

The association between glycaemic control and lifestyle habits in adults with Type 2 Diabetes Mellitus attending selected private health care practices in Thabazimbi, Limpopo Province.

by

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Thesis presented in partial fulfilment of the requirements for the degree of Master of Nutrition in the Faculty of Medicine and Health Sciences at Stellenbosch University



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December 2013

DECLARATION

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December 2013

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ABSTRACT

Introduction: Intensive lifestyle intervention in people with Type 2 Diabetes Mellitus (T2DM) is associated with weight loss, significant reductions in HbA1c% and a reduction in cardiovascular disease risk factors. Small towns unfortunately experience a deficit of dietitians, thus limiting access to lifestyle intervention. Furthermore, a limited number of South African studies have evaluated the effect of dietary habits, anthropometric status, activity level (AL) and dietitian-led medical nutrition therapy (MNT) on glycaemic control in patients with T2DM. This study thus aimed to identify the association between glycaemic control and lifestyle habits in adults with T2DM living in Thabazimbi. The role of the dietitian with regard to optimal glycaemic control was also investigated with great interest.

Methods: Individuals (>18 years) with T2DM who had a recent HbA1c test result and no acute infection/illness were included in the study over a 7 month recruitment period. Weight, height and waist circumference were measured, AL and dietetic contact evaluated, and dietary habits assessed by means of a structured questionnaire. Six home-measured post-prandial glucose (PPG) measurements and HbA1c% were used to evaluate glycaemic control.

Results: A total of 62 (59.7% males) patients were included. The mean age was 60.13 ± 10.85 years and mean T2DM disease duration was 121 ± 96.56 months. Only 6.45% of participants had a normal Body Mass Index classification. Most (90.32%) participants had a substantially increased waist circumference (WC). Half of the participants had a sedentary/low AL, whilst 48.39% had an active/moderately active AL. Almost all (95%) participants indicated it was necessary for persons with DM to consult a dietitian for MNT, however only 63% of participants actually consulted one. Mean dietary compliance was $74.53 \pm 10.93\%$. The average HbA1c% and PPG of participants were respectively $7.50 \pm 1.62\%$ and 8.90 ± 3.21 mmol/l. A significant negative association ($r=-0.31$; $p=0.02$) was found between HbA1c% and percentage dietary compliance. The number of dietetic sessions completed and average PPG were also significantly [($r=0.40$; $p=0.001$), ($r=-0.34$; $p=0.01$)] associated with percentage dietary compliance. In turn PPG had a significant positive ($r=0.30$; $p=0.02$) association with DM disease duration. Both the good HbA1c and good PPG control groups had significantly ($p=0.01$, $p=0.04$) better dietary habits than the poor HbA1c and PPG control groups. When compared to the poor PPG group, the good PPG group made significantly ($p=0.04$) better dietary decisions with regard to the main meal's carbohydrate quality and quantity. Body Mass Index, WC, AL and extent of dietetic contact didn't play a significant role in the glycaemic classification (good vs. poor) of participants.

Conclusion: The longer T2DM is present, the worse PPG control becomes. Optimal dietary habits play a significant positive role in both the long- and short term glycaemic control of people with T2DM in Thabazimbi. The choice and portion size of the main meal's carbohydrates has been identified to be the most important dietary role-player in the glycaemic control of this study population. This study also shows that if individuals with DM spend enough time with a dietician, it could potentially contribute to better dietary compliance and subsequent better glycaemic control.

OPSOMMING

Inleiding: Intensiewe leefstyl intervensie onder diegene met Tipe 2 Diabetes Mellitus (T2DM) word geassosieer met gewigsverlies, beduidende verlaging in HbA1c% asook 'n vermindering in verskeie kardiovaskulêre-siekte risiko faktore. Plattelandse dorpië beleef egter 'n tekort aan dieetkundiges, wat gevolglik toegang tot leefstyl intervensie beperk. Daar is ook 'n beperkte hoeveelheid Suid-Afrikaanse studies wat die impak van eetgewoontes, antropometriese status, aktiwiteitsvlak en dieetkundige-begeleide dieetterapie op glisemiese beheer in T2DM pasiënte evalueer. Die doel van die studie was dus om die verband tussen glisemiese beheer en leefstyl gewoontes in volwassenes met T2DM in Thabazimbi te bepaal. Die rol van die dieetkundige met betrekking tot optimale glisemiese beheer was ook met groot belangstelling nagevors.

Metodes: Diegene (>18 jaar) met T2DM wat oor 'n onlangse HbA1c toets uitslag beskik het en nie enige akute siektes/infeksie gehad het nie, is oor 'n 7 maande werwingsperiode ingesluit. Gewig, lengte en middel-omtrek was gemeet, aktiwiteitsvlak en dieetkundig-kontak bepaal, en eetgewoontes geassesseer m.b.v. 'n gestruktureerde vraelys. Ses tuis-bepaalde na-ete bloedsuiker lesings en HbA1c% was gebruik om glisemiese beheer te evalueer.

Resultate: Twee-en-sestig (59.7% mans) pasiënte het aan die studie deelgeneem. Die gemiddelde ouderdom was 60.13 ± 10.85 jaar en die gemiddelde T2DM duurte 121 ± 96.56 maande. Slegs 6.45% van die deelnemers het 'n gesonde Liggaam-Massa-Indeks gehad. Meeste (90.32%) deelnemers se middel-omtrek was ook ruimskoots verhoog. Die helfte van die deelnemers het 'n passiewe/lae aktiwiteitsvlak gehad, terwyl 48.39% 'n aktief/matig-aktiewe aktiwiteitsvlak gerapporteer het. Amper al (95%) die deelnemers het aangedui dat mense met T2DM 'n dieetkundige moet raadpleeg vir dieetterapie. Slegs 63% van die deelnemers het egter werklik 'n dieetkundige vir diabetes dieetterapie geraadpleeg. Gemiddelde dieet-gehoorsaamheid was $74.53 \pm 10.93\%$ en die gemiddelde HbA1c % en na-ete bloedsuiker vlakke van deelnemers was onderskeidelik $7.50 \pm 1.62\%$ en 8.90 ± 3.21 mmol/l. Daar was 'n beduidende negatiewe verband ($r=-0.31$; $p=0.02$) tussen HbA1c % en persentasie dieet-gehoorsaamheid. 'n Beduidende verband was ook tussen persentasie dieet-gehoorsaamheid en die hoeveelheid voltooide dieetterapie sessies ($r=0.40$; $p=0.001$) asook die gemiddelde na-ete bloedglukose vlak ($r=-0.34$; $p=0.01$) geïdentifiseer. Na-ete bloedglukose het ook 'n beduidende positiewe ($r=0.30$; $p=0.02$) verband met die duurte van diabetes getoon. Beide die goeie HbA1c en goeie na-ete glukose groepe het beduidend ($p=0.01$, $p=0.04$) beter eetgewoontes as die swak HbA1c en swak na-ete glukose groepe gehad. Die goeie na-ete glukose groep het veral beduidend ($p=0.04$) beter dieet keuses m.b.t die hoofmaal se koolhidraat kwaliteit en kwantiteit gemaak. Lengte-Massa-

Indeks, middel-omtrek, aktiwiteitsvlak en die mate van dieetkundige kontak het nie 'n beduidende rol in die glisemiese klassifikasie (goed teenoor swak) van deelnemers gespeel nie.

Gevolgtrekking: Na-ete bloedsuiker beheer word al hoe slegter hoe langer T2DM teenwoordig is. Optimale eetgewoontes speel 'n beduidende positiewe rol in beide die lang- en kort-termyn glisemiese beheer van mense met T2DM in Thabazimbi. Die keuse en porsie grootte van die hoofmaal se koolhidrate blyk die belangrikste dieet rolspeler in die glisemiese beheer van die studie populasie te wees. Die studie dui ook aan dat as mense met T2DM genoeg tyd saam met 'n dieetkundige deurbring, dit moontlik kan bydra tot beter dieet-gehoorsaamheid en gevolglik beter glisemiese beheer.

ACKNOWLEDGEMENTS

Firstly, I would like to express my sincere thanks to my supervisor Prof. Renée Blaauw, co-supervisor Dr. Leon Fouché, and statistician Prof. Daan Nel for their invaluable support and expertise throughout the progress of this study. Their input and assistance has been of immense value towards the completion of this study and thesis.

Secondly, I owe a big thanks to all the doctors in Thabazimbi who assisted me with attaining my study population. Thank you also to all the study participants that took part and invested their time in my research project.

Thirdly, I would like to thank my loving husband, family and friends for their enduring encouragement, patience and support. I am truly blessed to have such special people in my life.

Fourthly, a big thank you to Mr. Mike Philips and Miss Lauren Philips for assisting me with the spelling and grammar of this document. Your help has been of great value.

Lastly, I would like to thank and honour God for blessing me with the financial aid, health and ability to complete this degree.

CONTRIBUTIONS BY PRINCIPAL RESEARCHER AND FELLOW RESEARCHERS

The principal researcher (Maryke Carstens) developed the idea and the protocol for the research project. The principal researcher planned the study, undertook all data collection and captured the data for analyses. The data was analysed with the assistance of a statistician (Prof. DG Nel). The principal researcher interpreted the data and drafted the thesis. The study leaders, Prof. R Blaauw and Dr. LF Fouché, provided input at all stages of the project and revised the protocol and thesis.

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LIST OF ABBREVIATIONS

ACCORD	Action to Control Cardiovascular Risk in Diabetes
ADA	American Diabetes Association
ADVANCE	Action in Diabetes and Vascular Disease Controlled Evaluation
AGEs	Advanced Glycation End products
AHA	American Heart Association
AHEAD	Action for Health in Diabetes
AL	Activity Level
BMI	Body Mass Index
CHO	Carbohydrate
CNE	Clinical Nutrition Education
CVD	Cardiovascular Disease
DCCT	Diabetes Control and Complications Trial
DM	Diabetes Mellitus
DRI	Dietary Reference Intakes
EDIC	Epidemiology of Diabetes Interventions and Complications
FPG	Fasting Plasma Glucose
GI	Glycaemic Index
GL	Glycaemic Load
HbA1c	Glycosylated Haemoglobin A1c
HPCSA	Health Professions Council of South Africa
IDF	International Diabetes Federation
LOADD	Lifestyle Over and Above Drugs in Diabetes
MNT	Medical Nutrition Therapy
NNS	Non-Nutritive Sweeteners
NO	Nitric Oxide
PAL	Physical Activity Level
PKC	Protein Kinase C
PPD	Private Practising Dieticians
PPG	Post-Prandial Glucose
RAGE	Receptor for Advanced Glycation End products
RCT	Randomised Controlled Trial
RD	Registered Dietician
SA	South Africa
SANHANES	South African National Health And Nutrition Examination Survey

SEMDSA	Society for Endocrinology, Metabolism and Diabetes of South Africa
SMBG	Self Monitoring of Blood Glucose
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
TE	Total Energy
UKPDS	United Kingdom Prospective Diabetes Study
VADT	Veterans Affairs Diabetes Trial
WHO	World Health Organisation

CHAPTER 1: LITERATURE REVIEW AND MOTIVATION FOR THE STUDY

1.1 INTRODUCTION

Worldwide more than 347 million people suffer from Diabetes Mellitus (DM).¹ Statistics indicate that the prevalence of DM more than doubled from 153 (127-182) million in 1980, to 347 (314-382) million in 2008.¹ In the year 2000, the prevalence of DM in South Africa (SA) was reported to be 814 000 people.² In 2011, only eleven years later, the South African prevalence of DM increased to space 1.9 million people.³ The current conservative estimate for the DM prevalence amongst adults aged 20-79 years in SA is 6.5%.⁴

The overall mortality risk of individuals with DM is documented to be at least double the risk of persons living without diabetes.⁵ The World Health Organisation (WHO) foresees that DM will be the seventh leading cause of mortality by the year 2030.⁶ Current statistics published by the WHO show that approximately 3.4 million people globally died from hyperglycaemia related consequences in 2004.⁷ In turn the International Diabetes Federation (IDF) announced that DM attributed to 4.6 million deaths in 2011.⁸ The literature indicates that fifty percent of the DM population die of cardiovascular disease (CVD) and stroke.⁹ In 2011 the American Diabetes Association (ADA) reported that Americans with DM have CVD death rates about 2-4 times higher than adults without DM.¹⁰ Their risk for a stroke is also 2-4 times higher than the healthy individual's risk.¹⁰ Another secondary condition associated with DM is retinopathy (damage of the retina). Diabetic retinopathy is seen as an important cause of blindness and one percent of worldwide cases of the latter is attributed to DM.¹¹ Diabetes Mellitus is also amongst the leading causes of kidney failure.⁶ In 2008, 48 374 individuals with DM began treatment for end-stage kidney disease in North America.¹⁰ Diabetes related neuropathy (nerve damage) in the feet, combined with a reduction in blood flow, in turn increases the probability of foot ulcers, infection and the ultimate need for amputation.¹² The ADA indicates that around 60-70% of Americans with DM have mild to severe forms of nervous system degeneration.¹⁰ DM is also a component cause of several other important and often lethal infectious diseases; examples include pneumonia¹³, bacteraemia^{14,15} and tuberculosis¹⁶. The latter especially has a considerable impact on morbidity and mortality rates in Sub-Saharan Africa.¹⁷

1.2 THE IMPORTANCE OF OPTIMAL GLUCOSE CONTROL

Large controlled clinical trials found a significant decrease in the development and/or progression of diabetic related microvascular complications when stricter diabetes management was implemented.^{18,19} Subjects with Type 1 DM (T1DM) enrolled in the Diabetes Control and Complications Trial (DCCT) and the Epidemiology of Diabetes Interventions and Complications (EDIC) study who were initially managed intensively and achieved reduced glycosylated haemoglobin A1c (HbA1c) levels, continued to have superior protection against the development and/or progression of microvascular and neuropathic complications compared to those initially receiving only conventional

therapy.²⁰⁻²² These findings were confirmed for persons with Type 2 DM (T2DM) by the UK Prospective Diabetes Study (UKPDS) and the Kumamoto study.^{23,24}

Cardiovascular disease, compared to microvascular complications, is regarded as a more common cause of mortality in the DM population. Yet, there is a lot of controversy about the relationship between CVD and glucose control. The UKPDS however found a 16% reduction in cardiovascular events in the intensive glucose management group after 10 years of follow-up - the reduction almost reached statistical significance ($p=0.052$).²⁴ In contrast to the latter, three more recent large studies [Action to Control Cardiovascular Risk in Diabetes (ACCORD), Veterans Affairs Diabetes Trial (VADT) and Action in Diabetes and Vascular Disease Controlled Evaluation (ADVANCE)] found no significant reduction in CVD outcomes with more intensive glucose management in individuals with more advanced (8-11 year DM disease duration) T2DM.²⁵⁻²⁷

Epidemiological analyses of the DCCT and UKPDS suggest that the greatest number of complications will be prevented by helping individuals with very poor glucose control achieve fair or good glucose control. These analyses also propose that the further lowering of the HbA1c from 7% to 6% is linked with an additional lowering in microvascular complication risk.²⁰⁻²² There thus seems to be no apparent glycaemic threshold for a decline in DM complications.²⁸ It has also been established that acute hyperglycaemia and fluctuations in blood glucose values are viewed to be more harmful in the development of vascular damage than constant hyperglycaemia.²⁹ The prevention of glucose spikes is thus also of utmost importance.

1.3 TARGETS AND MEASURES OF BLOOD GLUCOSE CONTROL

HbA1c percentage is viewed as the gold standard for measuring glycaemic control.³⁰ The HbA1c-test measures the glycosylated haemoglobin (i.e. glucose irreversibly bound to haemoglobin by means of non-enzymatic glycosylation) levels of the individual over the lifespan of the erythrocytes. The HbA1c percentage is thus indicative of the average blood glucose control of the individual over the preceding three months. The test is seen as a strong risk predictor for microvascular pathology and atherosclerotic macrovascular complications.³¹ HbA1c assessment therefore plays a pivotal role in the optimal care and management of the patient with DM.³⁰ The ADA and the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) recommend that HbA1c levels be tested at least twice yearly in optimally controlled individuals and quarterly in persons whose therapy has changed or who are not meeting glycaemic targets.^{32,33} It is also recommended that the HbA1c result be available at the time the patient is seen (a.k.a. point-of-care-testing) as it is associated with more timely treatment changes.³²

Regrettably the HbA1c test has certain limitations. Medical conditions affecting red blood cell turnover (i.e. haemolysis or blood loss) and haemoglobin variants, impacts on the accuracy of the HbA1c result.³⁴ The HbA1c percentage also does not indicate glycaemic variability or the presence of hypoglycaemia.³² Glycaemic control of patients prone to glycaemic variability is thus best judged by a combination of the self-monitoring of blood glucose (SMBG) test results and HbA1c percentage.³² A Fructosamine test can be used as an alternative measure of glycaemic control when HbA1c test results are invalid or do not correlate with the clinical profile of the patient. Fructosamine is not affected by disorders of erythrocytes and also has the added benefit of portraying shorter-term changes in glucose control.³⁵ However, the relationship between Fructosamine results and average glucose levels and its prognostic significance is not as clear as for the HbA1c.³²

The reasonable HbA1c goal for most non-pregnant adults is regarded as <7%. Health professionals may however propose more intensive HbA1c targets (<6.5%) for patients with a short DM disease duration, long life expectancy and no significant CVD. Less stringent HbA1c targets (<8% or <7.5%) may in turn be viewed as acceptable for patients with a history of severe hypoglycaemia, limited life expectancy, advanced DM complications, multiple co-morbidities, and those with long-standing DM in whom the recommended target is hard to achieve. Research has found that HbA1c levels below or around 7% is associated with a reduction in microvascular complications of DM. If the target of <7% is reached soon after DM diagnosis it is also associated with long-term reduction in macrovascular disease.^{32,33} Table 1.1 depicts the correlation between HbA1c levels and mean plasma glucose levels.

