.

There are 5 questions related to this aspect of quality of life. It is a measure of the burden that diabetes is having on the participant's social life. At least 4 questions need to be answered for the result to be meaningful.

3.5.2.4 Anxiety and Worry.

Four questions are related to this aspect of quality of life. These quantify the anxiety and worry that having diabetes is causing in the participant's life. A minimum of 3 questions needs to be answered for the result to be meaningful.

3.5.2.5 Diabetes Control.

Twelve questions measure the effects of 'diabetes control' on the quality of life. This score determines the effect of all the measures that the participant takes to maintain normal blood glucose levels. At least 9 questions need to be answered for the result to be meaningful.

3.5.3 Severity and control of diabetes.

The measures of the severity and control of diabetes were obtained from patient files.

3.5.3.1 HbA1C.

The glycosylated haemoglobin was recorded from patient files. Clinicians request this test at each routine visit. Lancet Laboratories services the Centre.

3.5.3.2 BMI.

Clinicians at the Centre document the weight of patients at each visit. The height is documented at the initial assessment and thereafter at varying intervals by the clinician, biokineticist, dietician or the diabetes educator. The last recorded height was used to calculate the BMI.

3.5.3.3 Exercise.

This was ascertained from the questionnaire (Appendix 11.2/Page 75). The questions on exercise were very specific. Participants were deemed to be exercising if they attended a gymnasium at least 3 times per week or if they self-exercised for at least 30 minutes per session at least 3 times per week. Participants were asked to describe the type of exercise they did if they self exercised. This was done to ensure that activities such as “window shopping” were not considered to be exercise.

3.5.3.4 Medication.

This was determined from patient files. The use of insulin, oral hypoglycaemics, medication for hypertension, hyperlipidemia and for other diseases was documented.

3.5.3.5 Macrovascular disease.

Patient files were scrutinized for past history of myocardial infarction, angina pectoris, coronary artery surgery/angioplasty, heart failure, stroke, transient ischaemic attacks, and peripheral vascular disease.

3.5.3.6 Microvascualr disease.

Patients at the Centre undergo regular assessment to look for signs of and to grade retinopathy and other ocular disturbances. These are recorded on a separate card. Indicators of foot ulcers, amputations, neuropathy, microalbuminuria, manifest nephropathy, dialysis and renal transplant were sought for in the patient files.

4 ETHICAL ISSUES.

Prior to the commencement of the study a protocol was submitted to the Human Research Ethics Committee, University of Witwatersrand. The protocol was approved – clearance number M050403.

A copy of the clearance certificate is shown as Appendix 11.6/ page 84.

The patient information sheet (Appendix 11.1/page 73) was attached to the front of each questionnaire. The researcher was introduced to the participants in the information sheet. The sheet also explained the aim and importance of the research. Patients were assured that there would be no recriminations if they decided not to participate in the study. Participants were guaranteed that their responses would be confidential and that there would be total anonymity in reporting the data.

5 DATA COLLECTION AND ANALYSIS.

5.1 Data collection.

The practice manager at the Centre was given 120 packs of the questionnaires. The packs comprised of the 'patient information sheet' (Appendix 11.1/page 73), the 'questionnaire' (Appendix 11.2/page 75) and the 'Diabetes–39 questionnaire' (Appendix 11.3/page 76). The manager was also given a 'subject list' sheet. (Appendix 11.4/page 81) The allotted number column on the 'subject list' was filled in and cross-referenced with the number on the questionnaires that were handed to willing participants. The practice manager filled in the name of the participant, corresponding to the 'allotted number', in the 'subject sheet'. The manager kept the completed questionnaires. The researcher went to the Centre every time there was a batch of 5-6 completed questionnaires. The manager retrieved the patient files and these files were scrutinized for information pertaining to the HbA1C, BMI, macrovascular and microvascular complications, and information about medication prescribed for diabetes, hypertension and hyperlipidemia. This information was entered into 'data collection' sheets. (Appendix 11.5/page 82)

It took almost a year to get the required number of patients to participate in the study. Various reasons were forwarded for the delay including patients not willing to participate, too few patients attending the Centre etc. The request to include a record of patients who refused to participate in the study was not complied with. The researcher is not sure whether the staff (i.e. practice manager and receptionists) at the Centre introduced any type of bias when asking patients to become participants in the study.

5.2 Data analysis.

The Epi info programme was used to capture and analyse data. The programme was developed by the Centre for Disease Control (CDC), Alberta. USA. This programme if freely available to the public for use.

The statistical capability of the Epi info program was used extensively to analyse the data. Professor P. Becker of the Medical Research Council assisted in analysing the data. Associations were further determined using Hotelling test when there were 2 categories and Bonferreni test when there were more than 2 categories. A p-value of less than (0.05) was considered statistically significant.

Discrete parameters (e.g. sex, co-existing disease, exercise, macro/microvascular disease) are described using percentages and continuous parameters (e.g. HRQoL scores, HbA1C levels) are described using means. The Epi info programme computed these results. (95% confidence interval was used).

6 Limitations of Study.

The main limitation in interpreting these results is that this study was done in a specialist diabetes centre. Patients have to pay for the medication and services they receive. The funding comes from health insurance (medical aid) or payment from personal funds. This excludes patients who cannot afford the fees. The service providers at the Centre are diabetologists and other specialists who deal almost exclusively with diabetes. The Centre is situated in an exclusive suburb of Johannesburg. Patients attending here belong to the higher socio-economic bands of the population. The participants in this study were all well versed in the English language (a function of patients attending at this exclusive site).

The majority of patients in the country attend generalists either in the public or private sector. It will be interesting to compare these findings with studies done in other less affluent populations being treated at other sites.

The manager and receptionists at the Centre may have introduced some form of selection bias when requesting participants to fill in the questionnaires. (Section 5.1/page 27)

7 RESULTS.

(The results pertaining to the measurement of 'response rates', 'demographic features', 'indicators of severity and control of diabetes' and the 'parameters of HRQoL' are presented in this section. The associations between the 'severity and control of diabetes' and 'HRQoL' are presented in section 8)

7.1 Response rates.

Patients were asked to participate in the study when they presented for consultation. The request to document the patients who refused to participate in the study was not complied with. It was, therefore, impossible to get more details of the response rates. It took almost a year to obtain the required number of participants (97) to complete this study. (Section 9.1/Page 65)

7.2 Demographic Features.

7.2.1 Age and sex.

Participants were asked to fill in their date of birth - question (5) of the questionnaire (Appendix 11.2/Page 75). The age was calculated from this. The ages ranged from 39 years to 89 years. The mean age was 60.04 years. The mode was 58yrs (7 participants).

For comparative purposes, the participants were divided into age groups (i.e. age 20 yrs – 29 yrs in one group etc). There were 3 participants (3.10%) in the (30yrs-39yrs) age group. Thirteen participants (13.40%) belonged to the (40yrs – 49yrs) group. There were 33 participants in both the (50yrs–59yrs) and in the (60yrs–

69yrs) groups. There were 12 participants (12.40%) in the (70yrs-79yrs) group and 3 participants (3.10%) in the (80yrs-89yrs) group. (Table I)

Participants were also asked to fill in their sex (male/female) in question (11) of the questionnaire. (Appendix 11.2/page 75)

There were 22 females and 75 males in the study population. (Table II)

Table I: Age groups. (n=97)

Age group	Frequency	Percent	Cum Percent
30-39yr	3	3.10%	3.10%
40-49yr	13	13.40%	16.50%
50-59yr	33	34.00%	50.50%
60-69yr	33	34.00%	84.50%
70-79yr	12	12.40%	96.90%
80-89yr	3	3.10%	100.00%
Total	97	100.00%	100.00%

Table II: Sex distribution. (n=97)

Sex	Frequency	Percent
Female	22	22.70%
male	75	77.30%
Total	97	100.00%

There was no statistically significant association between the age groups and sex of participants in this study (p=0.7637).

7.3 Exercise.

Question (4) of the questionnaire (Appendix 11.2/page 75) asked participants about exercise. Participants were deemed to be exercising if they attended any gymnasium at least 3 times per week every week for the last month or if they self-exercised for at least 30 minutes per session a minimum of 3 times per week every week for the last month.

Forty-seven participants (48.50%) exercised regularly. Fifty-one participants (51.50%) did not exercise regularly. (Table III)

Twenty-eight participants self exercised whereas 19 participants exercised in a gymnasium. There was no statistically significant difference between these two groups for any of the parameters studied. The type of exercise i.e. whether they exercised in a gymnasium or self-exercised, was not pursued further in this study.

Table III: Exercise frequency. (n=97)

Exercise	Frequency	Percent
Yes	47	48.50%
No	51	51.50%
Total	97	100.00%

There was no statistically significant association between the age groups (p=0.5338) or sex (p=0.3166) and whether participants exercised or not.

7.4 Body Mass Index (BMI).

The BMI was calculated by dividing the weight (in kg) by the height in meters squared. Participants were then grouped into 4 categories for descriptive purposes.