Table 1.1 Correlation of HbA1c with average plasma glucose³⁶

HbA1c (%)	Mean plasma glucose	
	Mg/dL	mmol/L
6	126	7.0
7	154	8.6
8	183	10.2
9	212	11.8
10	240	13.4
11	269	14.9
12	298	16.5

Other measures of glucose control include fasting plasma glucose (FPG) – a blood glucose measurement taken after an 8-12 hour fast, usually measured in the early morning³⁷; and post prandial plasma glucose (PPG) – a blood glucose measurement taken 2 hours after the meal commenced.³² These measurements are used by the health care team to assess the effectiveness of the medical and dietary treatment respectively. The importance of FPG- and PPG monitoring is

demonstrated by data from the Baltimore longitudinal study (13.4 years follow-up). The study indicated a significant increase in all-cause mortality when FPG rose above 6.1mmol/l and PPG levels above 7.8mmol/l.³⁸ However, the matter of fasting vs. post prandial SMBG is documented in the literature as being complex.³⁹ Raised post-challenge (2 hour oral glucose tolerance test) glucose values have been linked to increased cardiovascular risk, regardless of fasting glucose values, in certain studies. Some measures of vascular pathology (e.g. endothelial dysfunction) are also adversely affected by post prandial hyperglycaemia.⁴⁰ Yet, both pre- and post-prandial glycaemia contribute to HbA1c levels. The contribution of PPG to overall blood glucose control increases as the HbA1c value decreases, indicative of the importance of strict PPG control when aiming for an optimal HbA1c.⁴¹ Research done by Monnier *et al.* showed that PPG contributed to $\pm 70\%$ of the HbA1c level when the HbA1c was $<7.3\%$.⁴² However, landmark glycaemic control trials (DCCT and UKPDS) relied heavily on pre-prandial SMBG to evaluate glucose control. The ADA thus recommend that PPG monitoring be done for DM patients who have FPG levels within target, but who have not yet achieved their HbA1c target.³² Table 1.2 displays adult glycaemic targets as defined by leading institutions in the field of DM.

Table 1.2 Glycaemic targets for adults with diabetes

Glycaemic measurement	Targets set by the ADA ³²	Targets set by Ceriello <i>et al.</i> ⁴¹	2009 SEMDSA Guidelines ⁴³
HbA1c (%)	<7.0*	<6.5	<7.0
Fasting plasma glucose (mmol/l)	3.9-7.2	<5.5	4.0-7.0
Post-prandial glucose (mmol/l)	<10.0	<7.8	5.0-8.0

* <6.5% for short DM duration, long life expectancy, no significant CVD; <8% for history of hypoglycaemia, limited life expectancy, advanced DM complications, multiple comorbidities, and those with long-standing DM in whom the recommended target is hard to achieve

The above glycaemic targets set by the ADA and SEMDSA overlap to a great extent with regard to HbA1c and FPG targets. The targets proposed by Ceriello *et al.* is noticeably more strict compared to the other HbA1c and FPG targets. With regard to PPG both Ceriello *et al.* and SEMDSA are more strict compared to the targets set by the ADA. As there seems to be no glycaemic threshold for a decline in macro- and microvascular complications²⁸, aiming for the most stringent targets would best prevent the onset and/or progression of DM related complications. The latest (2012) SEMDSA targets for glycaemic control have however changed greatly from their previous set of targets. The organisation's targets are now much more individualised in order to accommodate the different patient risk types (high risk vs. low risk) with DM. Table 1.3 summarises the 2012 SEMDSA glycaemic targets.

Table 1.3: 2012 SEMDSA glycaemic targets for adults with diabetes³³

Patient type	Target HbA1c (%)	Target FPG (mmol/l)	Target PPG (mmol/l)
Young Low risk Newly diagnosed No cardiovascular disease	<6.5	4.0-7.0	4.4-7.8
Majority of patients	<7	4.0-7.0	5.0-10.0
Elderly High risk Hypoglycaemic unaware Poor short-term prognosis	<7.5	4.0-7.0	<12.0

The efficacy of SMBG for T1DM and insulin-dependent T2DM is well established.³² However, there is much debate on the effectiveness of SMBG in achieving optimal glycaemic control in individuals with non-insulin dependent T2DM. A systematic review published by the Cochrane Collaboration in 2011 assessed the effects of SMBG in individuals with T2DM who were not using insulin. Twelve randomised controlled trials were included (n=3259) and intervention duration ranged from six to twelve months. From the review the authors' concluded that the overall effect of SMBG on glucose control in non-insulin T2DM individuals is small up to 6 months after introduction and subsides after 12 months.⁴⁴ A recent meta-analysis in turn found that SMBG lowered HbA1c percentage by 0.25% after 6 months.⁴⁵ It is also important to note that landmark clinical trials like the DCCP trial and the UKPDS, which show the effect of diabetes control on the incidence of long-term complications, also used SMBG to achieve good glucose control. These studies thus suggest that the monitoring of blood glucose is an important component of diabetes management. Self-monitoring of blood glucose is thought to enable the non-insulin dependent T2DM patient to notice the effects of food, exercise, and medication on blood glucose levels. This could then contribute to better adherence to therapy and glucose control.⁴⁶ SEMDSA acknowledges the use of SMBG in individuals on oral hypoglycaemic agents. They have found evidence that show that SMBG and structured testing, in combination with patient education, is of benefit to patients who were recently diagnosed with DM (Table 1.4).

Table 1.4 SEMDSA recommendations for SMBG of patients on oral medication³³

SEMDSA recommendations for SMBG of patients on oral medication
<ul style="list-style-type: none"> • SMBG should only be considered if sufficient education accompanies the initiation of testing • Three to five tests per week should be adequate for most individuals • SMBG must be structured and have meaning for the patient • Patients must be aware of their glycaemic targets, and know what to do if targets are not met
Circumstances demanding more frequent SMBG
<ul style="list-style-type: none"> • Acute illness • Periods of poor blood sugar control • Frequent episodes of hypoglycaemia • Pregnancy • Therapy adjustments

The ADA is adamant that patients performing SMBG should receive on-going instructions and regular assessment of their SMBG technique and results. Their ability to use SMBG to adjust therapy should also be verified.³² When prescribing SMBG, the education of patients regarding the possible reasons for hyper- and hypoglycaemia (Table 1.5) is essential for both preventative and curative measures.⁴⁷

Table 1.5 Possible reasons for hyper- and hypoglycaemia⁴⁷

Factors contributing to hyper- and hypoglycaemia	
Hyperglycaemia	Hypoglycaemia
<ul style="list-style-type: none"> • Insufficient insulin or oral anti-hyperglycaemic medicine • Excessive carbohydrate intake • Increased glucagon and other counter regulatory hormones secondary to stress, illness or infection 	<ul style="list-style-type: none"> • Excessive insulin or oral anti-hyperglycaemic medicine • Too little carbohydrate intake • Skipped or delayed meals • Unusual or excessive amount of exercise

1.4 THE ASSOCIATION BETWEEN GLUCOSE CONTROL AND THE DEVELOPMENT OF COMPLICATIONS

The strong association between hyperglycaemia and micro- and macrovascular complications, in both T1DM and T2DM, have been reported on numerous occasions.²⁰⁻²⁴ Macrovascular complications refers to diseases of large blood vessels, including coronary heart disease (CHD), peripheral vascular disease, and cerebral vascular disease. Microvascular complications in turn refer to diseases of small blood vessels. Nephropathy and retinopathy are both classified under microvascular complications. Neuropathy is also associated with uncontrolled DM and may affect both peripheral (hands and feet) and autonomic (organ) nervous systems. Gastropathy is a form of autonomic neuropathy and

specifically refer to nerve damage of the gastrointestinal tract. One of its manifestations include gastroparesis (delayed gastric emptying) which could have a detrimental effect on glucose control.⁴⁷

The aetiology of hyperglycaemia-induced vascular damage is thought to involve at least four major pathways: enhanced polyol activity, increased formation of advanced glycation end products, activation of protein kinase C (PKC) and nuclear factor kB, and increased hexosamine pathway flux. All of these metabolic events are proposed to be due to the overproduction of superoxide anion in the presence of hyperglycaemia.⁴⁸

Hyperglycaemia orchestrates a series of events that increase the production of superoxide anion (via the mitochondrial electron transport chain) that in turn inactivates nitric oxide (NO) and promotes the production of oxygen-derived free radicals (that cause oxidative stress). Superoxide anion activates PKC, or vice versa, as activation of PKC could also contribute to superoxide generation. PKC is a family of phosphorylating enzymes⁴⁹, with PKC α and PKC β most prevalent in the vasculature where hyperglycaemia predominately activates PKC β .⁵⁰ The effects of PKC activation are variable, including changes in cell signalling, production of vasoconstrictor substances, and conversion of smooth muscle and endothelial cells to a proliferative phenotype.⁵¹

Peroxynitrite, formed out of the interaction between NO and superoxide anion, oxidises the NO synthase co-factor (tetrahydrobiopterin), resulting in the favouring of superoxide anion production over NO production.⁴⁹ Other than peroxynitrite, nitrotyrosine is also derived from the interaction between NO and superoxide anion. Both peroxynitrite and nitrotyrosine are toxic and the toxicity of these substances can lead to endothelial damage.⁵² Intracellular production of advanced glycation end products (AGEs) are also increased as a result of the mitochondrial production of superoxide anion. AGEs negatively affect cellular function by affecting protein function and by activating the receptor for AGEs (RAGE). AGEs are known to increase the production of oxygen-derived free radicals, and RAGE activation in turn increases intracellular enzymatic superoxide production. In addition, increased superoxide anion production activates the hexosamine pathway, which diminishes NO synthase activation. These processes possibly recruit extracellular xanthine oxidase, which further increases the amount of oxidative stress. Oxidative stress induced by hyperglycemia may also increase levels of asymmetric dimethylarginine, an antagonist of NO synthase. It is thus clear that a cascade of effects occur that result in the ever-increasing production of superoxide anion and the inactivation of NO. Decreased NO levels are known to be detrimental to vascular health; as NO is responsible for vasodilatation and the protection of blood vessels from endogenous injury (atherosclerosis). Hyperglycaemia thus decreases endothelium-derived NO and activates oxidative stress which can then result in vascular damage.⁴⁹

The polyol pathway of glucose metabolism is activated when intracellular levels of glucose are high. In the polyol pathway glucose is reduced to sorbitol, which is then metabolised to fructose. Sorbitol accumulates intracellularly and causes osmotic damage due to its strong hydrophilic effect. Fructose in turn is phosphorylated to fructose-3-phosphate, which is then converted to 3-deoxyglucosone; both by-products being powerful glycosylating agents that are used in the formation of AGEs. The enzymatic and co-factor activity/changes associated with the polyol pathway also lessen the ability of cells to react to oxidative stress.⁵³⁻⁵⁵

1.5 MULTIDISCIPLINARY MANAGEMENT OF THE PATIENT WITH DIABETES

Diabetes care requires a high standard of initial and continuing education and care; best provided by a multidisciplinary health care team.^{56,57} The DCCT and UKPDS studies found that the use of a multidisciplinary approach towards behaviour change can improve glucose control and delay/reduce complications; some by as much as 50-75%.^{18,19} The diabetes team ought to consist of doctors, nursing staff, dieticians, and behavioural specialists that are experienced in the management of DM.^{56,57} The ADA also includes pharmacists and mental health professionals on their list of diabetes care team members.³²

The dietician assists the DM patient with glycaemic control by means of Medical Nutrition Therapy (MNT). MNT refers to a therapeutic approach in treating disease using specific dietary guidelines. MNT is regarded as important in diabetes prevention and management; as well as in the prevention and/or curbing of diabetes related complications.⁵⁸ The ADA recommends that a registered dietician (RD), experienced in the field of DM, be the leading role player in providing nutritional care.^{32,58} RD's were found to contribute meaningfully to comprehensive diabetes care plans by means of the dietary education of the patient with DM. Dietary education in turn has been found to improve anthropometric measures and glucose control as well as lessen the use of prescription medication.^{59,60}

Wilson *et al.* tested the relative efficiency of clinical nutrition education (CNE) when provided by a RD compared to an educator from a different discipline (non-RD). Those individuals who received CNE from a RD or from both a dietician and non-RD had the greatest as well as significant ($p < 0.0001$) improvements in HbA1c levels (-0.26 and -0.32%) compared to those who received CNE from a non-RD only or no CNE at all (-0.19 and -0.10%). The study thus shows that for CNE to be effective it should be delivered by a RD or health care team including a RD.⁶¹ Another study indicative of the value of the RD was a randomised controlled trial (RCT) that assessed the effect of RD-led management of DM on glucose control and macronutrient intake in 154 adult T2DM patients in Taiwan. The participants in the RD-led intervention group with an uncontrolled baseline HbA1c ($\geq 7\%$) had significantly greater improvements in their HbA1c% (-0.7 vs. -0.2%, $p = 0.034$) and FPG (-13.4 vs.

16.9 mg/dl, $p=0.007$) than the routine care control group. Significant ($p<0.001$) net intervention-control group variances in overall calorie (-229.06 ± 309.16 vs. 56.10 ± 309.41 kcal/day) and carbohydrate (-31.24 ± 61.53 vs. 7.15 ± 54.09 g/day) intake were also found for participants with uncontrolled baseline HbA1c levels. RD-led DM management in this study thus improved glucose control of individuals with uncontrolled T2DM.⁶²

The management plan of the DM patient should be designed as a joint therapeutic agreement among the patient and family, the doctor, and other members of the health care team. When developing the management plan, attention should be given to the patient's age, work schedule and conditions, activity level, eating patterns and habits, social position and cultural factors, and presence of complications (diabetes or other medical conditions). The management plan should also recognise diabetes self-management education and on-going diabetes support as an essential element of care.³² The Academy of Nutrition and Dietetics (formerly known as the American Dietetic Association) also specifically recommends that nutrition education and counselling be sensitive to the personal needs and cultural preferences of the individual, as well as to their readiness and ability to make the necessary changes. According to the Academy of Nutrition and Dietetics: "Research documents the benefits of dietitians addressing these challenges and improving outcomes in people with diabetes."⁶³

1.6 MEDICAL NUTRITION THERAPY

Nutrition is described in the literature as the cornerstone of diabetes care, and is regarded to be of great importance in intensive DM management. The main aim of the nutritional management of DM is to improve and optimise glycaemic control of individuals by balancing carbohydrate intake with available insulin (endogenous and/or exogenous).⁶⁴

There are four primary MNT goals for the patient with DM.⁵⁸

- Goal 1:** Achieving and maintaining blood glucose, lipid and blood pressure levels that are as close as possible to the normal range.
- Goal 2:** Prevention and/or curbing of the development of diabetes related complications by suitably adapting nutrient intake and lifestyle.
- Goal 3:** Addressing the individual nutritional needs of the patient.
- Goal 4:** Maintaining the pleasure of eating by only limiting foodstuffs when there is substantial scientific evidence to do so.

For MNT to be effective, the ADA advocates that individuals with DM receive individualised MNT.³² The MNT process is outlined in Table 1.6.

Table 1.6 The MNT process for DM⁶⁵

MNT comprises of:
<ul style="list-style-type: none"> • Patient-centred approach • Assessment of the patient's nutritional status • Assessment of the patient's diabetes self-management knowledge and skills • Identification and negotiation of individualised nutrition goals • Tailored nutrition intervention • Evaluation of outcomes • On-going monitoring and support

Numerous attempts have been made to control the glycaemic response to carbohydrate-rich food. Carbohydrate (CHO) counting, very low CHO- and starvation diets, artificial sweeteners and pharmacotherapy include some of the measures taken. One fairly new way of classifying the glycaemic response to food is the glycaemic index.⁶⁴ The glycaemic index (GI) concept was developed by Jenkins and co-workers and is based on the increase of blood sugar levels after the intake of 50g of CHO from a test-food, compared to a standard amount (50g) of CHO reference food (glucose/white bread).⁶⁶ The GI is thus a reflection of the rate of conversion of carbohydrates into glucose.⁶⁷ Foodstuffs are classified as high GI when they have a GI >70; as medium GI for a reading between 55–70, and as low GI when the GI is <55.⁶⁸ Correspondingly, the higher the GI the greater the insulin secretion/need.⁶⁷

The GI of a food item depends mainly on the rate of CHO digestion and speed of CHO absorption. Factors known to influence the GI of a foodstuff are: fibre content, type of starch molecule (amylopectin vs. amylose), presence of protein, fat and acids, degree of starch gelatinisation, and the physical structure of food (raw vs. cooked, whole vs. ground). A delay in gastric emptying due to the presence of fat, protein, acid (lemon juice/vinegar) or fibre in a food item or meal is associated with a lower GI response. Fibre further assists in lowering the GI by delaying intestinal glucose uptake through inhibiting the action of pancreatic enzymes on starch particles in the gut. Of the two types of starch molecules amylopectin is broken down more easily compared to amylose starch molecules that are more resistant to digestion. Therefore, the higher the amylose content of a carbohydrate, the lower the GI. Over cooking of starch (over done pasta or “sticky” rice) in turn leads to maximum absorption of water, making the CHO more readily digested and the GI higher. Whole grain food items are known to have a lower GI since their physical structure make them more resistant to digestion compared to refined grains.^{64,68}

Another concept known as the glycaemic load (GL) was developed by Harvard epidemiologists in 1997. The GL is a mathematically derived concept using both the GI and the amount of CHO ingested in its calculation. During the actual calculation the GI of a food item is multiplied by the amount of carbohydrate (in grams) provided by the food, after which the total is divided by one hundred [e.g. $GL = (GI \times CHO)/100$]. The GL is regarded to be of use as PPG and insulin responses are not only dependant on the GI (quality) of the carbohydrate, but also on the quantity. The GL thus assesses the impact of CHO consumption while taking the GI into account.⁶⁹ A GL of ≥ 20 is regarded as high, a GL of 11–19 is intermediately high, and a GL of ≤ 10 is regarded as low.⁶⁸

However, many inconsistent findings are present in the current literature with regard to the effectiveness of the GI and GL. A meta-analysis, done on literature published up until March 2009, evaluating the efficiency of low GI diets for people with diabetes found that low GI diets can significantly improve glycaemic control in individuals who are not optimally controlled. Low GI diets were also discovered to lower HbA1c percentage by 0.4%. This percentage decrease is seen as clinically significant, and is even comparable to the decrease achieved with medications for people with newly diagnosed T2DM.⁷⁰ On the other hand, in December 2010 the Academy of Nutrition and Dietetics published their diabetes nutrition recommendations indicating that there is conflicting evidence of effectiveness for the use of the GI. Reported limitations of current research included varying definitions of low- vs. high-GI diets, variability of GI response from food within and among individuals, as well as the limited number of participants and short study duration (<3 months) of 12 of the 15 studies evaluated.⁶³ SEMDSA does however acknowledge the use of the GI and GL and states that both the GI and GL may provide a modest additional benefit towards glycaemic control compared to considering total CHO content only.⁶⁵

However, when the GI tables are used by patients or health professionals it is very important to take note that the GI should only be used to classify carbohydrate-rich foods. It is also only regarded as meaningful when comparing foodstuffs within a like food category, i.e. breads, fruit or different types of cereals. The GI values should furthermore be interpreted whilst keeping other relevant food characteristics in mind, i.e. energy content, amount of other macronutrients (e.g. fat), available CHO, and dietary fibre.⁷¹

The ADA regards the monitoring of total CHO intake as a key strategy in achieving glucose targets.³² This ADA recommendation is supported by a Taiwanese RCT that investigated the association between changes in macronutrient intake and glycaemic measures. The investigators discovered an independent correlation between a reduction in CHO intake and improvements in HbA1c results ($p < 0.001$). The lowering of CHO consumption thus improved glycaemic status in this study.⁶² Meal and

snack CHO intake should also be consistently distributed throughout the day on a day-to-day basis as consistency in CHO intake has been shown to result in improved glucose control.⁶³

A 2012 scientific statement from the American Heart Association (AHA) and ADA with regard to the current use and health perspective of non-nutritive sweeteners (NNS), in turn concluded that there is inadequate data to determine conclusively whether the use of NNS lessens added sugar or CHO intake. The evidence reviewed by the AHA and ADA does however suggest that when used wisely, NNS could enable reductions in added sugar consumption.⁷²

A summary of the current MNT guidelines for DM can be found in Table 1.7.