- Participants with BMI of less than 20 were **underweight**
- Participants with BMI between 20 and 24.9 were **normal weight**
- Participants with BMI between 25 and 29.9 were **overweight**
- Participants with BMI greater than 30 were **obese.**

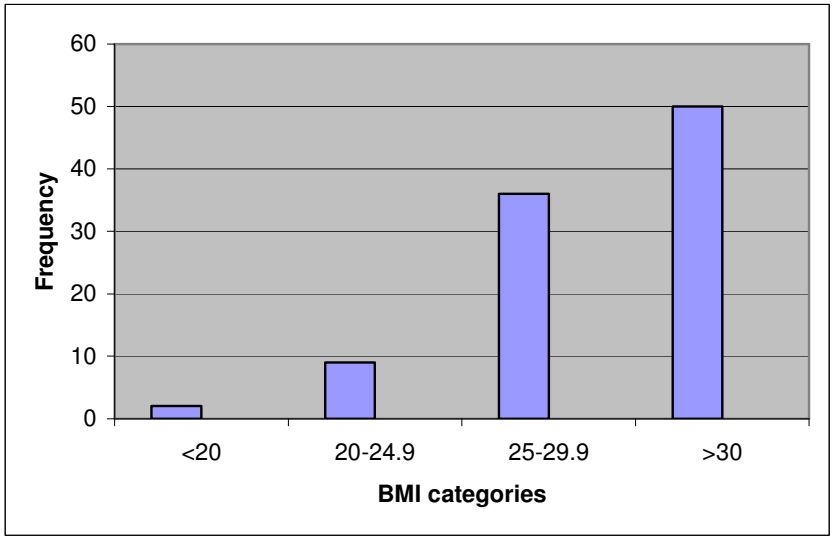

Figure 1: Frequency of BMI categories. (n=97)

Two participants (2.10%) were in the underweight category. Only 9 participants (9.30%) were in the normal weight category. Thirty-six participants (37.10%) were in the overweight category and 50 participants (51.50%) were in the obese category i.e. 88.60% of participants were above ideal BMI in this study. (Figure 1)

The mean BMI in this study was 31.23. This places the mean in the obese category. The mode was 27 with 6 participants having this score. (Range 18.35 – 55.82).

There was no statistically significant association between the age groups and BMI categories. (p=0.3950).

However, females were more likely to be in the obese category (77%) as opposed to males (44%). More males tended to be in the overweight category (44%) as opposed to females (13.6%). There were 7 males (9%) and 2 females (9%) in the normal BMI category. These differences were statistically significant (p 0.0373).

The 2 participants in the underweight category were both males.

7.5 Glycosylated Haemoglobin groups (HbA1C).

The target HbA1C is less than 7%[20]. Levels of less than 7% are desirable because they prevent or significantly delay the onset of complications of diabetes.[20]

For descriptive purposes, participants were grouped into 5 categories:

- HbA1C less than 7%
- HbA1c between 7 – 7.9%
- HbA1c between 8 – 8.9%
- HbA1c between 9 – 9.9%
- HbA1c greater than 10%

Thirty-four participants (35.1%) had the target HbA1c of less than 7%. Thirty-one participants (32%) had an HbA1C of between 7% and 7.9%. Twenty-one participants (21.6%) had an HbA1C of

between 8% and 8.9%. Six participants (6.2%) had an HbA1C between 9% and 9.9% and five participants (5.2%) had an HbA1C greater than 10%. (Figure 2)

The mean HbA1C in this study was 7.61%. The mode was 7.4% with 6 participants having this level. (Range 5.7% – 11.2%)

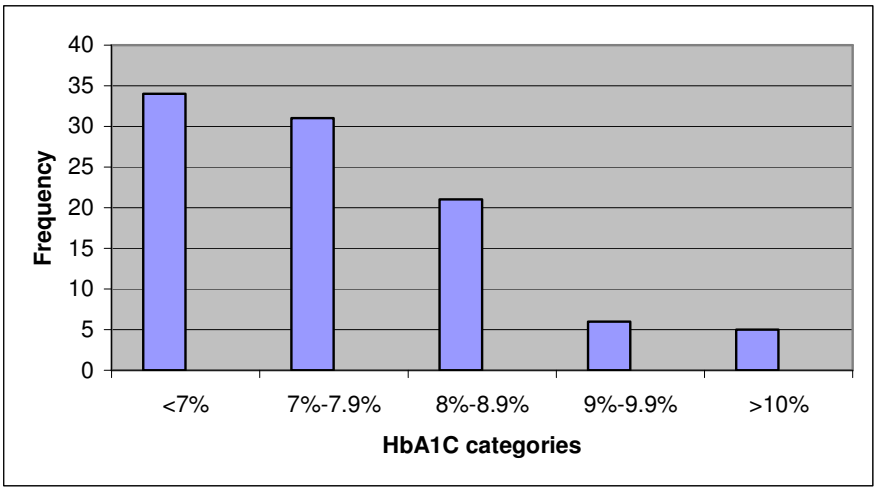

Figure 2: Frequency of HbA1C categories. (n=97)

There was no statistically significant association between the age groups (p=0.4405) or sex (p=0.3436) and the HbA1C categories.

7.6 Microvascular complications.

Forty-three participants had microvascular complications.(Table IV)

Peripheral neuropathy was the commonest microvascular complication in this study. Nineteen participants (19.6%) had signs/symptoms of peripheral neuropathy. Seventeen participants (17.5%) had signs of retinopathy. Nephropathy was present in 15

participants (15.5%). There were no participants with chronic foot ulcers or amputations.

Table IV: Frequency of Microvascular complications. (n=97)

Microvascular complications	Frequency	Percent
Yes	43	44.30%
No	54	55.70%
Total	97	100.00%

The prevalence of microvascular complications increased from 24% in the (50yrs-59yrs) group to 66.7% in the >80yrs group. Interestingly two of the three participants in (30yrs-40yrs) group already had microvascular complications. This increase in prevalence with age was statistically significant. (p=0.0106)

There was no statistically significant association between the sex of participants and the presence of microvascular complications. (p=0.1331).

7.7 Macrovascular complications.

Eighteen participants (18.60%) had macrovascular complications. (Table V)

Sixteen participants (16.50%) had a history of ischaemic heart disease. Six participants (6.20%) had peripheral vascular disease and 1 had transient ischaemic attacks. There were no participants with a history of stroke in this sample.

Table V: Frequency of Macrovascular complications. (n=97)

Macrovascular complications	Frequency	Percent
Yes	18	18.60%
No	79	81.40%
Total	97	100.00%

The prevalence of macrovascular complications increased from 6.1% in the (50yrs-59yrs) age group to 66.7% in the >80yrs age group. These differences with increasing age were statistically significant (p=0.0036).

There was no statistically significant association between the sex of participants and the presence of macrovascular complications (p=0.1320).

7.8 Co-existing diseases.

As anticipated, hypertension and hyperlipidemia were the most common co-existing diseases. The prevalence of other diseases such as gout, depression etc was minimal.

There was no statistically significant association between the age groups (p=0.0908) or sex (p=0.4680) of participants and the presence of hypertension. The associations for hyperlipidemia were also not statistically significant. (Age groups: p=0.1601; sex: p=0.0758).

7.8.1 Co-existing hypertension.

Sixty-seven participants (69.1%) were on medication for hypertension (Table VI). Of these, 61 (91%) were being treated with ACE inhibitors. No distinction was made between the ACE1 and ACE2 inhibitors in this study. Ten participants (14.9%) were on B-blockers and 24 participants (35.8%) were on the other classes of anti-hypertensives (calcium channel blockers, diuretics etc).

Table VI: Frequency of Hypertension. (n=97)

Anti-hypertensives	Frequency	Percent
Yes	67	69.10%
No	30	30.90%
Total	97	100.00%

7.8.2 Co-existing hyperlipidemia.

Fifty-one participants (52.60%) were on medication for hyperlipidemia. (Table VII)

Table VII: Frequency of hyperlipidemia. (n=97)

Lipid lowering agents	Frequency	Percent
Yes	51	52.60%
No	46	47.40%
Total	97	100.00%

The vast majority (50 participants) were on statins. Three participants were on fibrates to lower the lipid levels.

7.9 Insulin usage.

Fifty-five participants (56.70%) were using insulin as part of the treatment regimen (Table VIII). Twenty-three participants (23.71%) were on insulin alone (without oral hypoglycaemics). The other 32 (32.99%) were on a combination of insulin and oral hypoglycaemics. No distinction was made between the various types or dosages of insulin in this study.

Table VIII: Frequency of insulin usage. (n=97)

Insulin	Frequency	Percent
Yes	55	56.70%
No	42	43.30%
Total	97	100.00%

There was no statistically significant association between the age groups (p=0.7624) or sex (p=0.2520) of participants and the use of insulin.

The researcher then correlated insulin usage with the HbA1C categories (Table IX). Of the 55 participants who were on insulin only 9 had the target HbA1C of <7%. Of the 41 participants who were not on insulin 25 had the target HbA1C.

Table IX: Insulin usage and HbA1C category. (n=97)

Insulin	<7%	7%-7.9%	8%-8.9%	9%-9.9%	>10%	TOTAL
Yes	9	19	18	5	4	55
Row %	16.4	34.5	32.7	9.1	7.3	100.0
Col %	26.5	61.3	85.7	83.3	80.0	56.7
No	25	12	3	1	1	42
Row %	59.5	28.6	7.1	2.4	2.4	100.0
Col %	73.5	38.7	14.3	16.7	20.0	43.3
TOTAL	34	31	21	6	5	97
Row %	35.1	32.0	21.6	6.2	5.2	100.0
Col %	100.0	100.0	100.0	100.0	100.0	100.0

7.10 Oral hypoglycaemics.

Seventy-four participants (76.29%) were on oral hypoglycaemics (Table X). Of these 42 (56.76%) were on oral hypoglycaemics alone (without insulin). The study did not distinguish between the different classes of oral hypoglycaemics.

Only 1 participant was being adequately controlled on diet and exercise without other medication.

Table X: Frequency of oral hypoglycaemics. (n=97)

Oral hypoglycaemics	Frequency	Percent
Yes	74	76.30%
No	23	23.70%
Total	97	100.00%

There was no statistically significant association between the age groups (p=0.6616) or sex (p=0.5354) of participants and the use of oral hypoglycaemic agents.

7.11 HRQoL scores.

The Diabetes–39 questionnaire scores 5 aspects of quality of life viz. Energy and Mobility; Sexual Functioning; Social Burden; Anxiety and Worry; and Diabetes Control.

7.11.1 Energy and Mobility Score.

Of the 39 questions in the questionnaire, 15 questions are related to this aspect of QoL (quality of life). The minimum possible score is 7.5 and the maximum is 112.5. The higher the score that was achieved the worse was the QoL.

A minimum of 12 questions needed to be answered for the result to be included in the study. All 97 participants fulfilled the criteria. For those that answered more than 11 but not all 15 questions, the average score was calculated. This average was added for each of the unanswered questions. This methodology is as per the recommendations of the developers of the questionnaire.

The mean score for this sample of participants was 38.8. The most frequently observed score (mode) was 24. Six participants scored 24. (Range 14 – 93).

There was no statistically significant difference between the different age groups when cross-tabulated against the Energy/Mobility scores (p=0.8247). However, the mean scores for females were statistically significantly higher (p=0.0168). This implies that females were worse off in the 'Energy/Mobility' parameter of the study.

7.11.2 Sexual Functioning Score.

Three questions were related to this aspect of QoL. All three questions needed to be answered for inclusion in the study. Eighty-nine participants (91.75%) answered the three questions. This was the only aspect of the formal QoL assessment where all 97 participants' scores could not be included in the study.

The minimum possible score is 1.5 and the maximum is 22.5. The higher the score that was achieved the worse was the QoL. The mean score was 10.2. The score most commonly recorded (mode) was 3 with 20 participants achieving this score. (Range 1.5 –22).

Of the 89 participants who answered the questions, 73 (82.02%) were male and 16 (17.98%) were female. A higher percentage of males (97%) answered the questions on sexual function. Only 72.73% of females answered the questions on sexual functioning.

There was no statistically significant difference in the 'Sexual Functioning' scores between males and females ($p=0.4435$). There was also no statistically significant difference in the 'Sexual Functioning' scores when cross-tabulated against the different age groups. ($p=0.7503$).

7.11.3 Social Burden Score.

Five questions were related to this aspect of QoL. At least 4 questions needed to be answered for the result to be included in the study. All 97 participants answered the required number of questions.

The possible scores ranged from 2.5 to 37.5. The higher the score achieved the worse was the QoL. The mean score of the participants was 9.2. The mode was 5 with 23 participants achieving this score. (Range 2.5 – 35).

Neither the age group nor the sex of the participants had a statistically significant effect on this score. (Age group: p=0.6094; Sex: p=0.4244).

7.11.4 Anxiety and Worry.

Four questions were related to this aspect of QoL. At least 3 questions needed to be answered for the result to be included in the study. All 97 participants fulfilled this requirement.

The possible scores ranged from 2 to 30. The higher the score that was achieved the worse was the QoL. The mean score was 12.8. Eight participants had a score of 11 (mode). (Range 2.5 – 27).

The age group of the participants did not have a statistically significant effect on this score. (p=0.4259). However, females had a higher mean score (p=0.0356) implying that they had a worse QoL for this parameter.

7.11.5 Diabetes Control.

Twelve questions were related to this aspect of QoL. At least 9 questions had to be answered for the result to be included in the study. All 97 participants fulfilled this requirement.

The possible scores ranged from 6 to 90. The higher the score that was achieved the worse was the QoL. The mean score was 39.9.

Five participants scored 28 and another five scored 29 (mode). (Range 7.5 – 60).

The age group and sex of participants did not statistically significantly affect these scores. (Age group: p=0.4648; Sex: p=0.7261).

7.11.6 Overall Ratings.

Besides the 39 questions on the different aspects of diabetes related QoL, the developers have added two questions to gauge the overall rating of participants of their QoL. The answers to these 2 questions are not included in the formal analysis of the Diabetes-39 questionnaire. The first of these questions asks participants to rate their perception of their overall QoL and the second question asks them to rate how severe they think their diabetes is. (Appendix 11.3/Page 76)

Ninety-six participants answered the question on 'overall quality of life'. The possible scores ranged from 0.5 to 7.5. The higher the score that was achieved the better was the QoL. The mean score was 4.60. The mode was 5.00 with 23 participants scoring this level. (Range 1 - 7.5)

All ninety-seven participants answered the question on 'how severe they think their diabetes is'. The possible scores ranged from 0.5 to 7.5. The higher the score that was achieved the worse was the QoL. The mean score was 3.43. The mode was 3.00 with 28 participants scoring this level. (Range 1 – 7).

The scores for the overall QoL were not statistically significantly influenced by sex (p=0.1828) or by age groups (p=0.9203). The scores for the 'perceived severity of diabetes' were also not

statistically significantly influenced by age group or sex. (Age groups: p=0.1158 and sex: p=0.9203). Of particular note was the finding that insulin usage did not statistically significantly influence participants' perception of their 'overall QoL' (p= 0.3308) or their 'perception of the severity of their diabetes' (p=0.6379).

8 ASSOCIATIONS BETWEEN HEALTH RELATED QUALITY OF LIFE AND INDICATORS OF SEVERITY AND CONTROL OF DIABETES TYPE 2.

The statistical capability of the Epi info programme as well as Prof P Becker's expertise was used to determine these associations. A p-value of less than (0,05) was considered statistically significant.

8.1 QoL scores in relation to HbA1C categories.

The mean score for each of the QoL determinants (as described in section 7.11/page 41) was cross-tabulated against the HbA1C categories (as described in section 7.5/page 34) to determine whether there were any statistically significant associations.

8.1.1 Energy and Mobility.

The mean score for the 34 participants who had a HbA1C of <7% was 33.2. The mean score for the (7%-7.9%) category was 41.5. The mean scores for the (8%-8.9%), (9%-9.9%), and >10% categories were 43.8, 39.0 and 41.2 respectively. (Table XI).

There was no statistically significant difference between the HbA1C categories in relation to the mean 'Energy/Mobility' scores. (p=0.1246).

Table XI: Energy/Mobility scores and HbA1C categories. (n=97)

HbA1C category	Frequency	Total	Mean	Variance	Std Dev
<7%	34	1130.0	33.2	228.7	15.1
7%-7.9%	31	1288.0	41.5	258.0	16.0
8%-8.9%	21	920.5	43.8	230.9	15.1
9%-9.9%	6	234.5	39.0	369.2	19.2
>10%	5	206.0	41.2	275.2	16.5

P-value = 0.1246

8.1.2 Sexual Functioning.

The mean score for the participants who had a HbA1C of <7% was 8.5. The mean scores for the (7%-7.9%), (8%-8.9%), (9%-9.9%) and >10% categories were 11.9, 11.2,10.5 and 9.5 respectively. (Table XII).

Table XII: Sexual Functioning scores and HbA1C categories. (n=89)

HbA1C category	Frequency	Total	Mean	Variance	Std Dev
<7%	34	289.5	8.5	43.7	6.6
7%-7.9%	26	311.5	11.9	44.3	6.6
8%-8.9%	21	214.5	11.2	46.8	6.8
9%-9.9%	6	63.0	10.5	40.3	6.3
>10%	5	38.0	9.5	41.0	6.4

P-value = 0.3404

There was no statistically significant difference between the HbA1C categories in relation to the mean 'Sexual Functioning' scores. (p=0.3404).