Table 1.7 Summary of the current ADA and SEMDSA MNT guidelines^{32,65}

Healthy and balanced eating⁶⁵
<ul style="list-style-type: none"> • Consume a variety of fresh fruit and vegetables daily – no fruit juices • At least 50% of the grain intake must be from whole grains • Use low-fat dairy products and calcium enriched soya milk • Eat a variety of meat alternatives – pulses, soya and tofu • Have fish at least twice a week • Limit the intake of processed and convenience foodstuffs • Increase the consumption of water to meet daily fluid needs
Energy balance, overweight, and obesity³²
<ul style="list-style-type: none"> • Weight loss is recommended for all overweight/obese persons with DM • Low-CHO, low-fat energy-restricted, or Mediterranean diets may be effective for weight loss in the short term (up to 2 years) • Patients on low-CHO diets: Monitor lipid profiles, kidney function, and protein intake (those with nephropathy), and adjust hypoglycaemic therapy as needed • Physical activity and behaviour change are key constituents of weight loss programs and are very helpful in maintenance of weight loss
Carbohydrates⁶⁵
<ul style="list-style-type: none"> • 45-60% of total energy (TE) intake • Monitor CHO intake - a key strategy in achieving optimum glucose control³² <ul style="list-style-type: none"> ○ Carbohydrate counting ○ Exchanges ○ Experience-based estimation • GI and GL may provide a modest additional benefit for management inputs compared to only taking total CHO intake into account • Limit sugar alcohol (maltitol, mannitol, sorbitol, lactitol, isomalt, xylitol) intake to <10g per day • A sucrose intake up to 10% of TE is acceptable • Limit fructose intake to 60g per day • Increase total fibre intake to 25-50g per day • Artificial sweeteners (acesulfame-K, aspartame, saccharine and sucralose) are safe when consumed within the daily limits
Protein⁶⁵
<ul style="list-style-type: none"> • 15-20% of TE intake • In the presence of normal renal function there is no evidence to suggest that protein intake should be modified • Protein can increase the plasma insulin response and should therefore not be used in the treatment/prevention of hypoglycaemia

Fat⁶⁵
<ul style="list-style-type: none"> • <35% of TE intake • Saturated fat <7% of TE intake³² • Poly-unsaturated fat <10% TE intake • Minimal intake of trans-fats³² • Use mono-unsaturated fat and omega-3 fatty acids (both plant & marine) instead of saturated fat • Two or more servings of fatty fish per week will supply the recommended amount of omega-3 fatty acids
Salt⁶⁵
<ul style="list-style-type: none"> • Limit/avoid the consumption of packaged, processed and restaurant foods • Decreasing dietary sodium intake to <2300mg per day may help control blood pressure
Micronutrients⁶⁵
<ul style="list-style-type: none"> • There is no clear evidence for routine vitamin and mineral supplementation, except for vitamin D supplementation in people older than 50 years • Vitamin and mineral supplementation may be needed in selected groups (elderly, pregnant and lactating women, and vegans) • Routine antioxidant (vitamin E, vitamin C and beta-carotene) supplementation is not advised due to insufficient evidence proving efficacy and concerns related to long-term safety³²; supplementation may however be considered for smokers • The benefits of chromium supplementation has not been clearly demonstrated, and can therefore not be endorsed • Individualised meal planning should include optimisation of food choices to meet dietary reference intakes (DRI) for all micronutrients³²
Alcohol⁶⁵
<ul style="list-style-type: none"> • Those who choose to consume alcohol should do so in moderation:³² <ul style="list-style-type: none"> ○ ≤1 unit per day for women ○ ≤2 units per day for men • Moderate alcohol intake, with food, does not cause acute hyper-/hypoglycaemia • Patients on insulin therapy or insulin secretagogues should be aware of the risk of delayed hypoglycaemia when consuming alcohol; alcohol should therefore be ingested with food to reduce the risk of hypoglycaemia
General recommendations³²
<ul style="list-style-type: none"> • The division of carbohydrate, protein, and fat may be tailored to meet the metabolic goals and individual preferences of the patient • Persons with DM should receive individualised MNT (as needed) to achieve treatment goals, preferably provided by a RD knowledgeable about the components of diabetes MNT • Since MNT can result in cost-savings and better outcomes, MNT should be sufficiently covered by medical insurance

The data of the Indian Health Service Diabetes Care and Outcomes Audit (n=7490) was used to evaluate the efficiency of CNE in lowering HbA1c levels. The results showed a significant ($p < 0.001$) improvement in HbA1c levels amongst individuals who received CNE compared to those who did not (-0.09 vs. 0.06).⁶¹ The Academy of Nutrition and Dietetics reviewed the available literature with regard to the efficiency of diabetes MNT interventions. Included studies documented decreases in HbA1c percentages (0.5%-2.6%) similar to the effects of several anti-diabetes drugs.⁶³ While MNT was found to be effective at any stage in the DM disease process, it seemed to have the greatest effect in decreasing HbA1c percentage at initial diagnosis of DM.⁷³

Regrettably in the modern era people find the adherence to a healthy lifestyle difficult, and taking medication is often seen as an easier alternative.⁷⁴ The Lifestyle Over and Above Drugs in Diabetes (LOADD) study investigated the degree to which intensive evidence based dietary advice is able to affect blood glucose control and CVD risk factors. This RCT was performed on individuals with T2DM who had persistent hyperglycaemia and remained at high cardiovascular risk, despite their medication having been optimised. The intervention group received intensive individualised dietary advice for six months; whilst both groups continued with their usual medical surveillance. Improvements occurred in most measures (clinical and laboratory) of the intervention group, with minimal changes in the control group. After the investigators adjusted for age, gender, and baseline measurements, the difference in HbA1c% (-0.4%) between the two groups at six months was highly significant ($p = 0.007$). Significant changes were also found for the decreases in body weight ($p = 0.032$), BMI ($p = 0.026$), and waist circumference ($p = 0.005$). It is thus evident that intensive dietary advice has the potential to significantly improve blood glucose control as well as anthropometric measures in individuals with uncontrolled T2DM, this despite receiving optimal medicinal treatment.⁷⁵

It is however important to remember that a single approach to diabetes MNT does not exist. No two individuals respond exactly the same to MNT, just as there is no single medicinal regimen that applies to all people with DM.⁶³ Persons with DM should therefore receive individualised MNT (as needed) to achieve their treatment goals.³²

1.7 ANTHROPOMETRIC STATUS AND GLYCAEMIC CONTROL

Management of body weight [evaluated by means of the Body Mass Index (BMI)] is an important component of MNT, as excess body weight and obesity is known to be positively associated with insulin resistance.⁷⁶ Short-term studies have indicated that weight loss of just 5% of total body weight is associated with decreased insulin resistance, improved measures of glycaemia and lipemia, and a reduction in blood pressure in patients with T2DM.⁷⁷ Modest weight loss of 5-10% also increases life expectancy of overweight T2DM individuals with 3-4 years, reduces DM related deaths by more than

30%, and lowers fasting glucose by up to 50% in newly diagnosed individuals.⁷⁸ Weight loss is proposed to improve glucose homeostasis by means of: 1) The reduction of hepatic glucose output and fasting glucose levels, 2) the improvement in PPG excursions and peripheral insulin resistance, and 3) the enhancement of beta-cell sensitivity to insulinogenic stimuli.⁷⁹

The Look AHEAD (Action for Health in Diabetes) RCT investigated whether long-term weight loss would improve glucose control and prevent cardiovascular events in people with T2DM. After one year of intensive lifestyle intervention the participants achieved an average weight loss of 8.6%, significant reductions in HbA1c percentage and showed a reduction in numerous CVD risk factors. These benefits were still present at the 4th intervention year.^{80,81} In their meta-analysis regarding the metabolic effects of bariatric surgery on people with T2DM, Li *et al.* reported that the most clinically relevant effect of surgery-induced weight loss on T2DM is the ability to completely reverse established DM in a great number of individuals. In total, 80% of their patients achieved glycaemic control (HbA1c <7%) without diabetes medication, and 66.35% of the patients achieved a HbA1c percentage below 6%.⁸² Here the primary focus is not how weight loss was induced, but rather the effect of the reduction in body size on DM prevalence.

The positive association between an increase in waist circumference (the indicator for visceral or intra-abdominal fat) and risk for T2DM development is also well recognised.⁸³ Excess adiposity in the abdominal region is associated with insulin resistance.⁸⁴ A prospective cohort study, conducted by Blaha and Gebretsadik *et al.* found that a single measure of abdominal fatness, by means of waist circumference, is a significant predictor of hyperglycaemic relapse in T2DM with a history of poor glucose control.⁸⁵ It thus seem evident that insulin resistance and subsequent glycaemia will be positively affected by eliminating/reducing excess body weight and abdominal adiposity. SEMDSA recommends that obese T2DM patients lose 5-10% of their body weight, followed by continued weight loss and the prevention of weight regain.⁸⁶

1.8 PHYSICAL ACTIVITY

Physical activity is regarded as an important element of the DM management plan. Regular exercise is associated with improved glycaemic control, reduced cardiovascular risk factors, weight loss, and improved well being.⁸⁷⁻⁸⁹ The higher the level of exercise intensity the greater the improvement in HbA1c%.⁹⁰ All-cause and cardiovascular mortality risk was also 1.7–6.6 times higher in low-fit vs. high-fit men with T2DM, with the fittest men presenting the lowest risk.^{91,92} Exercise generates positive outcomes by improving insulin sensitivity and glucose disposal in the skeletal muscle, the expression of NO synthase in the endothelial cells, aiding in weight-loss, and body fitness.⁴⁶

The ADA recommends that individuals with DM do aerobic exercise (rhythmic, repetitive and continuous use of the same large muscle groups for at least ten minutes at a time⁹³), at a moderate intensity (50–70% of maximum heart rate), for at least 150 minutes per week. The 150 minutes should be spread over at least three days per week with no more than two successive days without exercise. People with T2DM should also do resistance training (exercise requiring muscle strength to work against a resistance load⁹³) at least twice per week.³² There is strong evidence for the HbA1c lowering value of resistance exercise in older adults with T2DM,^{94,95} and for an additive benefit of combined aerobic and resistance exercise in adults with T2DM.^{96,97}

The latest SEMDSA recommendations for exercise in DM are summarised in Tables 1.8 and 1.9.

Table 1.8 SEMDSA recommendations for aerobic exercise⁹³

Aerobic exercise recommendations		
Intensity	Frequency	Examples
Moderate: 50-70% of maximum heart rate	Minimum 150 minutes per week	Cycle, brisk walk, dance, continuous swimming, water aerobics
Or		
Vigorous: >70% of maximum heart rate	Minimum 75 minutes per week	Jogging, playing hockey, brisk walking at an incline, aerobics, basketball
Or		
Equivalent combination of moderate and vigorous aerobic exercise		

Table 1.9 SEMDSA recommendations for resistance exercise⁹³

Resistance exercise recommendations	
Frequency	Examples
<p>Two to three times per week:</p> <p>Start with 1 set of 10-15 repetitions with a moderate weight</p> <p>Progress to 2 sets of 10-15 repetitions</p> <p>Progress to 3 sets with heavier weights</p>	<ul style="list-style-type: none"> • Thera-Band exercise • Free weight lifting • Resistance weight machines

1.9 ASSOCIATION BETWEEN DM KNOWLEDGE, GLYCAEMIC CONTROL AND COST OF CARE

In aiming to achieve optimal glycaemic control, it is important to realise that insufficient knowledge regarding DM negatively impacts on patient behaviour and self-management.⁹⁸⁻¹⁰⁰ Adequate knowledge creates awareness and understanding about DM, and aids in motivation, self-care and subsequent glycaemic control. Furthermore, financial costs related to diabetes treatment are reduced by enhanced knowledge levels, as the latter contributes to the prevention of DM complications.¹⁰¹

In 2011 the global healthcare expenditure for DM were (conservatively estimated) a staggering 465 billion US dollars.⁸ Estimations for the whole Africa region indicate that a minimum of 2.8 billion US dollars was spent on DM healthcare in the same year. Presently, Africa has the lowest DM healthcare costs of any of the IDF regions, while the prevalence of DM is projected to almost double by 2030. The financial cost of DM in the African region is thus expected to drastically rise (by approximately 61%) by 2030.³

Ozcelik *et al.* assessed the relationship between glucose control and effective DM education by using a knowledge and awareness questionnaire in patients with T2DM. The participants who received diabetes education were found to have higher knowledge and awareness scores compared to the control group (24.0 ± 4.0 vs. 16.8 ± 5.37 ; $p < 0.0001$) as well as lower HbA1c results (6.5% vs. 8.5%; $p < 0.0001$). There was furthermore a strong negative correlation between the knowledge and awareness score and HbA1c result ($r = -0.8101$, $p < 0.0001$), as well as between the knowledge and awareness score and FPG ($r = -0.6524$, $p < 0.0001$). The investigators therefore concluded that the higher the knowledge and awareness score, the more efficient glycaemic control can be achieved.¹⁰²

A South African study done by van Zyl *et al.* evaluated the efficacy of a physician education program and structured consultation schedule in improving the quality of DM care at tertiary diabetes clinics. This physician-led intervention program was introduced at one of two comparable diabetes clinics. The remaining clinic continued with diabetes care as per usual (control). A baseline and one year post-intervention audit was done in 300 randomly selected patients ($n=141$ intervention clinic, $n=159$ control clinic) and results between the two clinics were compared. After completion of the study, the intervention clinic had significantly more process measures [foot examinations, eye examinations, urine tests for micro-albuminuria, dietary counselling (by a dietician), HbA1c tests, and lipid profiles] done in comparison with the control clinic. The intervention also significantly improved blood glucose control within the intervention group; however no significant difference in blood glucose control was found when compared to the control group. This was due to the fact that blood glucose control also improved over the one year period in the control group. This improvement was thought to be attributed to the Hawthorne effect (the non-specific beneficial effect of taking part in research), as all doctors were aware that their clinic were being observed and consented to participate in the study. They were however blinded as to which patients were included in the study. The average number of clinic visits for the intervention clinic also decreased significantly over time when compared to the control clinic, but the average consultation time was significantly longer. The investment of a greater portion of time and effort at each visit, not only resulted in improved blood glucose control, but also decreased the future work load, and possibly also the future expenses— fewer patient visits, and a potential reduction

in the prevalence and/or progression of diabetes related complications due to improved quality of diabetes care.¹⁰³

The two above mentioned studies thus prove the importance of investing in adequate DM knowledge when aiming to improve disease outcome and reduce potential future cost of care.

1.10 THE NUTRITION CARE PROCESS FOR DIABETES MELLITUS

The Academy of Nutrition and Dietetics published their diabetes nutrition recommendations in December 2010. These recommendations were used to update their description of the nutrition care process for individuals with DM.⁶³ Table 1.10 depicts the methodical approach of the RD during MNT.

Table 1.10 The updated nutrition care process for individuals with DM⁶³

Implementation of MNT
<ul style="list-style-type: none"> • The initial series of visits should consist of 3-4 visits with a RD lasting from 45 to 90 minutes • The series, commencing at diagnosis of DM or at first referral to a RD for diabetes MNT, should be completed within 3 to 6 months • The RD determines whether additional MNT sessions are needed • At least one annual follow-up session is recommended
Nutritional assessment
<ul style="list-style-type: none"> • The RD assesses nutrient intake (focusing on carbohydrates), medication, metabolic control (blood glucose, lipids, and blood pressure), anthropometric measurements, and physical activity. This will serve as the foundation for the implementation of the nutrition prescription, goals and intervention • The RD assesses glycaemic control and focuses MNT to achieve and maintain target blood glucose levels • The RD assesses the relative importance of weight management for individuals who are overweight or obese
Nutrition interventions
<ul style="list-style-type: none"> • The RD implements MNT by selecting from a range of nutrition interventions that will help patients to achieve nutritional goals • The RD encourages intake of macronutrients based on the DRI's for healthy adults • The RD implements nutrition education and counselling with an emphasis on the recommendations from the major and contributing factors to nutrition therapy
Nutrition monitoring and evaluation
<ul style="list-style-type: none"> • The RD coordinates diabetes care with a multidisciplinary team • The RD monitors and evaluates food intake, medication use, metabolic control, anthropometric measurements, and physical activity • The RD primarily use blood glucose monitoring results in evaluating the achievement of goals and efficiency of MNT

1.11 MOTIVATION FOR THE STUDY

According to the latest Health Professions Council of South Africa (HPCSA) statistics, there were only 2 397 dietitians registered in SA in 2012.¹⁰⁴ It is thus apparent that the South African dietetic profession has limited manpower due to its inadequate numbers. Small towns, such as Thabazimbi in the Limpopo province, experience a deficit of dietitians [especially private practising dietitians (PPD's)], thus limiting access of both patients and other health care professionals to sustainable dietetic services. Evidence of this phenomenon is clearly seen in the town in question, as prior to November 2010, the residents of Thabazimbi did not have access to a resident PPD for almost a decade. This resulted in both doctors and DM patients managing the sickness independent of dietetic advice. RD's were seldomly consulted, mostly attributed to the vast travelling distance to the nearest dietitian. This study will therefore be used to create awareness amongst the Thabazimbi community and health care providers alike, of the importance of MNT and lifestyle management in the attainment of optimal glucose control amongst people with T2DM. The role of the RD in this process will also be emphasized. The valuable region-specific data will also shed light on the glycaemic control and behaviour of Thabazimbi's diabetic population, as well as the extent of their exposure to RD-led MNT. This information will especially be of great value with regard to the individualised approach towards patient management and MNT. Furthermore, there are currently a limited number of South African studies available that have evaluated the effect of dietary habits, anthropometric status, activity level (AL) and RD-led MNT on glycaemic control in patients with T2DM. The study in question will thus also aid in obtaining country-specific data in this regard.

CHAPTER 2: METHODOLOGY

2.1 RESEARCH QUESTION

Do lifestyle habits have an effect on the glycaemic control of adults with type 2 Diabetes Mellitus (T2DM) attending selected private health care practices in Thabazimbi?

2.2 AIM

To determine the association between glycaemic control and lifestyle habits in adults with T2DM attending selected private health care practices in Thabazimbi.

2.3 OBJECTIVES

1. To determine the correlation between participants' long-term glycaemic control (HbA1c) and their:
 - Anthropometric status
 - Current dietary intake
 - Physical activity level (PAL)
 - Total number of diabetes related medical nutrition therapy (MNT) sessions completed with a registered dietician
2. To compare participants with good HbA1c control to participants with poor HbA1c control with regard to the above mentioned parameters.
3. To identify the most common dietary and lifestyle changes participants with good glycaemic control made to better their glycaemic control.

2.4 NULL HYPOTHESES (H₀)

1. There is no difference between the anthropometric status of participants with good versus those with poor HbA1c control.
2. There is no difference between the dietary habits of participants with good versus those with poor HbA1c control.
3. There is no difference between the PAL of participants with good versus those with poor HbA1c control.
4. There is no difference between the number of MNT sessions completed with a dietician of participants with good versus those with poor HbA1c control.

2.5 STUDY METHODOLOGY

2.5.1 Study Type

The study was designed to be a descriptive, cross-sectional study with an analytical component. Study techniques included anthropometrical measurements, an interviewer-administered questionnaire and two methods of blood glucose assessment.

2.5.2 Study Population

The study population consisted of adult (18 years and older) T2DM patients attending private medical and dietetic practices in Thabazimbi. Thabazimbi being a small mine town in the Limpopo Province with about 85 000 residents. The nearest city (Rustenburg, Lephalale, Bela-Bela or Brits) to Thabazimbi is about 130km away.

2.5.3 Sample Selection and Size

Participants were non-randomly recruited from all private health care practices that attended to adults with T2DM in Thabazimbi, Limpopo Province. These private health care practices consisted out of four medical practices, one (and the only) dietetic practice and a medical clinical research facility. Two of the medical practices were one-doctor practices and the other two medical practises were both three-doctor practices. Patient statistics of the respective medical practices ranged between 300-3000 patients per month. The research facility had about 30 T2DM patients and the dietetic practice about 40 T2DM patients. Participants from the various recruitment sites were then pooled together to form a study sample that represented patients from all the private health care practices in Thabazimbi. By doing so the probability of a large study population was also greater and selection bias was eliminated. Although the study sample was diverse in terms of practice-origin, the most important common principal was that all the participants were part of the private health care system in Thabazimbi.

All of the practices were individually consulted to inform them about the research project and to ask for their assistance with identifying potential study candidates. The physicians were given the study inclusion and exclusion criteria and asked to quickly assess their T2DM patients' eligibility for the study when they performed a HbA1c test on them or came across a recent HbA1c test result of a T2DM patient. The physicians only provided the investigator with the potential candidate's contact number if the patient consented to it. All T2DM patients of the dietetic practice that started with diet therapy ≥ 3 months ago at the time of recruitment were contacted and asked when their last HbA1c test was performed. If a new/recent HbA1c result was available and if they were eligible, they were invited to partake in the study.

The total number of participants ideally needed for the study was determined, with the help of a statistician, to be at least 88 individuals (44 in each glucose control sub-group). This number was calculated using a power analysis for ANOVA with two groups, significance level of 0.05 and an effect size of 0.5. Samples of size $n=44$ in each group would yield 90% power to detect the effect size. The total sample size ($n=88$) would also yield 90% power to detect a correlation of (at least) 0.337 as significantly different from zero ($\alpha = 0.05$). Unfortunately data collection took much longer than

expected and was subsequently called to a premature halt due to time and financial constraints. The main reason for not reaching the proposed participant target was the lack of patients fulfilling the inclusion criteria; and to be more specific the absence of a valid HbA1c measurement.

2.5.4 Inclusion and exclusion criteria

Inclusion criteria:

- Individuals diagnosed with type 2 Diabetes Mellitus
- Adults (>18 years)
- Individuals who gave their informed consent
- Individuals that could speak English or Afrikaans
- Literate individuals
- Willingness to perform six home blood glucose measurements
- An HbA1c measurement, performed within the preceding 6 months, available in the medical records

Exclusion criteria:

- Individuals whose weight profiles were affected by other factors, such as tumours, ascites, oedema and any other forms of fluid retention
- Organomegaly; if medically diagnosed
- Pregnant individuals
- Individuals who have had either one or both legs amputated
- Individuals who had an illness/infection at the time of recruitment

2.6 METHODS OF DATA COLLECTION

Data collection was conducted by the investigator and took place from 20 April to 7 December 2012. All the data was collected at the offices of the investigator, with the exception of blood glucose monitoring, which was done at the participants' homes. The initial plan was to collect each participant's data on two different occasions, one week apart, but due to time constraints and problems with participant availability, data collection was condensed into one contact session only.

Potential study participants were identified by the various recruitment sites, after which they were telephonically invited (by the investigator) to partake in the research project. Once the individual agreed to partake in the research project a contact session was arranged. Study participants were seen individually, on any day of the week (Monday - Saturday), in an enclosed office for approximately 45-60 minutes. Data collection took place between clients and at times that were most convenient for participants. Inclusion and exclusion criteria was verified for all participants before data collection

commenced. Demographic and anthropometrical data was collected first, followed by the completion of the dietary assessment questionnaire and the explanation of how post-prandial glucose (PPG) monitoring needed to be done at home. Except for minimal traveling costs, there was no form of financial burden for study participants.

2.6.1 Demographic information

Basic demographic information (gender, age and disease duration) was recorded (Addendum 1) for all participants.

2.6.2 Anthropometric assessment

All anthropometrical measurements (weight, height and waist circumference) were performed by the investigator as outlined in Table 2.1 below. The nutritional assessment method was used.¹⁰⁵

Table 2.1 Anthropometric measurements taken¹⁰⁵

Measurement and equipment	Methods	Validity and reliability measures
Body weight Digital platform scale (300kg capacity;Alpha)	<ul style="list-style-type: none"> • Zero calibration of scale before taking the measurement • Weighing of participant without shoes and with minimal clothing • Participant stands unassisted on the platform electronic scale • Participant stands still on the scale with their weight firmly distributed on both feet • Weight measured to the nearest 0.1kg 	<ul style="list-style-type: none"> • Calibrated scale used • Calibration done daily with 1kg & 10kg weight • Standardised weighing technique used • Average of 3 measurements recorded • Measurement done by investigator only
Height Non-stretchable plastic tape measure attached to a closed door; firm plastic ruler	<ul style="list-style-type: none"> • Participant barefoot for the measurement • Participant's heels together, arms to the side, legs straight, shoulders relaxed and the head in the Frankfurt horizontal plane • The heels, buttocks, scapulae and back of the head against the vertical surface • Nothing covering the head of the participant • Measurement taken at maximum inspiration • Ruler lowered on the highest point of the head with enough pressure to compress the hair • Measurement taken to the nearest 0.1 cm 	<ul style="list-style-type: none"> • Standardised tape measure used • Standardised measuring technique used • Average of 3 measurements recorded • Measurement done by the investigator only
Waist circumference Non-stretchable plastic tape measure	<ul style="list-style-type: none"> • Participant to stand in an upright position • All clothing covering the waist removed • Measuring tape positioned half way between the 10th rib and the ileac crest, perpendicular to the long axis of the trunk • Measuring tape in a horizontal position around the participant's waist • Measuring tape does not cut into the skin of the participant • Measurement taken after normal exhalation • Measurement taken to the nearest 0.1 cm 	<ul style="list-style-type: none"> • Standardised tape measure used • Standardised measuring technique used • Average of 3 measurements recorded • Measurement done by the investigator only

2.6.3 Dietary assessment

Each participant's dietary habits were assessed by means of a standard and structured questionnaire (Addendum 2 & 3). The seventeen question questionnaire was developed by the investigator using the principles of the food frequency questionnaire. The majority of questions posed to participants were close ended questions. A selection of possible answer options were also provided to make data collection as easy and simple as possible. The questionnaire thus aimed to gather information regarding participants' dietary (meals, snacks and beverages) choices, frequency of consumption and portion sizes. Questionnaire validity was ensured prior to data collection by evaluating the face- and content validity thereof. Four individuals with T2DM (2 males and 2 females) were asked to complete the dietary assessment questionnaire; from their comments several amendments were made to better explain each question. The four volunteers used to evaluate the face validity of the dietary questionnaire was then excluded from the research project. Content validity was assessed by an expert in the field of nutrition and diabetes [Ms Berna Harmse (Msc Dietetics NWU)]. All the recommended changes proposed by Ms Harmse were incorporated to better the scientific content of the questionnaire. The initial plan was that each participant would complete the questionnaire in the presence of the investigator at the second visit. However, as previously mentioned, participant contact time was limited, therefore it was decided that the investigator would administer and complete the questionnaire in a face-to-face interview for all study participants. Table 2.2 depicts the dietary component assessed at each question of the dietary questionnaire.

Table 2.2 Dietary assessment questionnaire content

Question	Dietary component assessed
Q1. Main meal frequency	Presence or absence of regular eating habits
Q2. Snacking frequency	Frequency, quality and quantity of daily snack choices
Q3. Take-away intake	Frequency, quality and quantity of take-away/restaurant meals
Q4. Bread quality and quantity	Frequency, quality and quantity of breads/rolls consumed most often
Q5. Breakfast quality and quantity	Frequency, quality and quantity of breakfast cereals/porridges or other breakfast alternatives
Q6. Dairy quality and quantity	Frequency, quality and quantity of milk and yoghurt variations
Q7. Starch quality and quantity	Frequency, quality and quantity of starches mostly associated with the main/cooked meal of the day
Q8. Fruit portion size	Number and/or the size of fruit consumed at a specific point in time
Q9. Total daily fruit intake	Total number of fruit portions consumed a day
Q10. Fruit form	Frequency, quality and quantity of all fruit forms (fresh/canned/dried) consumed
Q11. Weekly vegetable intake	Total number of days per week that vegetables are consumed
Q12. Total daily vegetable intake	Total number of vegetable portions consumed a day
Q13. Vegetable form	Frequency, quality and quantity of all vegetable forms (raw/cooked/candied/with potato) consumed
Q14 & Q15. Sweetening agents	Frequency, quality and quantity of sweetening agents and sweet spreads
Q16. Beverage quality and quantity	Frequency, quality and quantity of all (hot and cold) beverages consumed
Q17. Snack quality and quantity	Frequency, quality and quantity of all snacks consumed

Male participants were encouraged to bring their female partners along to assist with the dietary assessment. This was done to ensure the reliability of male participant's answers. In addition to this approach, the reliability of the dietary assessment was evaluated by verifying some of the participant's answers with them. This was done for any three questions on the questionnaire once the questionnaire was completed in full. If one or more of the answers did not correlate, the participant was asked to verify their entire dietary questionnaire. The reliability assessment was then repeated again.

2.6.4 Physical activity level

Physical activity level (PAL) was assessed with a question on the dietary assessment questionnaire (Addendum 2 & 3). The participants had three PAL's (sedentary, active and very active) to choose from. They had to identify the activity level that best described their PAL at the time. Each PAL was defined¹⁰⁶ to assist the participants in identifying their PAL.

The reliability of the PAL was evaluated by verifying the participant's answer with them. The validity of the PAL assessment was ensured by using the pre-defined WHO/FAO/UNU (World Health Organization, Food and Agriculture Organization of the United Nations, United Nations University) PAL classification.¹⁰⁶

2.6.5 Total number of medical nutrition therapy sessions with a registered dietician

The total number of diabetes-related MNT sessions completed with a RD was also assessed with a question on the dietary assessment questionnaire.

2.6.6 Blood glucose control

- Long-term blood glucose control:

Long-term blood glucose control was assessed by evaluating the participant's latest (performed within the preceding 6 months) glycosylated haemoglobin A1c (HbA1c) test result. The HbA1c test result was only obtained from the medical folder once the patient gave consent to partake in the research project. Reliability and validity of the HbA1c test results were ensured by only using test results obtained from certified laboratories.

- Short-term blood glucose control:

Participants measured and documented six post-prandial blood glucose measurements at home. These measurements were used to assess short-term blood glucose control. A standard home glucose monitoring template (Addendum 4), designed by the investigator, was provided at data collection and methodically explained to each participant.

All of the instructions were repeated on the template:

1. Use the glucose monitoring template to record home blood glucose readings
2. Wash hands before taking the measurement
3. Measure post-meal blood sugar levels two hours after commencing with the meal
4. Record two breakfast, lunch and supper post meal glucose readings respectively, in the same sequence as specified on the template

Potential participants were asked to bring their glucometer to the data collection visit; if they had one. During data collection participants were asked whether they would mind using their glucometer and test strips to measure the PPG measurements. Most participants did not mind. If a participant was unwilling to use their own test strips or did not have a glucose monitor and/or test strips, it was supplied by the investigator. Roche Diagnostics sponsored 25 Accu-Chek Active glucometers and an adequate amount of test trips to assist with the latter. All glucose monitors (the participant's and the

sponsored ones) were validated by the investigator during the data collection visit. This was done by testing a reference solution [syrup simplex BP (Medicolab)] on each monitor. Invalid glucometers were replaced with an accurate sponsored glucometer, and PPG monitoring were repeated if the validity of home measurements were in question. Once participants concluded their PPG monitoring at home they returned the completed template (and sponsored glucometer) to the offices of the investigator.

2.6.7 Most common dietary and lifestyle changes of participants with good glycaemic control

Dietary assessment questionnaires and PAL's of participants with optimal PPG control were compared to the data of those with poor PPG control in order to identify the most common dietary and lifestyle changes made by patients with good glycaemic control.

2.7 ANALYSIS OF DATA

Study data was processed and captured by the investigator and statistically analysed with the assistance of a statistician, Prof. D.G. Nel, appointed by Stellenbosch University (SU). Participant data was processed and classified on the relevant data form before it was entered into a pre-coded Microsoft Excel (2010) datasheet.

2.7.1 Anthropometrical data

Anthropometrical data (weight, height and waist circumference) was used to calculate Body Mass Index (BMI) and interpret and classify the nutritional status of each participant. BMI and waist circumference measurements were classified into one of eight (category 1-8) and one of three (category 1-3) categories respectively. Table 2.3 depicts the calculation and classification process.

Table 2.3 Calculation and classification of anthropometrical data^{107,108}

Anthropometrical measurement	Calculation thereof	Interpretation and classification				
Body Mass Index (BMI) (kg/m²) ¹⁰⁷	Weight (kg)/ Height ² (m)	Undernutrition:	<18.5		Category:	
		Severe thinness	<16.00			1
		Moderate thinness	16–16.99			2
		Mild thinness	17–18.49			3
		Healthy body weight:	18.5–24.99			4
		Over weight:	25–29.99			5
		Obese:	>30			
		Obese, Class 1	30–34.99			6
Obese, Class 2	35–39.99		7			
Obese, Class 3	≥40		8			
Waist Circumference (cm) ¹⁰⁸	N/A		Males	Females	Category:	
		Healthy	<94	<80		1
		Moderately increased	>94	>80		2
Greatly increased	>102	>88	3			

2.7.2 Dietary data

The dietary assessment questionnaire was processed and evaluated by the investigator only, whilst using the latest evidence-based practices.^{46,63,109} Each answer on the questionnaire was carefully evaluated (carbohydrate quality, quantity and frequency of consumption) and awarded a mark out of three. Marks were awarded according to the quality of the dietary decision (Table 2.4) made. Once the evaluation process was completed the marks were totalled and expressed as a percentage of the maximum mark (48) that could have been obtained (% dietary compliance). Dietary questionnaires were not evaluated one by one, but rather in two batches (n=30; n=32) to ensure consistency throughout the evaluation process. Important decisions made during the evaluation of the first batch were documented and filed for the second evaluation process. All dietary questionnaires were evaluated twice to ensure reliability of the assessment process. Dietary compliance of 50-60% was regarded as average and anything above 60% was regarded as above average.

Table 2.4 Mark allocation rational

Quality of dietary decision	Mark awarded
Poor	1
Acceptable	2
Excellent	3

2.7.3 Activity level data

The physical activity level of each participant was evaluated and categorised (category 1-3) by the investigator using the pre-defined FAO/WHO/UNU PAL criteria (Table 2.5).

Table 2.5 Physical activity level classification¹⁰⁶

Physical activity level	Definition	Category
Sedentary/Low active	People who have occupations that do not demand much physical effort, who do not walk long distances, generally use vehicles for transportation, do not exercise or participate in sports regularly, and spend most of their free time sitting or standing.	1
Active/Moderately active	People who have occupations that are not strenuous in terms of energy demands, but involve more energy expenditure than that described for sedentary lifestyles. Alternatively, they are people with sedentary occupations who regularly spend a certain amount of time partaking in moderate to vigorous physical activity.	2
Very active	People who engage regularly in strenuous work or in strenuous leisure activities for several hours.	3

2.7.4 Glycaemic control data

The HbA1c and average PPG value was respectively used to assess the long- and short-term glucose control of participants. The average PPG value was calculated through adding the six measurements and then dividing the total by six. Blood glucose control were assessed using the 2009 SEMDSA glycaemic targets⁴³ (Table 2.6). The 2012 SEMDSA targets were not used as they were not available when the study protocol was developed and early data processing commenced.

Table 2.6 2009 SEMDSA glycaemic targets⁴³

Evaluation period	Glycaemic measurement	Target
Long-term	HbA1c%	<7.0%
Short-term	Post-Prandial Glucose	5.0-8.0mmol/l

Participants were subsequently grouped into one of two (good or poor) glycaemic control groups for each variable (Table 2.7).

Table 2.7 Glycaemic group classifications

HbA1c/PPG Group classification	HbA1c (%)	Average PPG (mmol/l)
Good	<7.0	≤8.0
Poor	≥7.0	>8.0

2.7.5 Other data

Demographic information, together with the few close ended questions, were captured directly on to the data sheet.

2.7.6 Statistical procedures

STATISTICA version 11 [StatSoft Inc. (2011) STATISTICA (data analysis software system), www.statsoft.com] was used to analyse the data. Summary statistics were used to describe the variables and the distributions of variables were presented with histograms and frequency tables. Medians or means were used as the measures of central location for ordinal and continuous responses. Standard deviations and quartiles were indicators of spread.

The relationship between two continuous variables were analysed with regression analysis and the strength of the relationship measured with Spearman correlation (continuous variables were not normally distributed). The relationships between continuous response variables and nominal input variables were analysed using appropriate analysis of variance (ANOVA). When ordinal response variables were compared against a nominal input variable, non-parametric ANOVA methods (Mann-Whitney test) were used. The relation between nominal variables were investigated with contingency tables and appropriate chi-square tests. A p-value of $p < 0.05$ represented statistical significance in hypothesis testing and 95% confidence intervals were used to describe the estimation of unknown parameters.

2.8 ETHICAL AND LEGAL ASPECTS

The study protocol and all the relevant addenda were submitted to the Health Research Ethics Committee of Stellenbosch University for ethical approval. The latter was obtained in March 2012 and the approval number S12/02/060 was given to the proposed study.