8.1.3 Social Burden.

The mean 'Social Burden' scores for the <7%, (7%-7.9%), (8%-8.9%), (9%-9.9%) and the >10% HbA1C categories were 8.3, 9.6, 10.1, 9.0 and 9.2 respectively. (Table XIII).

Table XIII: Social Burden scores and HbA1C categories. (n=97)

HbA1C category	Frequency	Total	Mean	Variance	Std Dev
<7%	34	283.0	8.3	32.7	5.7
7%-7.9%	31	299.0	9.6	17.3	4.1
8%-8.9%	21	214.0	10.1	31.6	5.6
9%-9.9%	6	54.0	9.0	16.4	4.0
>10%	5	46.0	9.2	21.2	4.6

P-value = 0.7302

There was no statistically significant difference between the HbA1C categories in relation to the mean 'Social Burden' scores. (p=0.7302).

8.1.4 Anxiety and Worry.

The mean 'Anxiety and Worry" scores for the <7%, (7%-7.9%), (8%-8.9%), (9%-9.9%) and the >10% HbA1C categories were 10.3, 12.9, 15.8, 15.5 and 14.2 respectively. (Table XIV).

Table XIV: Anxiety/Worry scores and HbA1C categories. (n=97)

HbA1C category	Frequency	Total	Mean	Variance	Std Dev
<7%	34	350.5	10.3	29.2	5.4
7%-7.9%	31	400.5	12.9	37.5	6.1
8%-8.9%	21	332.5	15.8	44.2	6.6
9%-9.9%	6	93.0	15.5	50.3	7.0
>10%	5	71.0	14.2	23.7	4.8

P-value = 0.0173

There was a statistically significant difference between the HbA1C categories in relation to the mean 'Anxiety and Worry' scores. (p=0.0173)

The researcher then compared each of the HbA1C categories in relation to the Anxiety/Worry scores. This was done to determine which of the categories were statistically significantly different. (Table XV).

There was a statistically significant difference in the mean scores between the (<7%) HbA1C category and the (8%-8.9%) HbA1C category. (p=0.014). The mean score for the (8%-8.9%) category was 15.8 whereas the mean score for the <7% category was 10.3. A higher mean score indicates a poorer quality of life.

Table XV: HbA1C categories and HbA1C categories. (n=5)

(Bonferroni)

HbA1C category	<7%	7%-7.9%	8%-8.9%	9%-9.9%
7%-7.9%	2.6 (p=0.881)			
8%-8.9%	5.5 (p=0.014)	2.9 (p=0.868)		
9%-9.9%	5.1 (p=0.546)	2.5 (p=1.000)	-.8 (p=1.000)	
>10%	3.8 (p=1.000)	1.2 (p=1.000)	-1.6 (p=1.000)	-1.3 (p=1.000)

8.1.5 Diabetes Control.

The mean 'Diabetes Control' scores for the <7%, (7%-7.9%), (8%-8.9%), (9%-9.9%) and the >10% HbA1C categories were 26.0, 32.2, 38.5, 37.0 and 38.0 respectively. (**Error! Reference source not found.**).

Table XVI: Diabetes Control scores and HbA1C categories. (n=97)

HbA1C category	Frequency	Total	Mean	Variance	Std Dev
<7%	34	885.0	26.0	159.4	12.6
7%-7.9%	31	999.5	32.2	189.1	13.7
8%-8.9%	21	809.0	38.5	173.4	13.1
9%-9.9%	6	222.5	37.0	170.0	13.0
>10%	5	190.0	38.0	180.0	13.4

P-value = 0.0102

There was a statistically significant difference between the HbA1C categories in relation to the mean 'Diabetes Control' scores. (p=0.0102).

The different HbA1C categories were then compared with each other to determine which of the categories were statistically significantly different. (Table XVII).

Table XVII: HbA1C categories and HbA1C categories. (n=5)

(Bonferroni)

HbA1C category	<7%	7%-7.9%	8%-8.9%	9%-9.9%
7%-7.9%	6.2 (p=0.704)			
8%-8.9%	12.4 (p=0.010)	6.2 (p=0.886)		
9%-9.9%	11.0 (p=0.633)	4.8 (p=1.000)	-1.4 (p=1.000)	
>10%	11.9 (p=0.629)	5.7 (p=1.000)	-.5 (p=1.000)	.9 (p=1.000)

There was a statistically significant difference in the mean scores between the (<7%) HbA1C category and the (8%-8.9%) category. (p=0.010). The mean score for the (<7%) category was 26.0 whereas the mean for the (8%-8.9%) category was 38.5. The higher mean score indicates a poorer QoL.

8.2 QoL scores in relation to BMI categories.

The mean score for each of the QoL determinants (as described in section 7.11/page 41) was cross-tabulated against the BMI categories (as described in section 7.4/page 33) to determine whether there were any statistically significant associations.

8.2.1 Energy and Mobility.

The mean 'Energy/Mobility' scores for the <20, (20-24.9), (25-29.9) and >30 BMI categories were 34.5, 38.4, 36.9 and 40.7 respectively. (Table XVIII)

Table XVIII: Energy/Mobility scores and BMI categories. (n=97)

BMI category	Frequency	Total	Mean	Variance	Std Dev
<20	2	69.0	34.5	220.5	14.8
20-24.9	9	346.0	38.4	343.9	18.5
25-29.9	36	1328.5	36.9	210.2	14.4
>30	50	2035.5	40.7	286.2	16.9

P-value = 0.7232

There was no statistically significant difference between the groups in the different BMI categories in relation to the mean 'Energy/Mobility' scores. (p=0.7232).

8.2.2 Sexual Functioning.

The mean 'Sexual Functioning' scores for the <20, (20-24.9), (25-29.9) and the >30 BMI categories were 12.0, 10.8, 12.6 and 8.4 respectively. (Table XIX)

There was a statistically significant difference between the groups in the different BMI categories in relation to the mean 'Sexual Functioning' scores. (p=0.0431).

Table XIX: Sexual Functioning scores and BMI categories. (n=89)

BMI category	Frequency	Total	Mean	Variance	Std Dev
<20	1	12.0	12.0	0.0	0.0
20-24.9	8	86.5	10.8	37.2	6.1
25-29.9	34	430.5	12.6	43.5	6.5
>30	46	387.5	8.4	41.5	6.4

P-value = 0.0431

The individual BMI categories were then compared to determine which categories were statistically different. (Table XX)

Because there was only 1 participant in the <20 BMI category, this participant was added to the (20-24.9) BMI category.

Table XX: BMI categories and BMI categories. (n=3)

(Bonferroni)

BMI cat	20-24.9	25-29.9
25-29.9	1.7 p=1.000	
>30	-2.5 p=0.852	-.2 p=0.014

There was a statistically significant difference between the (25-29.9) category and the >30 category. (p=0.014). The mean score for the group belonging to the (>30) category was 8.4 whereas the score for the (25-29.9) category was 12.6. This is very surprising because this implies that the sexual QoL was better in the group belonging to the obese category when compared to the group belonging to the overweight category.

8.2.3 Social Burden.

The mean 'Social Burden' scores for the <20, (20-24.9), (25-29.9) and the >30 BMI categories were 7.0, 9.2, 10.2 and 8.6 respectively. (Table XXI).

Table XXI: Social Burden scores and BMI categories. (n=97)

BMI category	Frequency	Total	Mean	Variance	Std Dev
<20	2	14.0	7.0	2.0	1.4
20-24.9	9	83.0	9.2	31.3	5.6
25-29.9	36	369.0	10.2	34.6	5.8
>30	50	430.0	8.6	18.7	4.3

P-value = 0.4576

There was no statistically significant difference between the different BMI categories in relation to the mean 'Social Burden' scores. (p=0.4576).

8.2.4 Anxiety and Worry.

The mean 'Anxiety and Worry' scores for the <20, (20-24.9), (25-29.9) and the >30 BMI categories were 8.5, 12.7, 12.9 and 13.0 respectively. (Table XXII).

There was no statistically significant difference between the different BMI categories in relation to the mean 'Anxiety and Worry' scores. (p=0.8066).

Table XXII: Anxiety/Worry scores and BMI categories. (n=97)

BMI category	Frequency	Total	Mean	Variance	Std Dev
<20	2	17.0	8.5	0.5	0.7
20-24.9	9	115.0	12.7	62.1	7.8
25-29.9	36	465.0	12.9	34.2	5.8
>30	50	650.5	13.0	41.6	6.4

P-value = 0.8066

8.2.5 Diabetes Control.

The mean 'Diabetes Control' scores for the <20, (20-24.9), (25-29.9) and the >30 BMI categories were 30.5, 32.3, 33.0 and 31.2 respectively. (Table XXIII).

Table XXIII: Diabetes Control scores and BMI categories. (n=97)

BMI category	Frequency	Total	Mean	Variance	Std Dev
<20	2	61.0	30.5	60.5	7.7
20-24.9	9	291.0	32.3	164.2	12.8
25-29.9	36	1189.5	33.0	234.7	15.3
>30	50	1564.5	31.2	178.7	13.3

P-value = 0.9495

There was no statistically significant difference between the various BMI categories in relation to the mean 'Diabetes Control' scores. (p=0.9495).

8.3 QoL scores in relation to exercise.

The mean score for each of the QoL determinants (as described in section 7.11/Page41) was cross-tabulated against exercise (as described in section 7.3/Page 32), to determine whether there were any statistically significant associations.

The mean 'Energy/Mobility', 'Sexual Functioning', 'Social Burden', 'Anxiety/Worry' and 'Diabetes Control' score for the group that exercise regularly was 36.6, 9.7, 9.6, 12.8 and 32.7 respectively and for the group that did not exercise regularly it was 41.0, 10.8, 8.8, 12.9 and 31.3 respectively. (Table XXIV).

Table XXIV: QoL parameters and exercise.

QoL parameter	Exercise	Freq	Total	Mean	Variance	Std Dev	P value
Energy/ Mobility	Yes	46	1684.5	36.6	244.4	15.6	(P=0.1739)
	No	51	2094.5	41.0	264.4	16.2	
Sexual Function	Yes	43	9.7326	9.7	47.4	6.8	(P=0.4433)
	No	46	498.0	10.8	42.3	6.5	
Social Burden	Yes	46	444.5	9.6	32.1	5.6	(P=0.4334)
	No	51	451.5	8.8	19.7	4.4	
Anxiety/ Worry	Yes	46	589.5	12.8	35.1	5.9	(P=0.9462)
	No	51	658.0	12.9	43.9	6.6	
Diabetes Control	Yes	46	1507.5	32.7	211.8	14.5	(P=0.6146)
	No	51	1598.5	31.3	176.7	13.2	

There was no statistically significant difference between the group that exercised and the group that did not exercise for any of the parameters of QoL studied. ($p>0.05$)

8.4 QoL scores in relation to the use of Insulin.

The mean score for each of the QoL determinants (as described in section 7.11/page 41) was cross-tabulated against insulin usage (as described in section 7.9/page 39) to determine whether there was any statistically significant association.

The mean 'Energy/Mobility', 'Sexual Functioning', 'Social Burden', 'Anxiety/Worry' and 'Diabetes Control' score for the group that use insulin was 43.3, 11.8, 10.5, 14.6 and 36.0 respectively and for the group that does not use insulin it was 33.1, 8.0, 7.5, 10.5 and 26.6 respectively. (Table XXV).

Table XXV: QoL parameters and use of insulin.

QoL parameter	Insulin	Freq	Total	Mean	Variance	Std Dev	P value
Energy/ Mobility	Yes	55	2386.0	43.3	264.0	16.2	(P=0.0015)
	No	42	1393.0	33.1	194.1	13.9	
Sexual Function	Yes	52	618.5	11.8	42.1	6.4	(P=0.0068)
	No	37	298.0	8.0	40.3	6.3	
Social Burden	Yes	55	10.5182	10.5	30.4	5.5	(P=0.0038)
	No	42	317.5	7.5	14.6	3.8	
Anxiety/ Worry	Yes	55	803.0	14.6	39.1	6.2	(P=0.0015)
	No	42	444.5	10.5	31.2	5.5	
Diabetes Control	Yes	55	1985.0	36.0	198.3	14.0	(P=0.0007)
	No	42	1121.0	26.6	136.7	11.6	

There was a statistically significant difference between the group that used insulin and the group that did not use insulin for all of the parameters of QoL that were studied. ($p<0.05$).

The Hotelling T squared Test was then used to determine whether there was a statistically significant difference between the insulin users and non-users taking all the parameters of QoL together.

Table XXVI: All parameters of QoL in relation to Insulin use.

Insulin Users (n=38)

Parameter	Frequency	Mean	Std. Dev	Min	Max
Ener/Mob	38	31.17105	12.94702	14	69
Sex Func	38	7.921053	6.322981	1.5	21
Soc Burd	38	6.947368	2.990502	4.5	16
Anx/Worr	38	9.671053	5.052797	2.5	24
Diab Cont	38	26.05623	11.94401	10.5	53

No Insulin (n=51)

Parameter	Frequency	Mean	Std. Dev	Min	Max
Ener/Mob	51	43.41176	16.3134	15.5	93
Sex Func	51	12.05882	6.444104	3	2
Soc Burd	51	10.5098	5.675817	2.5	35
Anx/Worr	51	14.66667	6.096447	. 4	27
Diab Cont	51	36.46078	14.25828	7.5	60

2-group Hotelling's T-squared = 24.632523

F test statistic: ((89-5-1)/(89-2)(5)) x 24.632523 = 4.6999987

H0: Vectors of means are equal for the two groups

F (5,83) = 4.7000

Prob > F (5,83) = 0.0008

This also confirmed a statistically significant poorer QoL (p=0.0008) for insulin users when compared to non-users.

8.5 QoL scores in relation to use of oral hypoglycaemics.

The score for each of the QoL determinants (as described in section 7.11/page 41) was cross-tabulated against oral hypoglycaemic use (as described in section 7.10/page 40) to determine whether there were any statistically significant associations.

The mean 'Energy/Mobility', 'Sexual Functioning', 'Social Burden', 'Anxiety/Worry' and 'Diabetes Control' score for the group that use oral hypoglycaemics was 38.3, 10.1, 8.8, 12.2 and 31.1 respectively and for the group that does not use oral hypoglycaemics it was 40.9, 10.8, 10.5, 14.8 and 34.8 respectively. (Table XXVII).

Table XXVII: QoL parameters and use of oral hypoglycaemics.

QoL parameter	Oral hypogly	Freq	Total	Mean	Varian	Std Dev	P value
Energy/ Mobility	Yes	74	2838.0	38.3	252.1	15.8	(P=0.5064)
	No	23	941.0	40.9	281.1	16.7	
Sexual Function	Yes	67	677	10.1	46.7	6.8	(P=0.6364)
	No	22	239.5	10.8	39.6	6.2	
Social Burden	Yes	74	653.0	8.8	28.4	5.3	(P=0.1501)
	No	23	243.0	10.5	14.7	3.8	
Anxiety/ Worry	Yes	74	906.5	12.2	37.4	6.1	(P=0.0855)
	No	23	341	14.8	42.1	6.4	
Diabetes Control	Yes	74	2305.5	31.1	186.1	13.6	(P=0.2721)
	No	23	800.5	34.8	209.0	14.4	

The use of oral hypoglycaemics did not make any statistically significant difference for any of the parameters of QoL that were studied. (p=>0.05).

8.6 QoL scores in relation to the use of anti-hypertensives.

The score for each of the QoL determinant (as described in section 7.11/page 41) was cross-tabulated against the use of anti-hypertensive medication (as described in section 7.8.1/page 38) to determine whether there were any statistically significant associations.

The mean 'Energy/Mobility', 'Sexual Functioning', 'Social Burden', 'Anxiety/Worry' and 'Diabetes Control' score for the group that use anti-hypertensive medication was 39.8, 9.4, 9.1, 12.7 and 31.1 respectively and for the group that does not use anti-hypertensive medication it was 37.0, 11.9, 9.4, 13.1 and 34.0 respectively. (Table XXVIII).

Table XXVIII: QoL parameters and use of anti-hypertensives.

QoL parameter	Anti-hyperten	Freq	Total	Mean	Varian	Std Dev	P value
Energy/ Mobility	Yes	67	2668.0	39.8	286.3	16.9	(P=0.4318)
	No	30	1111.0	37.0	194.6	13.9	
Sexual Function	Yes	59	558.0	9.4	46.5	6.8	(P=0.0963)
	No	30	358.5	11.9	37.9	6.1	
Social Burden	Yes	67	612.0	9.1	29.4	5.4	(P=0.7664)
	No	30	284.0	9.4	17.5	4.1	
Anxiety/ Worry	Yes	67	853.5	12.7	41.4	6.4	(P=0.7764)
	No	30	394.0	13.1	35.9	5.9	
Diabetes Control	Yes	67	2084.5	31.1	193.2	13.8	(P=0.3369)
	No	30	1021.5	34.0	189.2	13.7	

The use of anti-hypertensive medication did not make any statistically significant difference for any of the parameters of QoL that were studied. (p=>0.05)

The researcher then compared the use of B-blockers and ACE inhibitors individually with the various parameters of the QoL. There was no statistically significant association between either group of drugs and any of the parameters of the QoL. (p=>0.05)

8.7 QoL scores in relation to the use of lipid lowering drugs.

The score for each of the QoL determinants (as described in section 7.11/page41) was cross-tabulated against the use of lipid lowering medication (as described in section 7.8.2/page 38) to determine whether there were any statistically significant associations.