All potential participants were aware that participation in the research project was completely voluntary and that withdrawal from the study could take place at any stage. Written informed consent was obtained in the preferred language (English or Afrikaans) of all participants before data collection commenced. The consent form (Addendum 5 & 6) obtained permission to:

- partake in the study
- answer the relevant questions and the dietary questionnaire
- be weighed and measured
- obtain the most recent HbA1c result from their medical records
- use all the information obtained in the results section of the research project.

Participants were interviewed and measured in a private room to ensure comfort and privacy. Privacy and confidentiality of participant information was ensured by using an anonymous approach. Study participants were allocated a 3 digit number (001-062) instead of using their names. Study data was also kept in a locked steel cabinet to which only the investigator had access. All participants who were found to have poor blood glucose control were telephonically invited [and reminded with a short message (SMS)] to a diabetes group-education session. The latter was held subsequent to data collection and took place on Saturday 8 December 2012 from 08:00–10:00am. The education session was free of charge and completely voluntary.

CHAPTER 3: RESULTS

3.1 DEMOGRAPHICS

A total of 62 individuals agreed to partake in the study. The number of participants obtained from each of the recruitment sites are outlined in Table 3.1. Complete data sets were obtained for all variables (demographics, anthropometry, dietary assessment, physical activity level [PAL] assessment, number of sessions with a dietician and assessment of long-term glycaemic control) except for the assessment of short term blood glucose control (post-prandial glucose [PPG]). Four participants had not returned their completed home-measured PPG log in time for inclusion in these results; despite numerous phone calls and reminders. PPG logs were thus only obtained for 58 participants. The study sample predominately consisted out of middle-age to older white individuals with a middle-income socio-economic status. The mean age of study participants were 60.13 years (40-84, SD:10.85) and the mean DM disease duration was calculated to be 121 months (2-456, SD:96.56) or rather 10.08 years. The study population consisted out of 37 men (59.7%) and 25 women (40.3%).

Table 3.1 Total number of participants obtained from each recruitment site (n=62)

Recruitment site	Number of participants	Percentage of study sample (%)
1	0	0.00
2	10	16.13
3	10	16.13
4	19	30.65
5	11	17.74
6	12	19.35

3.2 ANTHROPOMETRIC STATUS

Anthropometrical results are outlined in Table 3.2. The mean weight of study participants was 101.23kg (55.90-153.40, SD:19.71). The average weight of female participants [98.83kg (55.90-153.40, SD24.89)] did not differ much from the men's average weight [102.85kg (76.60-142.90, SD:15.45)]. Female participants consequently had a higher mean BMI [36.72kg/m² (21.30-54.29, SD:8.37)] than their male counterparts [32.35kg/m² (23.76-43.56, SD:4.31)]. The median BMI category for the total study population was category 6 (obese, class 1), category 7 (obese, class 2) for women and category 6 (obese, class 1) for men.

Table 3.2 Anthropometrical results of participants (n=62)

Participants	Variable	Valid N	Mean	Min	Max	SD
All participants	Weight (kg)	62	101.23	55.90	153.40	19.71
	BMI (kg/m ²)	62	34.11	21.30	54.29	6.57
	BMI category (1-8)	62	6.00*	4.00	8.00	N/A
	WC (cm)	62	113.76	75.00	150.00	13.92
	WC category (1-3)	62	3.00*	1.00	3.00	N/A
Females	Weight (kg)	25	98.83	55.90	153.40	24.89
	BMI (kg/m ²)	25	36.72	21.30	54.29	8.37
	BMI category (1-8)	25	7.00*	4.00	8.00	N/A
	WC (cm)	25	110.72	75.00	150.00	17.65
	WC category (1-3)	25	3.00*	1.00	3.00	N/A
Males	Weight (kg)	37	102.85	76.60	142.90	15.45
	BMI (kg/m ²)	37	32.35	23.76	43.56	4.31
	BMI category (1-8)	37	6.00*	4.00	8.00	N/A
	WC (cm)	37	115.81	99.00	137.00	10.50
	WC category (1-3)	37	3.00*	2.00	3.00	N/A

* Median; N/A = Not Applicable

Only 6.45% (n=4) of the participants had a healthy BMI. The rest of the study population (n=58; 93.54%) was classified as over nourished. Most participants were obese (n=46; 74.19%) and 19.35% (n=12) overweight. BMI classification is graphically displayed in Figure 3.1.

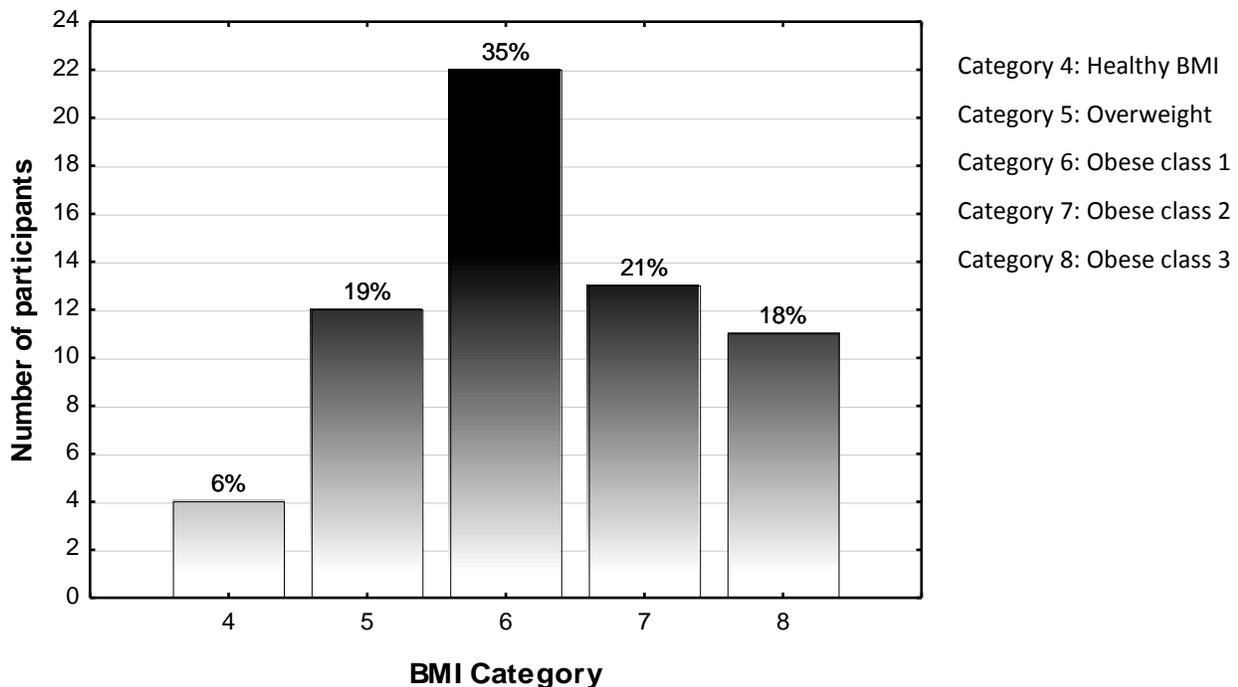


Figure 3.1 BMI category classification of participants

Most (n=56; 90.32%) participants had a substantially increased waist circumference (WC) (high risk of developing metabolic complications) and was therefore classified into the third WC category (Figure 3.2). Only 2 participants (3.23%) had a WC within the healthy range. The average WC of female participants [110.72cm (75.0-150.0, SD:17.65)] greatly exceeded the recommended WC targets (<80-88cm) for females. Men also had a high mean WC measurement of 115.81cm (99.0-137.0, SD:10.50). When WC was expressed as a percentage of the upper limit (UL) for each gender respectively; female participants were found to have significantly (p<0.01) more (126% vs. 114%) adipose tissue around their waistline than their male counterparts (Figure 3.3).

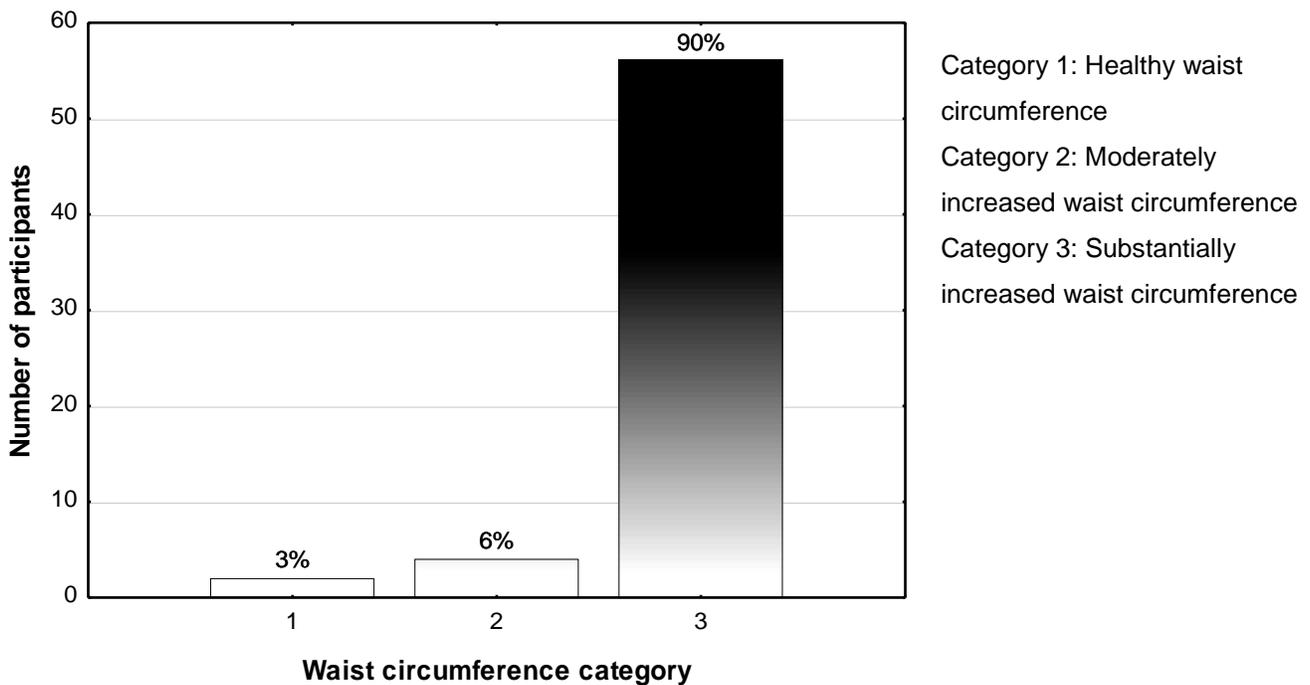


Figure 3.2 Waist circumference category classification of participants

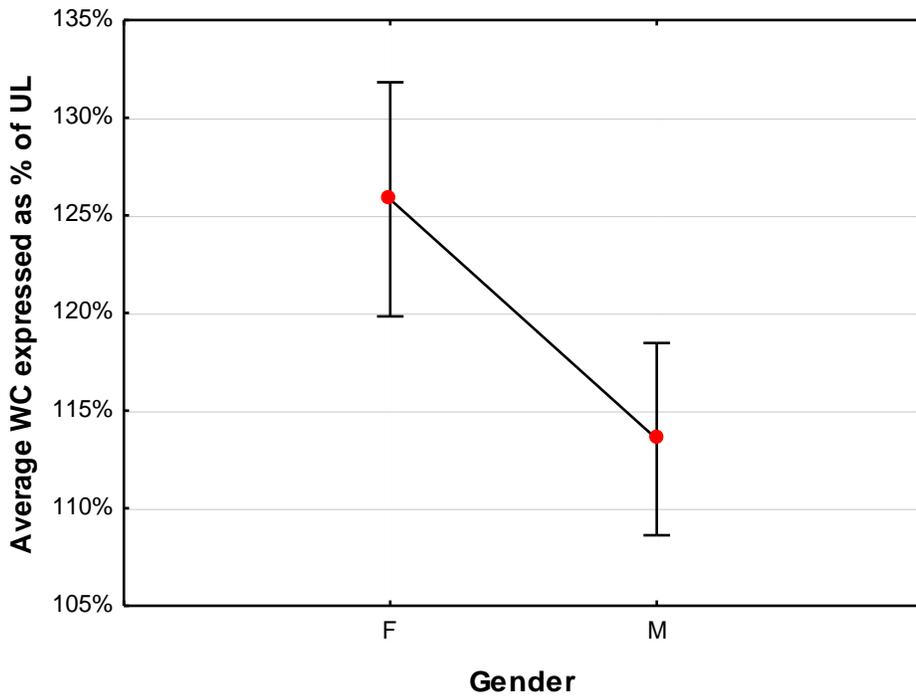


Figure 3.3 Gender comparison of average waist circumference (expressed as % of the upper limit) ($p < 0.01$)

3.3 DIETARY INTAKE

The mean percentage of dietary compliance, for the total study population, was 74.53% (52.08-97.92, SD:10.93). Almost all participants (n=59, 95.16%) achieved a score above 60%, with the bulk of participants obtaining scores between 60-70% (n=19, 30.65%) and 70-80% (n=23, 37.1%). Only 27.42% (n=17) of participants obtained a score above 80%. Figure 3.4 displays the percentage dietary compliance of participants.

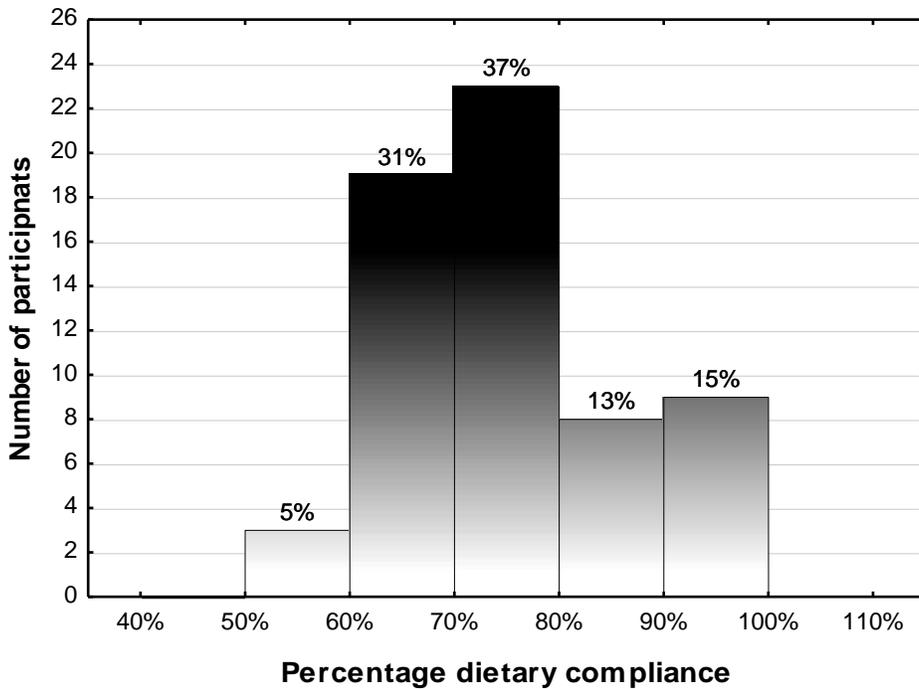


Figure 3.4 Percentage dietary compliance of participants

Table 3.3 reflects the average score participants (n=62) obtained for each question of the dietary assessment questionnaire. Most questions (12 out of the 16) had an average score above 2 (out of a maximum of 3), indicative that mostly acceptable dietary decisions were made by the study population. Only four questions (Q2: snacking frequency, Q5: breakfast quality and quantity, Q7: starch quality and quantity, and Q17: snack quality and quantity) received an average score below 2. The highest average scores obtained were for question 1 (presence of main meals), question 6 (dairy quality and quantity) and question 9 (total daily fruit intake).

Table 3.3 Average scores obtained for dietary assessment questionnaire (n=62)

Variable	Valid N	Mean	Min	Max	SD
Q1. Presence of main meals	62	2.79	1.00	3.00	0.60
Q2. Frequency of snacking	62	1.81	1.00	3.00	0.77
Q3. Take-away intake	62	2.24	1.00	3.00	0.80
Q4. Bread quality and quantity	62	2.00	1.00	3.00	0.91
Q5. Breakfast quality and quantity	62	1.74	1.00	3.00	0.79
Q6. Dairy quality and quantity	62	2.74	1.00	3.00	0.51
Q7. Starch quality and quantity	62	1.60	1.00	3.00	0.80
Q8. Fruit portions	62	2.66	1.00	3.00	0.75
Q9. Total daily fruit intake	62	2.82	1.00	3.00	0.56
Q10. Fruit form	62	2.60	1.00	3.00	0.64
Q11. Weekly vegetable intake	62	2.40	1.00	3.00	0.84
Q12. Total daily vegetable portions	62	2.05	1.00	3.00	0.76
Q13. Vegetable form	62	2.08	1.00	3.00	0.95
Q14 & Q15. Sweetening agents	62	2.52	1.00	3.00	0.78
Q16. Beverage quality and quantity	62	2.10	1.00	3.00	0.90
Q17. Snack quality and quantity	62	1.63	1.00	3.00	0.87

3.4 PHYSICAL ACTIVITY LEVEL

The average activity level (AL) of participants were 1.52 (1.0-3.0, SD:0.54). Half (50%; n=31) of the study population indicated that they had a sedentary/low (level 1) AL, whilst 48.39% (n=30) stated that they had an active/moderately active (level 2) AL. Only one participant had a very active (level 3) AL.