The mean 'Energy/Mobility', 'Sexual Functioning', 'Social Burden', 'Anxiety/Worry' and 'Diabetes Control' score for the group that use lipid lowering medication was 40.4, 10.6, 10.0, 13.3 and 32.7 respectively and for the group that does not lipid lowering medication it was 37.3, 9.9, 8.2, 12.3 and 31.1 respectively. (Table XXIX).

There was no statistically significant association between the use of lipid lowering medication and any of the parameters measured to determine the QoL. (p>0.05)

Statins are reputed to cause weakness as a side effect. This was not confirmed in this study.

Table XXIX: QoL parameters and use of lipid lowering agents.

QoL parameter	Lipid lowering	Freq	Total	Mean	Varian	Std Dev	P value
Energy/ Mobility	Yes	51	2061.5	40.4	258.3	16.0	(P=0.3470)
	No	46	1717.5	37.3	256.7	16.0	
Sexual Function	Yes	46	490.5	10.6	46.1	6.7	(P=0.5964)
	No	43	426.0	9.9	43.7	6.6	
Social Burden	Yes	51	514.5	10.0	35.5	5.9	(P=0.0807)
	No	46	381.5	8.2	13.2	3.6	
Anxiety/ Worry	Yes	51	678.5	13.3	40.9	6.3	(P=0.4669)
	No	46	569.0	12.3	38.0	6.1	
Diabetes Control	Yes	51	1671.5	32.7	209.3	14.4	(P=0.5752)
	No	46	1434.5	31.1	175.4	13.2	

8.8 QoL scores in relation to macrovascular complications.

The score for each of the QoL determinants (as described in section 7.11/page 41) was cross-tabulated against the presence or absence of macrovascular disease (as described in section 7.7/page 36) to determine whether there were any statistically significant associations.

The mean 'Energy/Mobility', 'Sexual Functioning', 'Social Burden', 'Anxiety/Worry' and 'Diabetes Control' score for the group that had macrovascular complications was 43.1, 11.8, 9.9, 12.1 and 28.9 respectively and for the group that did not have macrovascular complications it was 38.0, 9.9, 9.0, 13.0 and 32.7 respectively. (Table XXX).

Table XXX: QoL parameters and macrovascular complications.

QoL parameter	Macrovasc complicati	Freq	Total	Mean	Varian	Std Dev	P value
Energy/ Mobility	Yes	18	776.0	43.1	274.3	16.5	(P=0.2255)
	No	79	3003.0	38.0	252.0	15.8	
Sexual Function	Yes	16	189.0	11.8	49.8	7.0	(P=0.3192)
	No	73	727.5	9.9	43.4	6.5	
Social Burden	Yes	18	178.5	9.9	53.0	7.2	(P=0.5302)
	No	79	717.5	9.0	19.7	4.4	
Anxiety/ Worry	Yes	18	218.0	12.1	26.2	5.1	(P=0.5770)
	No	79	1029.5	13.0	42.5	6.5	
Diabetes Control	Yes	18	521.0	28.9	186.8	13.6	(P=0.2989)
	No	79	2585.0	32.7	192.7	13.8	

There was no statistically significant association between the presence of macrovascular complications and the QoL as measured in this study. (p>0.05)

8.9 QoL scores in relation to microvascular complications.

The score for each of the QoL determinants (as described in section 7.11/page 41) was cross-tabulated against the presence or absence of microvascular disease (as described in section 7.6/page 35) to determine whether there were any statistically significant associations.

The mean 'Energy/Mobility', 'Sexual Functioning', 'Social Burden', 'Anxiety/Worry' and 'Diabetes Control' score for the group that had microvascular complications was 39.9, 11.0, 9.4, 12.0 and 32.0 respectively and for the group that did not have microvascular

complications it was 38.1, 9.7, 9.0, 13.4 and 31.9 respectively. (Table XXXI).

Table XXXI: QoL parameters and microvascular complications.

QoL parameter	Microvasc complicati	Freq	Total	Mean	Varian	Std Dev	P value
Energy/ Mobility	Yes	43	1719.0	39.9	204.3	14.2	(P=0.5797)
	No	54	2060.0	38.1	302.6	17.3	
Sexual Function	Yes	39	430.5	11.0	50.6	7.1	(P=0.3584)
	No	50	486.0	9.7	40.0	6.3	
Social Burden	Yes	43	408.0	9.4	38.3	6.1	(P=0.6645)
	No	54	488.0	9.0	15.8	3.9	
Anxiety/ Worry	Yes	43	519.5	12.0	35.0	5.9	(P=0.2773)
	No	54	728.0	13.4	42.6	6.5	
Diabetes Control	Yes	43	1379.0	32.0	189.2	13.7	(P=0.9753)
	No	54	1727.0	31.9	197.5	14.0	

There was no statistically significant association between the presence of microvascular complications and the QoL as measured in this study. (p>0.05).

9 Discussion.

9.1 Response rates, demographics and exercise.

During the planning of this study, it was estimated that it would take 1-2 months to get the required number (97) patients to participate in the study. However, the process took much longer (about 12 months). The researcher was dependent on the practice manager and receptionists at the Centre to ask patients to become participants in the study. Various reasons were given for the poor uptake including apathy on part of patients, too few patients etc. Some form of selection bias may have been introduced at this stage. (Section 5.1/Page 27). This was the most disappointing aspect of the study.

A mean age of 60.04 years for diabetics in this study is consistent with the WHO assertion that diabetes type 2 is more common in the older generation in developed societies. (This study was in the higher socio-economic groups of our society).

There were many more males (77.30%) than females (22.70%) in this study. There is no obvious explanation for the preponderance of males in this study. Selection bias may be a possible explanation. This age and sex distribution is not necessarily a reflection of the demographic features of patients attending at the Centre. This study was not designed to reflect on the Centre. It would be incorrect to extrapolate any of the findings of this study as a reflection of what is happening at the Centre e.g. although 77.30% of participants in this study were males it does not imply that 77.30% of patients attending at the Centre are males. The selection criteria and design of the study would be very different if the researcher was attempting to determine the demographic features, treatment, control etc of patients attending at the Centre.

Only 47 participants (48.5%) exercised regularly in this study. This is rather disappointing considering the amount of effort clinicians expend in stressing the importance of exercise. The importance of exercise is highlighted by the fact that the Centre has a gymnasium on site. Resident biokineticists advise on exercise regimens. However, patients are not obliged to join the gymnasium.

The beneficial effects of exercise have been demonstrated in many studies including "The Harvard Alumni Study"[21] and "The Insulin Resistance Atherosclerosis Study"[22].

9.2 Indicators of severity and control of diabetes.

Weight control is a cornerstone of diabetes management. A qualified dietician is consulted by all patients at the Centre periodically for advise on diet. Despite this, there were a large percentage (88.60%) of overweight and obese participants. Only 9 participants (9.30%) were in the ideal BMI category (Figure 1/ page 33).

Only 34 participants (35.1%) had the target HbA1C. Interestingly neither the BMI category (P=0.2464) nor the exercise category (p=0.5002) had a statistically significant association with the HbA1C categories. Of the 34 participants who had the target HbA1C of <7%, 9 (26.5%) were on insulin. Of the 63 participants who had an HbA1C of >7%, 46 (73%) were using insulin. (Table IX/ Page 40). Of the participants who were on insulin 37 (67.2%) had an HbA1C between 7% and 8.9%. Given that both the BMI category and exercise category were not statistically significantly associated with the HbA1C categories, a possible interpretation of this could be that the dosages of insulin that were being prescribed for this sample of participants were insufficient to achieve the target HbA1C levels.

The higher prevalence of both macrovascular and microvascular complications with increasing age is consistent with the assertion that these are the chronic complications of diabetes.

During the planning stages of this study, it was anticipated that there would be a high prevalence of hypertension and hyperlipidemia. The high prevalence of co-existing hypertension and hyperlipidemia is consistent with the anticipated high prevalence of the Metabolic Syndrome in this population. This was borne out by the results in the study. The prevalence of hypertension was 69.1% (Table VI/page 38) and of hyperlipidemia was 52.60% (Table VII/ page 38).

The combination of diabetes, hypertension, hyperlipidemia, obesity and lack of exercise in the large number of participants in this study is a very poor prognostic feature. As stated earlier it would be wrong to extrapolate this finding to the general population of patients attending at the Centre.

9.3 Quality of Life scores.

It is important to note that the absolute values (i.e. mean scores) are not of significance. These values can only be used to compare two groups and then deduce which of the groups has a better or worse score (QoL) for the parameter being studied.

Five parameters of QoL are analysed by the Diabetes-39 questionnaire viz. Energy and Mobility, Sexual Functioning, Social Burden, Anxiety and Worry and Diabetes Control. Of the five parameters studied, females scored worse in the “Energy/Mobility” parameter (section 7.11.1/page41) and in the “Anxiety/Worry” parameter (section 7.11.4/page 43). The mean scores for the other

3 parameters were not affected by the sex of participants. However, despite these higher scores, females did not 'perceive their diabetes to be more severe' or their 'overall QoL' to be worse than males. (Section 7.11.6/page 44).

Despite assurances of confidentiality and anonymity, more females did not answer the questions on sexual functioning (females 27.3% and males 3%). However, those that did answer the questions did not have a statistically significant different mean score when compared with the males. (p=0.9790)

None of the parameters studied were statistically significantly influenced by the age of participants.

9.4 Associations between HRQoL and indicators of severity and control of diabetes.

The HbA1C levels are extremely important in determining whether glucose levels are being adequately controlled. Clinicians use this to determine whether treatment is optimal or needs to be intensified. The association between HbA1C categories and mean QoL scores was weak. There was no statistically significant difference between the categories for the Energy/Mobility score, Sexual Functioning score and the Social Burden score. There was a statistically significant difference between the categories for the mean Anxiety/Worry score (p=0.0173) and for the mean Diabetes Control score (p=0.0102). However, further analysis showed that the difference was only statistically significant between the (<7%) HbA1C category and the (8%-9%) HbA1C category. The mean scores for the (8%-9%) category were higher in both cases implying a poorer QoL than the <7% group. There was no statistically significant difference between the other HbA1C categories for either Anxiety/Worry score or the Diabetes Control score.

This weakness of association between QoL scores and HbA1C categories was a surprising finding in the study. This weak association implies that better control of blood sugar levels does not make patients 'feel much better'. This may be one of the reasons why patients do not easily follow the stringent treatment regimens that are prescribed i.e. no obvious short-term benefit.

It is well known that obesity is a major risk factor for the development of diabetes type 2. Only the 'Sexual Functioning' score was statistically significantly affected by the BMI categories. The obese category (BMI >30) had a lower mean score than the overweight (BMI 25-29.9) category (Table XX/page 53). This implies a better QoL for the obese group when compared to the overweight group. All the other parameters of QoL were not statistically significantly affected by BMI categories.

The association between the different BMI categories and the quality of life was very weak. This could be one of the reasons why it is so difficult to get patients to lose weight, i.e. no apparent short-term benefit.

None of the parameters of QoL were statistically significantly affected by exercise (Table XXIV /Page 56). It is generally accepted that exercise improves the sense of well-being in people. This has not been confirmed in this study. This lack of a statistically significant association confirms the findings of Holton, Colberg and Nunnold.[23]

The most significant finding in this study was the association between QoL and the use of insulin. There was a statistically significant difference for all of the parameters of QoL in relation to the use of insulin. In each case the use of insulin was associated with a poorer QoL. (Table XXV/page 57) The Hotelling T squared

test also confirmed the poorer QoL when all the parameters of QoL were taken together as a group. (Table XXVI/Page 58). This study confirms the findings of Redekop et al.[14]

A possible explanation for this association could be that insulin usage would be more frequent in severe diabetes and thus the insulin usage is really a marker of the severity of diabetes. However, this explanation is not consistent with the finding that severity of diabetes as measured by HbA1C levels, BMI groups, macrovascular disease and microvascular disease does not show a strong correlation with poor QoL. Another possible explanation could be the fact that any injection (other than insulin) would also be associated with a poorer QoL. The difference in the social acceptability of taking oral medication and of injecting oneself daily may be responsible for the difference observed in this study. Interestingly, participants who were on insulin did not perceive their diabetes to be more severe or their overall QoL to be worse than those that were not on insulin (Section 7.11.6/Page 44). This aspect needs further study.

None of the other indicators of severity and control of diabetes (viz. use of oral hypoglycaemics, use of anti-hypertensives, use of lipid lowering agents, presence of macrovascular complications and presence of microvascular complications) had any statistically significant association with any of the parameters of QoL that were studied.

ACE inhibitors are the drugs of choice when hypertension co-exists with diabetes. The vast majority (91%) of hypertensives were on ACE inhibitors in this study. Only 10 participants (14.9%) were on B-blockers. Sexual dysfunction is a well-known side effect of B-blockers.[24] Of particular note was the fact that B-blockers were not associated with a statistically significant higher mean score for the sexual functioning parameter in this study. ($p=0.4615$)

Statins were also not associated with a poorer QoL for any of the parameters studied. These surprise findings may be a function of the study design and selection criteria of participants. This study was not designed to determine the association between individual drugs and QoL.

10 Conclusion and Recommendations.

The findings in this study have very significant implications for clinicians. Clinicians generally assume that better control of blood glucose levels, increasing exercise and loss of weight will make patients 'feel better'. This assumption is not consistent with the findings of this study. A worrying finding is that the use of insulin is associated with a poorer QoL in this study. The implications of this are very significant. Clinicians will need to be cognisant of this when prescribing insulin for better glucose control.

More studies are needed to confirm or refute the findings of this study. This study has been undertaken in a 'private' exclusive centre in Johannesburg. This study must be repeated in centres dealing with patients from the other socio-economic classes of our population.

11 APPENDICES.

11.1 Appendix (Patient information sheet)

Number……..

Consent form for study on "The Association between Health Related Quality of Life and some indicators of control and severity of diabetes type 2 at a centre in Johannesburg."

(**PLEASE DO NOT FILL IN THE QUESTIONNAIRE IF YOU ARE UNDER 18 YEARS OF AGE)**

My name is Dr G Daya. I am a medical doctor.

I am studying for the Master in Family Medicine degree at the University of the Witwatersrand. I am conducting this research as part of my studies.

The aim of this research is to determine the health related quality of life of diabetic patients and correlate this with the parameters to which doctors pay particular attention when treating diabetes. This research will give us information, which may improve the quality of care given to diabetic patients by their caregivers.

Please take this as an invitation to participate in the research. If you are willing to participate, I would like you to fill in the attached questionnaire. It will not take more than 10minutes of your time. Please fill in the questionnaire as completely and carefully as possible. If you don't wish to answer any particular question for whatever reason, please feel free to leave it unanswered.

If you do not participate in the study, you will not be penalized in any way. You may withdraw from the study at any stage. The care you receive from your doctor will not be affected in any way by your decision to participate or not to participate in the study.

If you are willing to fill in the questionnaire please do so now if possible or immediately after seeing your doctor. If you are unclear about anything please ask the receptionist/myself for clarification. Unfortunately you cannot take the form home and return it later. After you have filled in the questionnaire, please place it in the marked box at the reception desk.

I also need permission to view your medical file to record measures of the severity and control of your diabetes. I assure you that the information obtained will remain confidential and will not be able to be traced back to you. I have obtained permission from the

Committee for Research on Human Subjects and they are satisfied that you will not be compromised in any way by this research. By signing this form you will be giving me permission to view your medical records related to diabetes.

If you decide not to fill in the questionnaire, I request you to please place the unanswered form in the marked box at the reception desk.

Thank you for your time and assistance

I agree to participate in this study. I fully understand the contents of this form.

…… ……

Signature date

1

[1] Name of researcher: Dr G Daya
Address of researcher: P.O.Box 185, Kliptown 1812.
Tel: (011) 3423883

11.2 Appendix (Questionnaire)

Number …….

Questionnaire for study on "The association between Health Related Quality of Life and some indicators of control and severity of diabetes type 2 at a centre in Johannesburg."

Please encircle the appropriate answer/ or answer the questions in the spaces provided.

1. Are you on medication for high blood pressure……Yes/No
2. Are you on medication for high cholesterol……Yes/No
3. Are you on regular medication for any other illness…? Yes/No
    - If the answer to (3) is **YES**, which illness/es…….
4. Do you belong to a gymnasium……Yes/No
    - If the answer is **YES**, have you exercised at least three times per week every week in the last month……Yes/No
    - If the answer is **NO**, have you exercised in any other way at least three times per week (at least 30 minutes per session) every week in the last month?……Yes/No
    - If you exercise regularly outside of a gymnasium what type of exercise do you do?……
5. What is your date of birth?…….
6. . How old were you when your diabetes was diagnosed…yrs
7. What is your sex……..Male/Female

11.3 Appendix (Diabetes 39 Questionnaire).

Diabetes-39
Quality of Life Questionnaire

During the <u>past month</u> how much was the quality of <u>your</u> life affected by:

B 1. your daily medication for your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

2. worries about money matters

Not affected at all	1	2	3	4	5	6	7	Extremely affected

3. limited energy levels

Not affected at all	1	2	3	4	5	6	7	Extremely affected

4. following your doctor's prescribed treatment plan for diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

5. food restrictions required to control your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

6. concerns about your future

Not affected at all	1	2	3	4	5	6	7	Extremely affected

7. other health problems besides diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

8. stress or pressure in your life

Not affected at all	1	2	3	4	5	6	7	Extremely affected

9. feelings of weakness

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Diabetes-39
Quality of Life Questionnaire

During the <u>past month</u> how much was the quality of <u>your</u> life affected by:

10. restrictions on how far you can walk

Not affected at all	1	2	3	4	5	6	7	Extremely affected

11. any daily exercises for your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