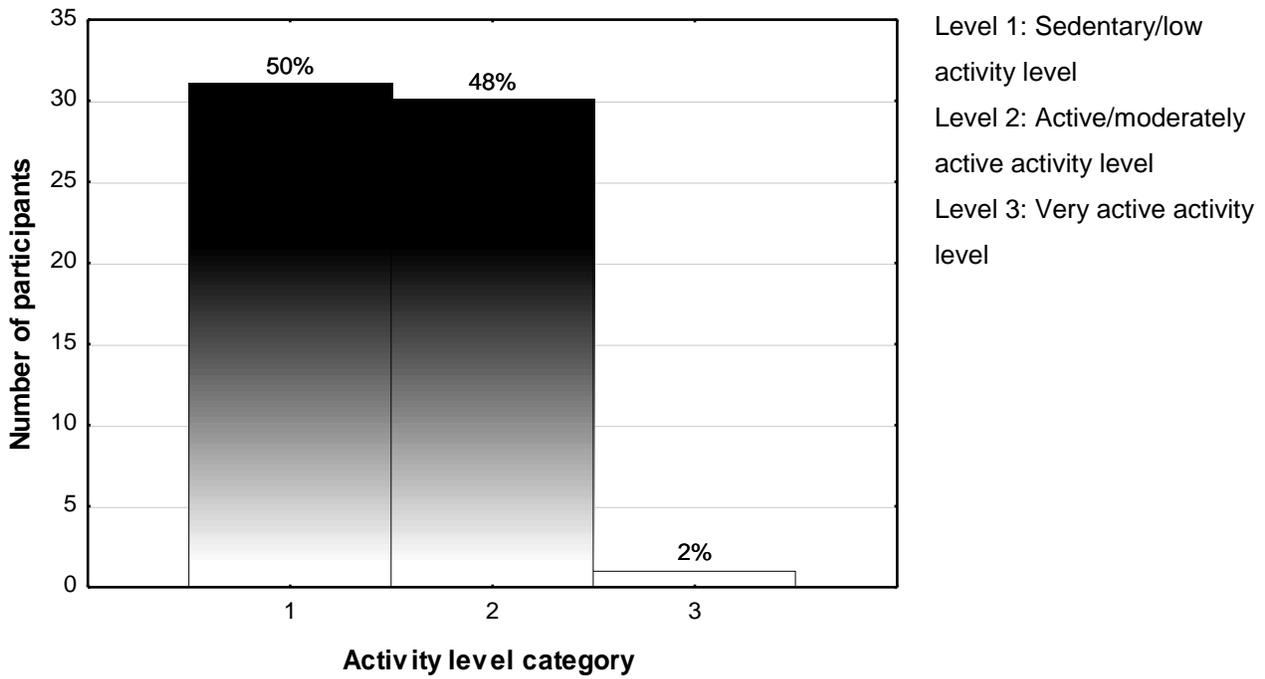
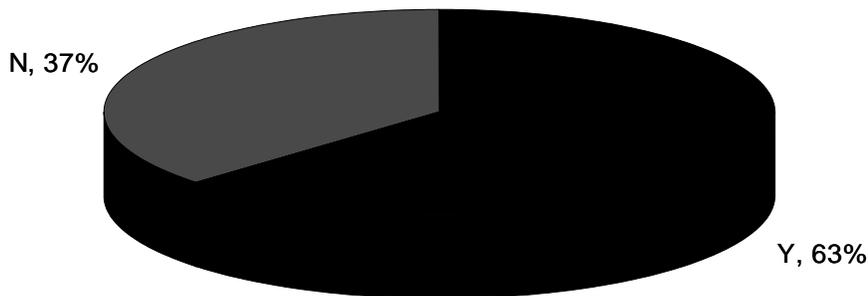


Figure 3.5 Activity level category classification of participants

3.5 DIETETIC CONSULTATION

Almost all (95%; n=59) of the participants indicated that it was necessary for an individual with DM to consult a dietician for appropriate MNT. However, only 63% (n=39) of the participants actually consulted a dietician for the dietary management of DM (Figure 3.6).



DM-related MNT from a dietician: Yes (Y) or No (N)

Figure 3.6 Percentage participants who received DM-related MNT from a dietician

Of those patients that consulted a dietician (n=39), the average number of visits made to a dietician was 4.28 (1.0-16.0, SD:4.06) visits. Most (n=23; 59%) participants had ≥ 3 sessions with a registered dietician. Yet, almost one third (n=12; 31%) of participants only had one session with a dietician. Only one of the six participants who consulted a dietician ≥ 10 times came from the dietetic practice. The other five participants came from the medical practices. The participant from the dietetic practice consulted the investigator on ten occasions. Figure 3.7 depicts the total number of sessions the participants (n=39) spent with a dietician.

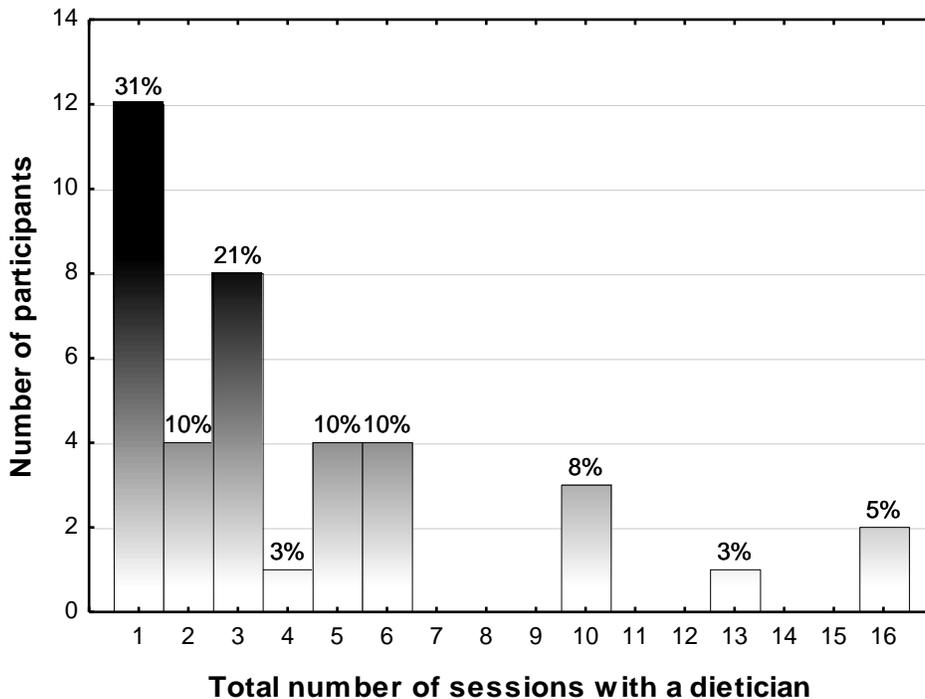


Figure 3.7 Total number of sessions that participants (n=39) spent with a dietician

3.6 GLYCAEMIC CONTROL

The glycaemic results of the participants and the various groups are summarised in Table 3.4. The average HbA1c percentage and PPG of the study population was respectively 7.50% (4.90-11.30, SD:1.62) and 8.90mmol/l (4.52-19.03, SD:3.21), demonstrating both long and short-term poor glucose control. The poor HbA1c group had a high average HbA1c % of 8.69% (7.0-11.30, SD:1.27) whilst the poor PPG group had an alarming high mean PPG of 11.52mmol/l (8.18-19.03, SD:3.11). The good glycaemic control groups respectively had an average HbA1c % of 6.13% (4.90-6.90, SD:0.52) and an average PPG of 6.76mmol/l (4.52-7.87, SD:0.83).

Table 3.4 Glycaemic results of participants and sub-groups

Participants	Variable	Valid N	Mean	Min	Max	SD
All participants	HbA1c (%)	62	7.50	4.90	11.30	1.62
	Average PPG (mmol/l)	58	8.90	4.52	19.03	3.21
HbA1c groups	Good (%)	29	6.13	4.90	6.90	0.52
	Poor (%)	33	8.69	7.00	11.30	1.27
PPG groups	Good (mmol/l)	32	6.76	4.52	7.87	0.83
	Poor (mmol/l)	26	11.52	8.18	19.03	3.11

The HbA1c % of participants ranged from <5% to <12% (Figure 3.8). Almost half (n=29; 47%) of the participants had an HbA1c <7% whilst the bulk of the study population (n=42; 68%) had an HbA1c <8%.

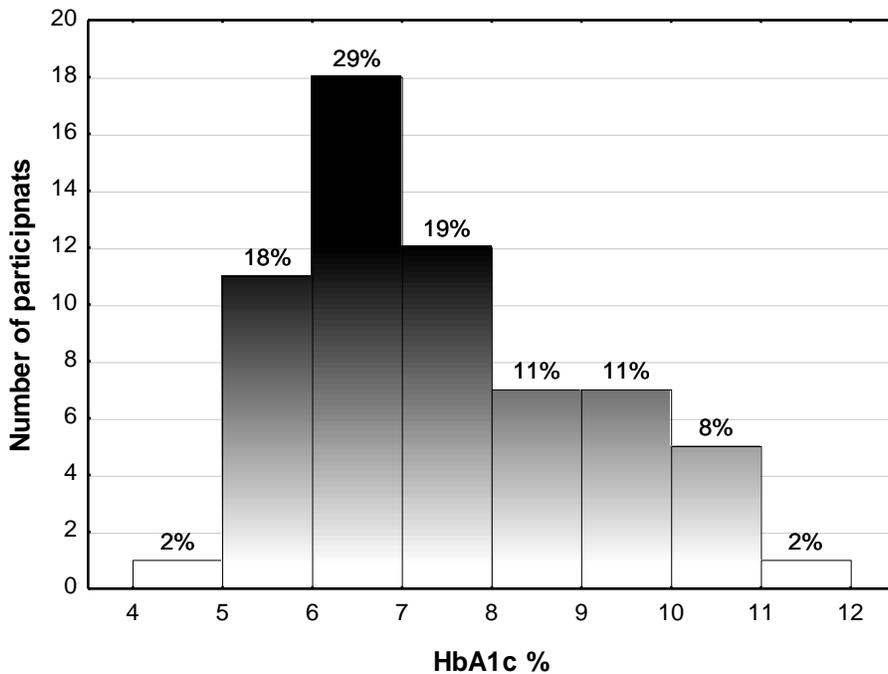


Figure 3.8 HbA1c % results of participants

Although the two HbA1c groups were fairly equal in participant numbers, there were more participants (n= 33; 53%) in the poor HbA1c group than in the good (n=29; 47%) HbA1c group.

The average HbA1c percentage differed significantly ($p < 0.01$) between the HbA1c groups (Figure 3.9).

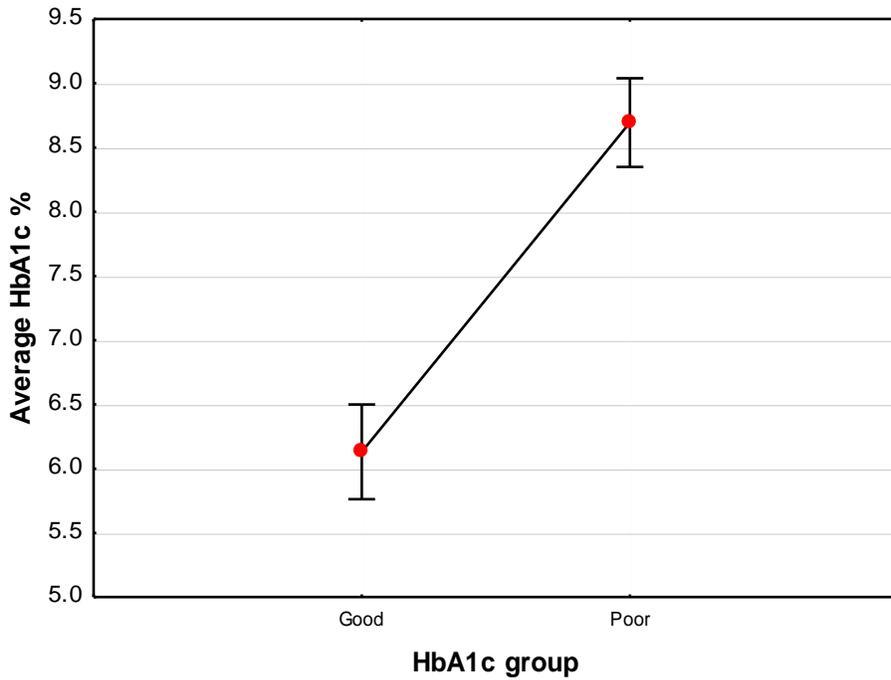


Figure 3.9 HbA1c group comparison of average HbA1c percentage ($p < 0.01$)

Figure 3.10 graphically displays the average PPG results of participants ($n=58$). Most participants ($n=26$; 45%) obtained an average PPG result between 6-8mmol/l and 10% of participants ($n=6$) even obtained a mean PPG below 6mmol/l. There were thus more participants in the good PPG control group ($n=32$; 55%) than in the poor PPG control group ($n=26$; 45%). The average PPG differed significantly ($p < 0.01$) between the PPG groups, as depicted by Figure 3.11.

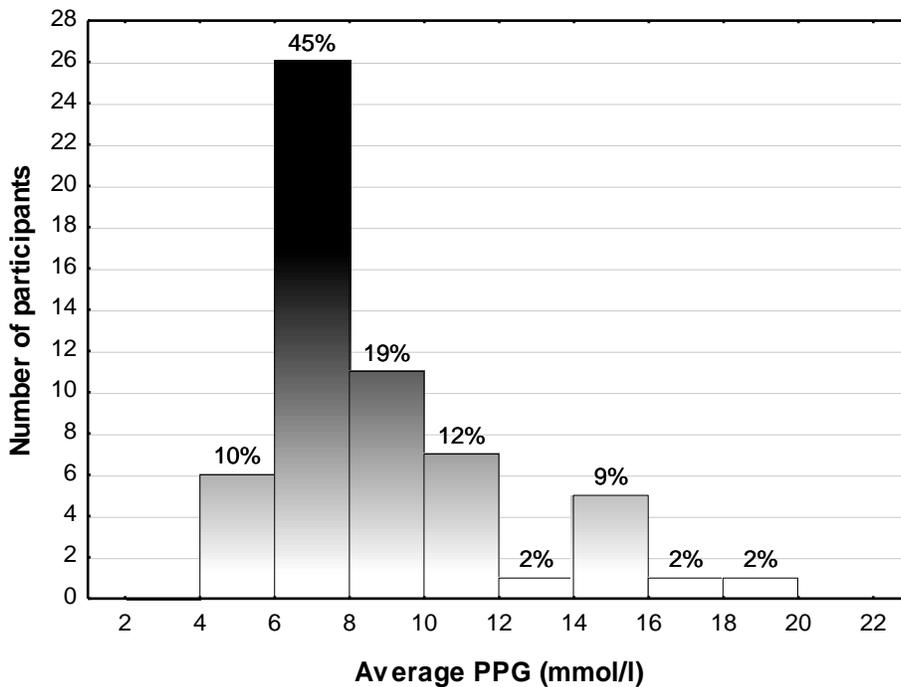


Figure 3.10 Average PPG of participants

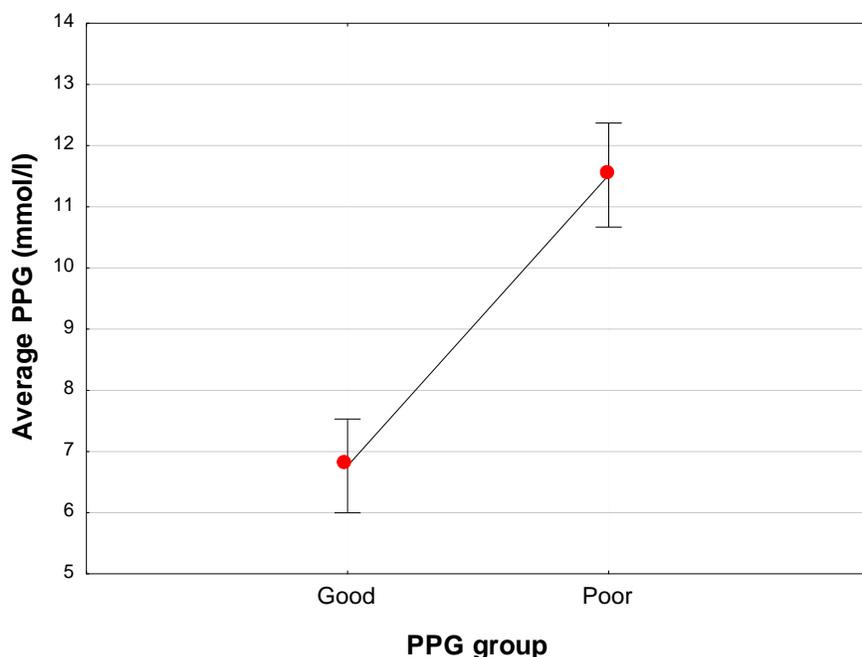


Figure 3.11 PPG group comparison of average PPG ($p < 0.01$)

Female participants were found to have better long (HbA1c%; 7.14% vs. 7.74%) and short-term (average PPG; 8.25mmol/l vs. 9.35mmol/l) glycaemic control when compared to men (Table 3.5). The difference in glycaemic control was however not statistically significant between genders.

Table 3.5 Glycaemic results according to gender

Gender	Variable	Valid N	Mean	Min	Max	SD
Male	HbA1c (%)	37	7.74	4.90	11.30	1.68
	Average PPG (mmol/l)	34	9.35	5.65	19.03	3.37
Female	HbA1c (%)	25	7.14	5.20	10.90	1.49
	Average PPG (mmol/l)	24	8.25	4.52	15.92	2.92

3.7 CORRELATION TESTING

Spearman’s correlation testing was done to determine the association between long-term glycaemic control (HbA1c%) and various study variables (BMI, waist circumference, dietary compliance, activity level and no. of dietetic sessions completed) of participants (n=62). The only significant association found was the negative association ($r = -0.31$; $p = 0.02$) between HbA1c % and percentage dietary compliance (Figure 3.12). None of the other variables (BMI, waist circumference, activity level and no. of dietetic sessions completed) seemed to influence the HbA1c control of the group. Additional correlation testing was done to determine the association between percentage dietary compliance and: 1) the number of dietetic sessions completed and 2) average PPG. Both variables were significantly [$(r = 0.40$; $p = 0.001$), $(r = -0.34$; $p = 0.01$)] associated with the percentage dietary compliance

of participants (Figures 3.13 and 3.14). The association between DM disease duration and glycemic control (both HbA1c % and PPG) were also investigated. Only PPG control was significantly ($r=0.30$; $p=0.02$) associated with DM disease duration (Figure 3.15). Table 3.6 displays the correlation test results.