12. loss or blurring of vision

Not affected at all	1	2	3	4	5	6	7	Extremely affected

13. not being able to do what you want

Not affected at all	1	2	3	4	5	6	7	Extremely affected

14. having diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

15. losing control of your blood sugar levels

Not affected at all	1	2	3	4	5	6	7	Extremely affected

16. other illnesses besides diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

17. testing your blood sugar levels

Not affected at all	1	2	3	4	5	6	7	Extremely affected

18. the time required to control your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Diabetes-39
Quality of Life Questionnaire

During the <u>past month</u> how much was the quality of <u>your</u> life affected by:

19. the restrictions your diabetes places on your family and friends

Not affected at all	1	2	3	4	5	6	7	Extremely affected

20. being embarrassed because you have diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

21. diabetes interfering with your sex life

Not affected at all	1	2	3	4	5	6	7	Extremely affected

22. feeling depressed or low

Not affected at all	1	2	3	4	5	6	7	Extremely affected

23. problems with sexual functioning

Not affected at all	1	2	3	4	5	6	7	Extremely affected

24. getting your diabetes well controlled

Not affected at all	1	2	3	4	5	6	7	Extremely affected

25. complications from your diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

26. doing things that your family and friends don't do

Not affected at all	1	2	3	4	5	6	7	Extremely affected

27. keeping a record of your blood sugar levels

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Diabetes-39
Quality of Life Questionnaire

During the <u>past month</u> how much was the quality of <u>your</u> life affected by:

28. the need to eat at regular intervals

Not affected at all	1	2	3	4	5	6	7	Extremely affected

29. not being able to do housework or other jobs around the house

Not affected at all	1	2	3	4	5	6	7	Extremely affected

30. a decreased interest in sex

Not affected at all	1	2	3	4	5	6	7	Extremely affected

31. having to organize your daily life around diabetes

Not affected at all	1	2	3	4	5	6	7	Extremely affected

32. needing to rest often

Not affected at all	1	2	3	4	5	6	7	Extremely affected

33. problems in climbing stairs or walking up steps

Not affected at all	1	2	3	4	5	6	7	Extremely affected

34. having trouble caring for yourself (dressing, bathing, or using the toilet)

Not affected at all	1	2	3	4	5	6	7	Extremely affected

35. restless sleep

Not affected at all	1	2	3	4	5	6	7	Extremely affected

36. walking more slowly than others

Not affected at all	1	2	3	4	5	6	7	Extremely affected

Diabetes-39
Quality of Life Questionnaire

During the <u>past month</u> how much was the quality of <u>your</u> life affected by:

37. being identified as a diabetic

Not affected at all	1	2	3	4	5	6	7	Extremely affected

38. having diabetes interfere with your family life

Not affected at all	1	2	3	4	5	6	7	Extremely affected

39. diabetes in general

Not affected at all	1	2	3	4	5	6	7	Extremely affected

OVERALL RATINGS

1. Please place an 'X' on the line below to indicate your overall rating of quality of life

Lowest quality	1	2	3	4	5	6	7	Highest quality

2. Please place an 'X' on the line below to show how severe you think your diabetes is

Not severe at all	1	2	3	4	5	6	7	Extremely severe

11.4 Appendix (Subject list).

Subject List for study on "The Association between Health Related Quality of Life and some indicators of control and severity of diabetes type 2 at a centre in Johannesburg."

Patient Name	Allotted number	Agree/disagree to fill in questionnaire

11.5 Appendix (Data collection forms).

Data collection for study on "The Association between Health Related Quality of Life and some indicators of control and severity of diabetes type 2 at a centre in Johannesburg."

Allotted Number……..

Age:……..
Sex……..

Latest HBA1C …….. Date when done ……

<7% 7-8% 8-9% 9-10% >10%

Latest BMI…… date of measurement……..

Underweight Normal weight Overweight Obese

Microvascular complications (details)

……
……
……
……
……
……
……

Macrovascular complications (details)

……
……
……
……
……
……
……

Medication prescribed for diabetes control

……
oral hypoglycaemic insulin insulin+oral

Medication prescribed for other chronic disease

……
Hypertension (class) Hyperlipideamia other

Exercise:

Attends gymnasium ……..Yes/No

Self exercise……..Yes/No

<u>Diabetes-39 scores:</u>

Energy/Mobility……

Sexual Functioning…….

Social Burden…….

Anxiety and Worry……..

Diabetes control……

11.6 Appendix (clearance certificate).

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Daya

CLEARANCE CERTIFICATE	PROTOCOL NUMBER M050403
PROJECT	The Association Between Health Related Quality of Life and Some Indicators of Severity and Control in Diabetic Type 2....
INVESTIGATORS	Dr G Daya
DEPARTMENT	Family Medicine
DATE CONSIDERED	05.04.29
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 05.05.20 CHAIRPERSON .....
(Professor PE Cleaton-Jones

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof B Sparks

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementione research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated fr m the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

12REFERENCES.

[1] Beaglehole R, Lefebvre P. "Diabetes Action now". www.who./int/diabetes [Accessed 10 February 2005]

[2] Distiller LA. Centre for Diabetes and Endocrinology. Notes of lecture delivered at Centre on 21 June 2004.

[3] Funnell MM, Anderson RM. The problem with compliance in diabetes. JAMA 2000; 284:1709.

[4] World Health Organization (1984) The constitution of the World Health Organization. WHO Chronicle. 1:13.

[5] Jenkinson C,McGee H. Health status measurement. Radcliff Medical Press Ltd 1998.General health status profiles 4: 2

[6] Ware JE, Sherbourne CD(1992) The MOS 36 – Item Short-Form Health Survey (SF36). Medical Care 1992 June; 30 (6): 473-483.

[7] Kaplan RM, Ganiats TG, and Sieber WJ. The quality of Well-Being scale, self-administered. 1996 copyright material.

[8] Jenkinson C,McGee H. Health status measurement. Radcliff Medical Press Ltd 1998.General health status profiles 4: 71

[9] Jenkinson C, Gray A, Doll H et al. Evaluation of index and profile measures of health status in a randomize controlled trial: comparison of the SF-36, EuroQol and disease specific measures. Medical Care1997; 35: 1109-1118

[10] Boyer JG, Earp JA. The development of an instrument for assessing the quality of life of people with diabetes. Diabetes-39.Medical care 1997 May; 35(5); 440-453

[11] Garratt AM, Schmidt L, Fitzpatrick R. Patient-assessed health outcome measures for diabetes: a structured review. Diabetic Med 2002 Jan; 19(1):1-11

[12] Lacey LA, Keech ML, Boyer JG. Evaluation of Diabetes-39 Quality of Life questionnaire in patients with type2 diabetes. European meeting for the implementation of the St. Vincent declaration, Athens, Greece. –April 1995

[13] Lloyd A, Keech M, Boyer JG. Validation of the Diabetes-39 disease specific quality of life instrument in Danish, Finnish, Norwegian and Swedish. International Diabetes Federation, Helsinki, Finland 1997

[14] Redekop W.K.,Stolk R P.,Rutten EHM et al. Health-Related quality of life and treatment satisfaction in Dutch patients With type 2 diabetes. Diabetes Care 2002; 25:458-463.

[15] Coffey JT, Zhou H, Burke R, Engelgau MM, Kaplan R, Herman WH. Valuing Health-Related quality of life in diabetes. Diabetes Care 2002;25: 2238-2243.

[16] Lau C, Qureshi AK, Scott SG. Association between glycemic control and quality of life in diabetes mellitus. J Postgrad Med. 2004 July-Sept;50(3):189-194

[17] Robb Holton D, Colberg SR, Nunnold T et al. The effect of an aerobic exercise training program on quality of life in type 2 diabetes. The Diabetes Educator 2003: 29(5); 837-846.

[18] Senez B, felicioli P, Moreau A, Le Goaziou MF. Quality of life assessment of type 2 diabetic patients in general medicine. Presse Med. 2004 Feb 14; 33(3): 161-166.

[19] Mehta Z, Cull C, Stratton I, et al. 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. Diabetes Care July 1999; 22(7):1125-1136

[20] Intensive diabetes Management: Implications of the DCCT and UKPDS. The Diabetes Educator, Sept 1 2002; 28 (5): 735-740

[21] Mayer-Davis EJ, D'Augostini RJ, Haffner SM et al. Intensity and amount of physical activity in relation to insulin sensitivity. The Insulin resistance atherosclerosis study. JAMA 1998 March 4; 279(9): 669-74

[22] Paffengerger RS Jr, Kambert JB, Lee IM. Physical activity and health of college men: longitudinal observations. Int J Sports Med July 1997; 18 Supplent 3: 520-523

[23] Robb Holton D, Colberg SR, Nunnold T et al. The effect of an aerobic exercise training program on quality of life in type 2 diabetes. The Diabetes Educator 2003: 29(5); 837-846.

[24] Weiss RJ. Effects of antihypertensive agents on sexual function. Am Fam Physician 1991 Dec; 44(6): 2075-82.