Table 3.6 Correlation test results

Pair of variables	Spearman Rank Order Correlations			
	Valid N	Spearman R	t(N-2)	p-value
HbA1c % & BMI	62	-0.05	-0.42	0.68
HbA1c % & Waist circumference	62	0.00	0.02	0.98
HbA1c % & % Dietary compliance	62	-0.31	-2.50	0.02
HbA1c % & Activity level	62	-0.05	-0.39	0.70
HbA1c % & Number of sessions with a dietician	62	-0.18	-1.40	0.17
Number of sessions with a dietician & % Dietary compliance	62	0.40	3.35	0.001
Average PPG & % Dietary compliance	58	-0.34	-2.72	0.01
DM disease duration & HbA1c %	62	0.17	1.36	0.18
DM disease duration & PPG	58	0.30	2.39	0.02

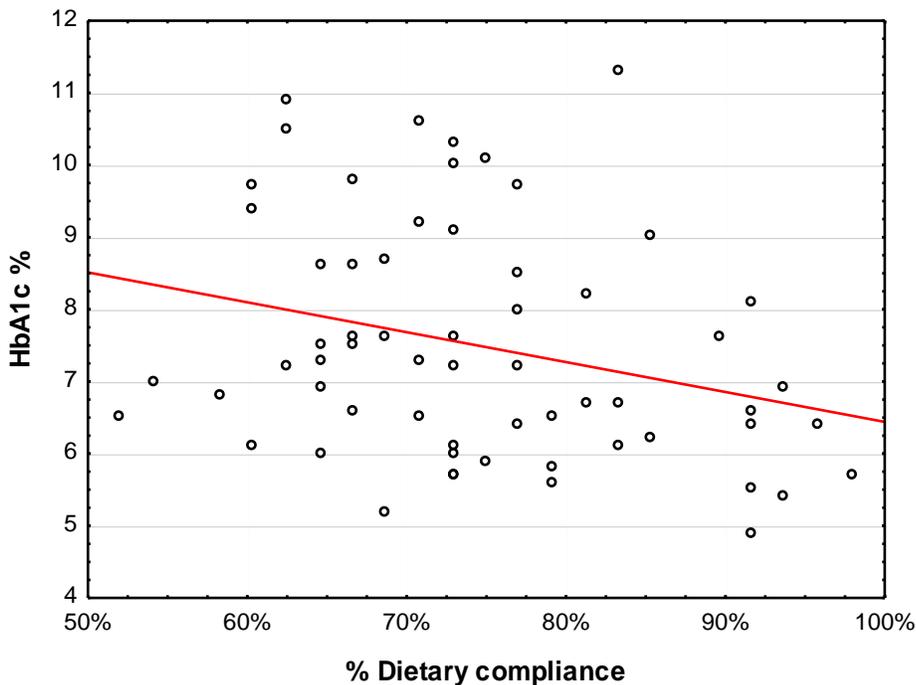


Figure 3.12 Negative correlation between HbA1c % and % dietary compliance ($p=0.02$)

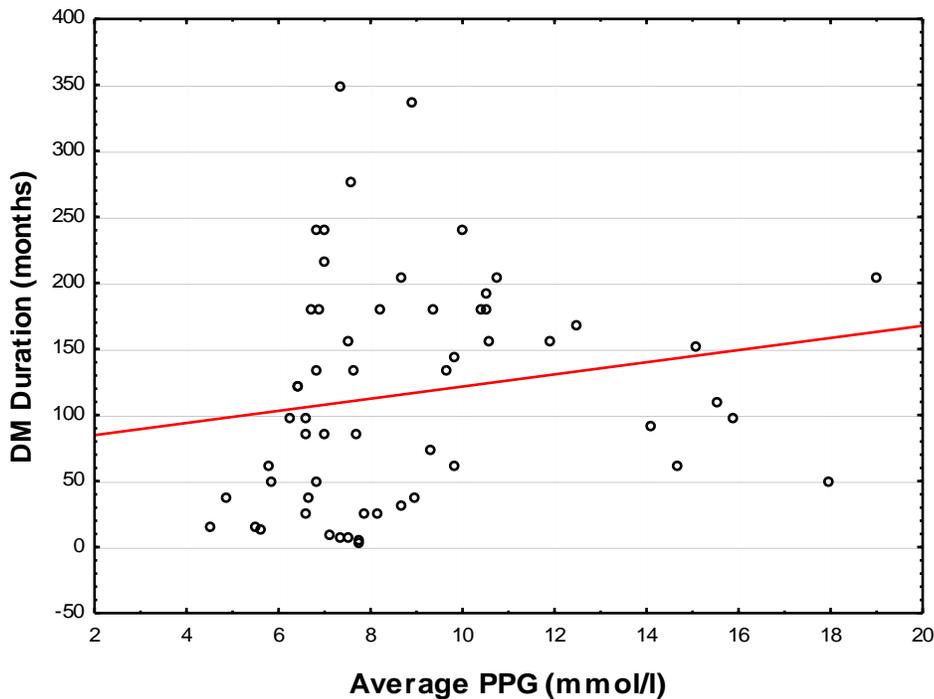


Figure 3.15 Positive correlation between diabetes duration and average PPG (p=0.02)

3.8 HYPOTHESIS TESTING

Hypothesis testing was performed between the HbA1c groups (Table 3.7). All null-hypotheses, except for one, were not rejected. The hypothesis that there was no difference between the dietary habits of participants with good versus those with poor glycemic control has been rejected (p=0.01). The group with good HbA1c control thus had significantly better dietary habits than the group with poor HbA1c control (Figure 3.16).

Table 3.7 Hypothesis testing between HbA1c groups

	Poor HbA1c control (n = 33)					Good HbA1c control (n = 29)					p-value
	Mean	Std. Dev.	Std. Err	- 95.0%	+95.00%	Mean	Std. Dev.	Std. Err	- 95.0%	+95.00%	
BMI (kg/m²)	33.79	5.14	0.89	31.96	35.61	34.48	7.98	1.48	31.44	37.51	0.68
Waist circum.(cm)	114.88	12.18	2.12	110.56	119.20	112.48	15.81	2.94	106.47	118.50	0.50
Dietary compl. (%)	71.28	8.57	1.49	68.24	74.31	78.23	12.23	2.27	73.58	82.89	0.01
Activity level	1.52	0.57	0.10	1.31	1.72	1.52	0.51	0.09	1.32	1.71	0.99
No. of sessions with RD	2.36	3.99	0.69	0.95	3.78	3.07	3.65	0.68	1.68	4.46	0.47

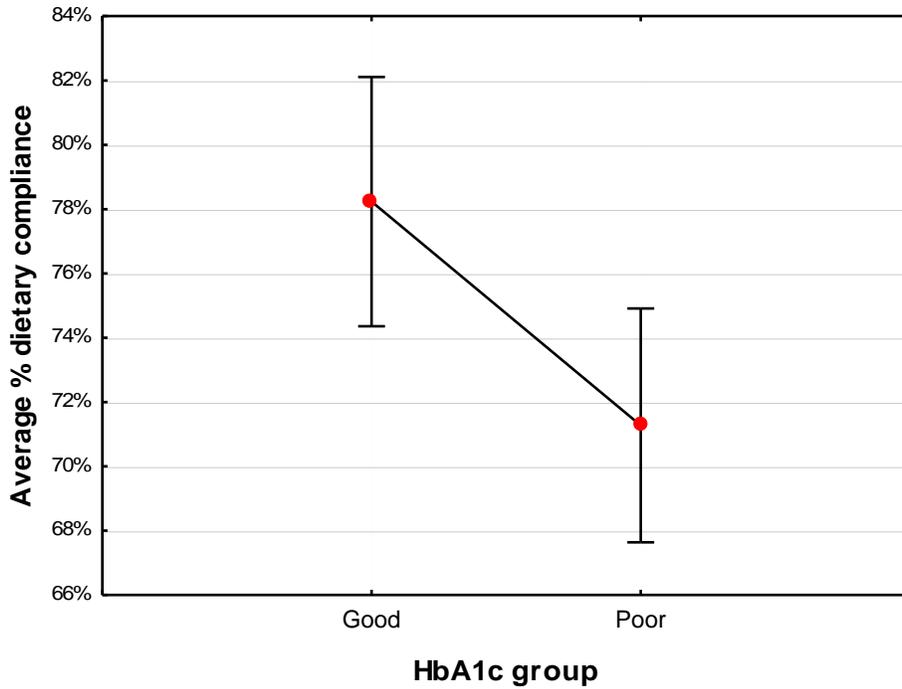


Figure 3.16 HbA1c group comparison of average % dietary compliance (p=0.01)

Hypothesis testing was also performed between the PPG groups (Table 3.8). Once again the only significant difference between the two PPG groups were their dietary compliance. The good PPG group had significantly (p=0.04) better dietary habits than the group with poor PPG control (Figure 3.17).

Table 3.8 Hypothesis testing between PPG groups

	Poor PPG control (n = 26)					Good PPG control (n = 32)					p-value
	Mean	Std. Dev.	Std. Err	-95.0%	+95.0%	Mean	Std. Dev.	Std. Err	-95.0%	+95.0%	
Dietary compl. (%)	71.39	9.62	1.89	67.51	75.28	77.54	11.81	2.09	73.28	81.80	0.04
No. of sessions with RD	2.31	3.50	0.69	0.90	3.72	3.03	4.03	0.71	1.58	4.48	0.47
Activity level	1.46	0.58	0.11	1.23	1.70	1.53	0.51	0.09	1.35	1.71	0.63

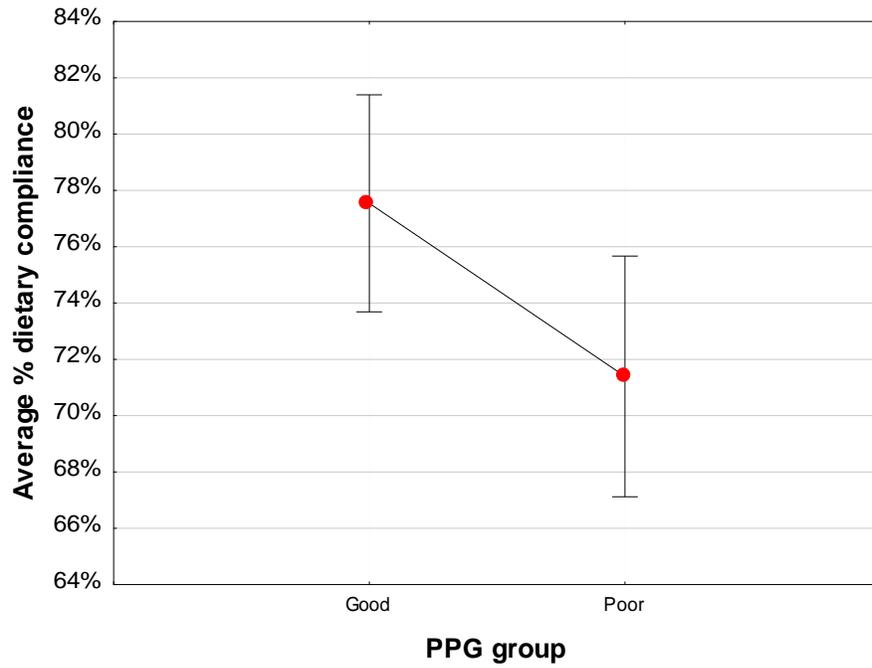


Figure 3.17 PPG group comparison of average % dietary compliance (p=0.04)

Table 3.9 shows the mean scores for the two PPG groups as obtained for each question on the dietary assessment questionnaire. Table 3.9 also indicates the extent (p-value) to which the groups differ from one another when compared per question.

Table 3.9 Dietary assessment results according to PPG groups

	Poor PPG control (n = 26)					Good PPG control (n = 32)					p-value
	Mean	Std. Dev.	Std. Err	-95.0 %	+95.0 %	Mean	Std. Dev.	Std. Err	-95.0 %	+95.0%	
Q1. Presence of main meals	2.77	0.65	0.13	2.51	3.03	2.88	0.49	0.09	2.70	3.05	0.74
Q2. Frequency of snacking	1.73	0.87	0.17	1.38	2.08	1.91	0.64	0.11	1.68	2.14	0.31
Q3. Take-away intake	2.15	0.78	0.15	1.84	2.47	2.34	0.79	0.14	2.06	2.63	0.37
Q4. Bread quality and quantity	2.00	0.89	0.18	1.64	2.36	2.00	0.92	0.16	1.67	2.33	1.00
Q5. Breakfast quality and quantity	1.58	0.76	0.15	1.27	1.88	1.91	0.78	0.14	1.63	2.19	0.12
Q6. Dairy quality and quantity	2.73	0.53	0.10	2.52	2.95	2.75	0.51	0.09	2.57	2.93	0.94
Q7. Starch quality and quantity	1.31	0.62	0.12	1.06	1.56	1.81	0.86	0.15	1.50	2.12	0.04
Q8. Fruit portions	2.65	0.75	0.15	2.35	2.95	2.69	0.74	0.13	2.42	2.95	0.85
Q9. Total daily fruit intake	2.81	0.57	0.11	2.58	3.04	2.81	0.59	0.10	2.60	3.03	0.91
Q10. Fruit form	2.42	0.70	0.14	2.14	2.71	2.75	0.57	0.10	2.55	2.95	0.08
Q11. Weekly veg. intake	2.31	0.88	0.17	1.95	2.66	2.50	0.80	0.14	2.21	2.79	0.46
Q12. Total daily veg. portions	2.00	0.75	0.15	1.70	2.30	2.03	0.74	0.13	1.76	2.30	0.89
Q13. Veg. form	1.88	0.95	0.19	1.50	2.27	2.31	0.90	0.16	1.99	2.64	0.12
Q14. & Q15. Sweetening agents	2.27	0.96	0.19	1.88	2.66	2.66	0.60	0.11	2.44	2.87	0.25
Q16. Beverage quality and quantity	2.04	0.92	0.18	1.67	2.41	2.16	0.88	0.16	1.84	2,47	0.66
Q17. Snack quality and quantity	1.62	0.80	0.16	1.29	1.94	1.72	0.96	0.17	1.37	2.06	0.88

The only significant difference between the two PPG groups regarding dietary habits were the average score obtained for question 7 (starch quality and quantity). The poor PPG group had a significant ($p=0.04$) lower (1.31 vs. 1.81) mean than the good PPG group (Figure 3.18). Although not significant, the p-value obtained after comparing the groups for question 10 (fruit form) was much closer ($p=0.08$)

to the level of significant difference than all the other questions. Hence indicating another area of potential difference between the dietary habits of the two groups.

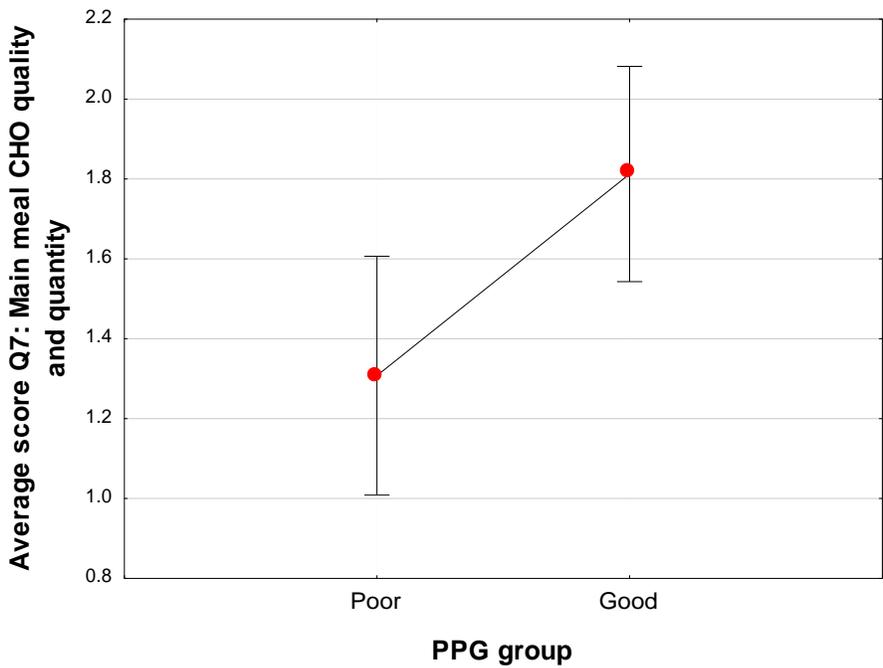


Figure 3.18 PPG group comparison of question 7 (main meal CHO quality and quantity) (p=0.04)

The scores of each participant in the respective PPG groups were totalled for each question. The totals of each question were then compared between PPG groups. Results similar to the above mentioned results were obtained (Table 3.10). In this case the p-value indicating a significant difference between the starch quality and quantity of the two PPG groups were even lower (p=0.03).

Table 3.10 PPG group comparison of total scores obtained per dietary question

Variable	Rank Sum Good	Rank Sum Poor	U	Z-adjusted	P-value	Valid N Good	Valid N Poor	2*1 sided exact p
Q1. Presence of main meals	966	745	394	0.69	0.49	32	26	0.74
Q2. Frequency of snacking	1010	701	350	1.10	0.27	32	26	0.31
Q3. Take-away intake	1002	709	358	0.97	0.33	32	26	0.37
Q4. Bread quality and quantity	944	767	416	-0.01	0.99	32	26	1.00
Q5. Breakfast quality and quantity	1043	668	317	1.66	0.10	32	26	0.12
Q6. Dairy quality and quantity	949.5	761.5	410.5	0.11	0.91	32	26	0.93
Q7. Starch quality and quantity	1079	632	281	2.40	0.02	32	26	0.03
Q8. Fruit portions	956.5	754.5	403.5	0.29	0.77	32	26	0.85
Q9. Total daily fruit intake	951.5	759.5	408.5	0.21	0.84	32	26	0.91
Q10. Fruit form	1055	656	305	2.13	0.03	32	26	0.08
Q11. Weekly vegetable intake	992	719	368	0.87	0.38	32	26	0.46
Q12. Total daily vegetable portions	953.5	757.5	406.5	0.15	0.88	32	26	0.88
Q13. Vegetable form	1043.5	667.5	316.5	1.71	0.09	32	26	0.12
Q14. & Q15. Sweetening agents	1017.5	693.5	342.5	1.38	0.17	32	26	0.25
Q16. Beverage quality and quantity	973	738	387	0.48	0.63	32	26	0.66
Q17. Snack quality and quantity	954.5	756.5	405.5	0.18	0.86	32	26	0.87

With the exception of four questions (questions 2, 7, 14, and 17), there were no significant difference between the PPG groups regarding the frequency at which scores (1-3) were allocated (by the investigator) for each question. The first question that was scored significantly ($p=0.006$) different from the other group's was question 2 (frequency of snacking). The majority of participants in the good PPG group made acceptable (59%) and excellent (16%) decisions, whilst the majority of the poor PPG group made poor (54%) decisions. It thus seem evident that the good PPG group tended to snack more appropriately compared to the poor PPG group.

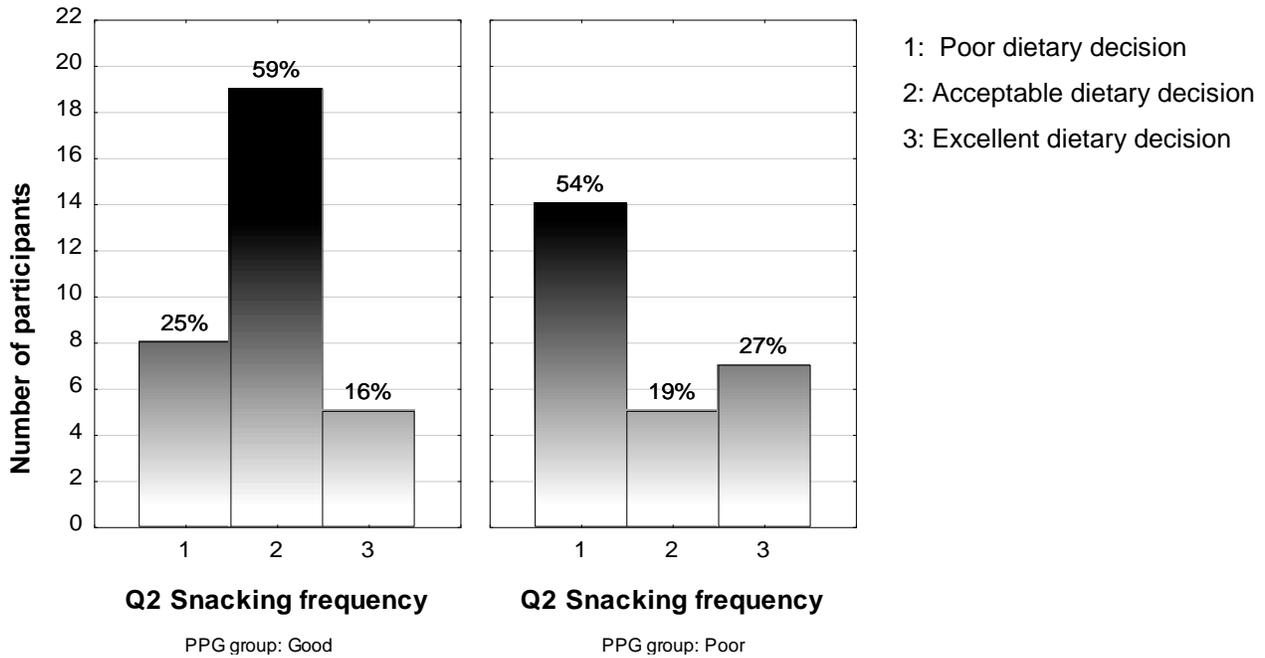


Figure 3.19 The frequency at which dietary scores (1-3) were made for Q2 per PPG group (p=0.006)

The frequency at which scores (1-3) were made also differed significantly (p=0.04) between PPG groups for question 7 [main meal carbohydrate (CHO) quality and quantity]. More than three-quarters (77%) of the poor PPG group obtained a poor score opposed to the 47% of participants in the good PPG group. The good PPG group also made more acceptable (25% vs. 15%) and excellent (28% vs. 8%) dietary decisions than the poor PPG group (Figure 3.20).

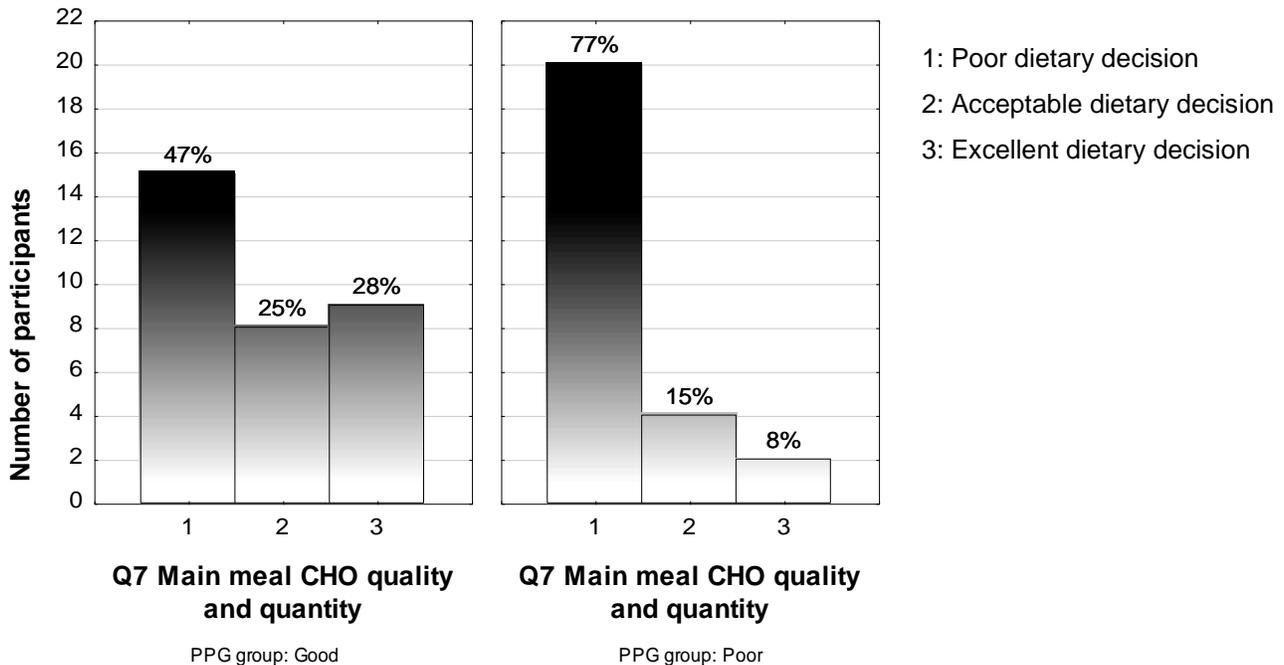


Figure 3.20 The frequency at which dietary scores (1-3) were made for Q7 per PPG group (p=0.04)

Question 14 (sweetening agents) was also scored significantly ($p=0.005$) different between the two PPG groups. The group with good PPG control made excellent dietary decisions more frequently (72% vs. 62%) than the group with poor PPG control. The latter also made more poor (35% vs. 6%) dietary decisions compared to the good PPG group (Figure 3.21).

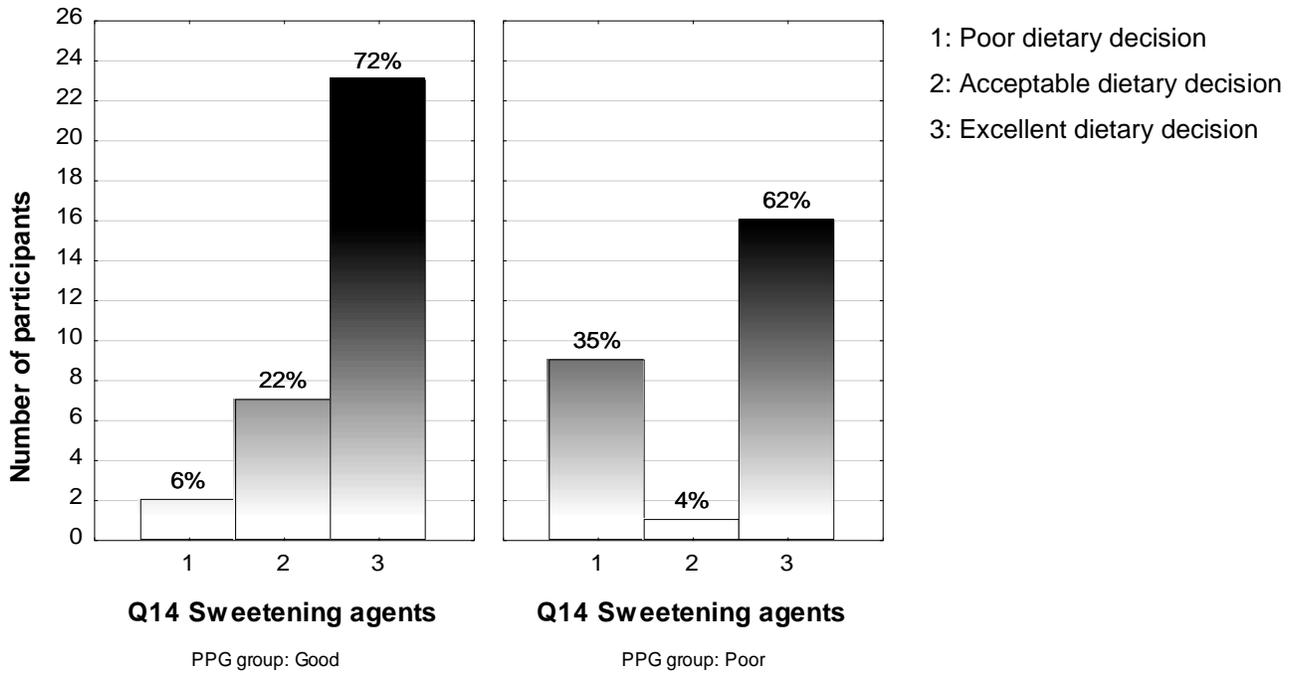


Figure 3.21 The frequency at which dietary scores (1-3) were made for Q14 per PPG group ($p=0.005$)

The last question indicative of a significant ($p=0.04$) difference between the frequency at which dietary scores (1-3) were made between groups, were question 17 (snack quality and quantity). Both groups made predominantly poor dietary decisions (63% vs. 58%), but the group with good PPG control made almost twice as much (34% vs. 19%) excellent dietary decisions when compared to the group with poor PPG control (Figure 3.22).

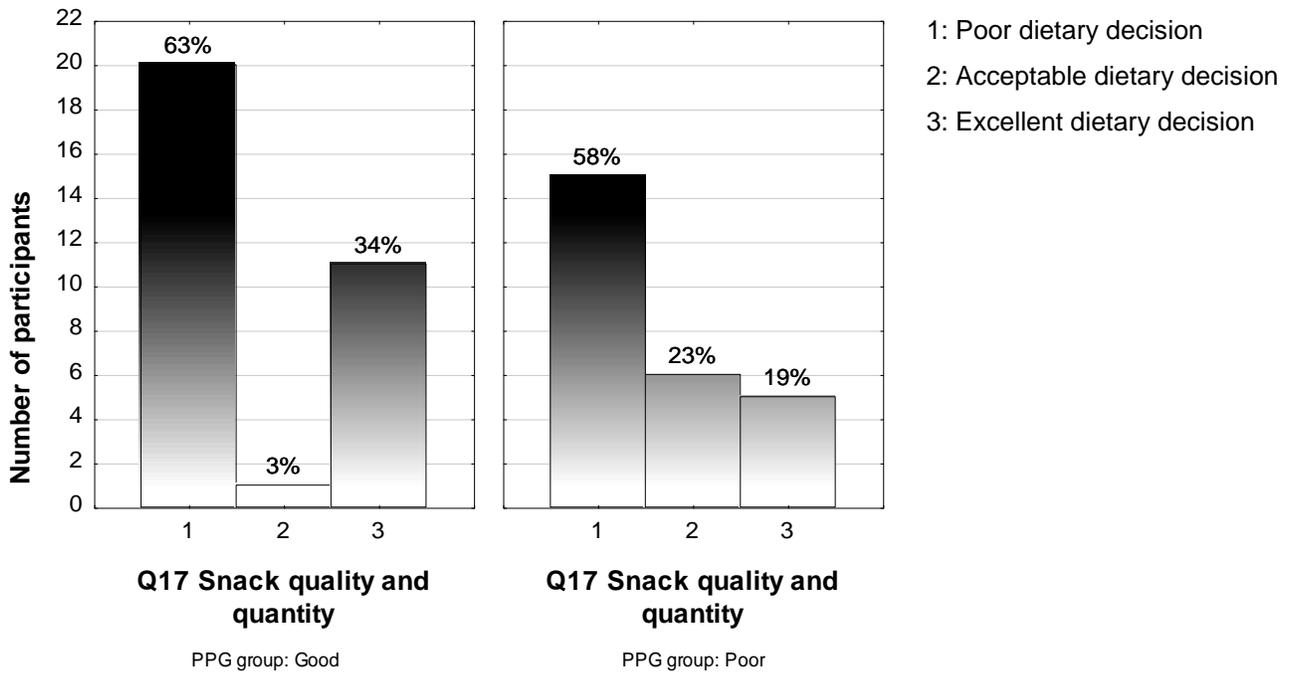


Figure 3.22 The frequency at which dietary scores (1-3) were made for Q17 per PPG group ($p=0.04$)

Additional analysis of variance were done for the 39 participants who consulted a dietician for diabetes related MNT. The average number of sessions these participants completed with a dietician were compared according to PPG grouping. Although the group with good PPG control consulted a dietician more, the difference was not significant (Figure 3.23).

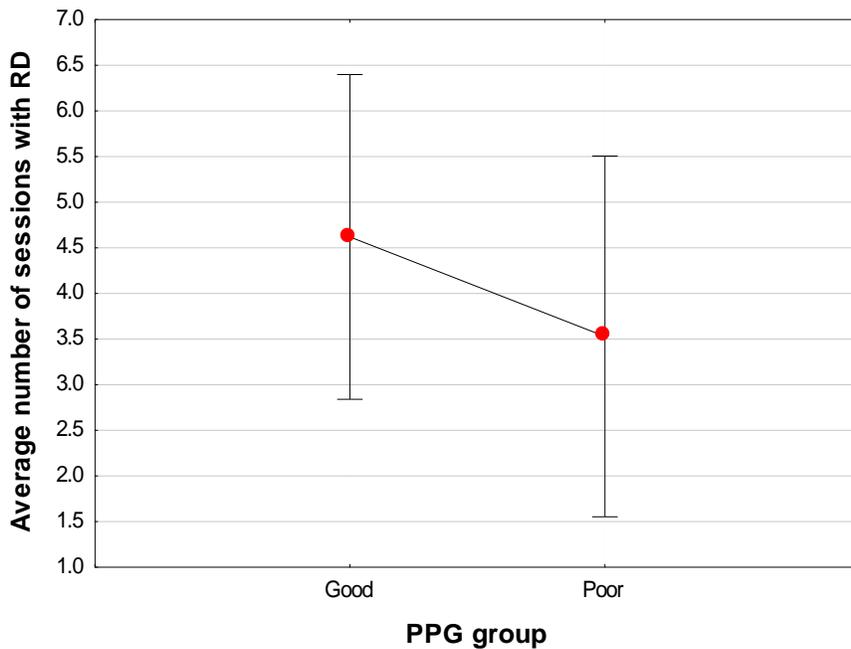


Figure 3.23 PPG group (n=39) comparison of the average number of sessions completed with a dietician ($p=0.41$)

CHAPTER 4: DISCUSSION

Intensive lifestyle intervention in people with Type 2 Diabetes Mellitus (T2DM) is associated with weight loss, significant reductions in HbA1c % and a reduction in numerous cardiovascular disease risk factors.⁷⁵ Small towns unfortunately experience a deficit of dietitians, thus limiting access to lifestyle intervention. Furthermore, a limited number of South African studies have evaluated the effect of dietary habits, anthropometric status, activity level (AL) and dietitian-led medical nutrition therapy (MNT) on glycaemic control in patients with T2DM. This study aimed to identify the association between glycaemic control and lifestyle habits in adults with T2DM attending selected private health care practices in Thabazimbi. The role of the dietitian with regard to optimal glycaemic control was also investigated with great interest.

4.1 SAMPLE SIZE

A satisfactory study population size, which came fairly close (70%) to the pre-calculated sample size required, was obtained. The study population was large enough to identify significant results within the primary group; and although the various sub-group numbers were lower than the required target, the groups were still large enough to detect significant differences between them. The primary reason for not reaching the proposed participant target was the lack of patients fulfilling the inclusion criteria; and to be more specific the absence of a valid HbA1c measurement. In addition only three of the four medical practices contributed to the study population pool. Recruitment site no.1 identified several possible study candidates, but none of the patients were eligible in the end.

4.2 ANTHROPOMETRIC STATUS

The anthropometrical findings of the study were found to be far from the recommended healthy targets.^{107,108} Almost none (93.54%) of the participants had a healthy body weight. Most participants (74.19%) were obese and the rest (19.35%) were overweight. Almost all (90.32%) of the participants also had a substantially increased waist circumference (WC). This high prevalence of obesity, and especially abdominal obesity, is regarded as very concerning as excess body weight and visceral adiposity is associated with insulin resistance.^{76,84} When compared to the latest national statistics, the average BMI and WC of male (32.35kg/m² vs. 25.2kg/m²; 115.81cm vs. 87.4cm) and female (36.72kg/m² vs. 31.3kg/m²; 110.72cm vs. 95.7cm) study participants was much greater than that of the average 55-64 year old South African.¹¹⁰ The prevalence of obesity is also almost 7 times more than the 2008 WHO global estimate (11%) of obesity amongst adults.¹¹¹

It is however important to remember that the study participants are reflective of individuals with T2DM. Overweight and obesity are considered to be common risk factors for the development of T2DM³² and accounts for about 80-90% of all T2DM cases.¹¹² Weight loss aiming towards the healthy BMI range is ideal, but not always easily achievable by the obese T2DM patient.⁸⁶ Taking this into consideration, it

was therefore anticipated that study participants might be overweight, but not necessarily obese and not at the observed prevalence (74.19%).

Results published from a 1998 T2DM cross-sectional survey (n=284) in the central region of the Limpopo Province reported that obesity was noted in 29.38% of participants. This is two and a half times less than what was found in the present study (74.19%). It is however important to note that the previous Limpopo study was conducted 15 years ago in then one of the most poverty-stricken provinces in South Africa (SA); their study population also comprised of black South-Africans only. The present study in turn predominately consisted out of white (i.e. culturally different) middle-income South-Africans.¹¹³

Findings from the Third National Health and Nutrition Examination Survey (NHANES III) was used to describe the anthropometric status of American adults with T2DM. Eighty-two percent of participants were found to have a BMI ≥ 25 kg/m², with 36% classified as being overweight and 46% as obese.¹¹⁴ The present study however exceeds these statistics. When looking at national statistics it is evident that obesity is of a greater problem amongst the female gender in SA. The South African National Health And Nutrition Examination Survey (SANHANES) found the prevalence of overweight and obesity to be significantly higher amongst females than in males (24.8% & 39.2% vs. 20.1% & 10.6%).¹¹⁰ The current study highlighted the implied association between the female gender and over-nutrition. Female study participants were found to be more obese than their male counterparts and also had significantly ($p < 0.01$) more central adipose tissue when compared to men. Although it was not the objective of the study to determine the contributing factors to the presence of obesity in participants, some dietary habits reported in this study indicate the possibility that poor dietary decisions and inactivity played a role in the development of obesity in at least some individuals. Excessive kilojoule intake and inactivity are however not the sole determinants of obesity. Genetics, intra-uterine and early life influences, parity, education level, socio-cultural factors and stress are all potential causative factors known to contribute to the development of obesity.¹¹⁵

4.3 DIETARY HABITS

4.3.1 Dietary compliance

In general the dietary compliance of the study participants could be described as above average. Almost all participants obtained a mark above 60%, with the bulk of participants obtaining marks between 60-80%. Good dietary compliance were also reported in an observational study in Iraq where more than one third (36%) of participants had good dietary compliance and half of the participants an average dietary compliance.¹¹⁶ In their study, dietary compliance was defined as good when the

participant strictly followed the prescribed dietary regimen, average when the participant sometimes did not follow the regimen, and poor when the participant did not follow the dietary regimen at all. An older study, performed in Saudi Arabia, made use of the same dietary compliance evaluation criteria than the Iraq study. In their study 40.8% of the sample had good dietary compliance and 47.5% an average dietary compliance; results very similar to the Iraq study's results.¹¹⁷ Although these two studies are not designed exactly the same as the present study, they can be seen as appropriate comparisons as they are based on the same principle of excellent, acceptable and poor dietary decisions that were made by participants.

The investigators of the Iraq study postulated that poor adherence to the dietary regimen could be attributed to the lack of dietary knowledge and that compliance could be improved by spending more time and efforts on dietary education and the provision of appropriate educational materials.¹¹⁶ Although it can not be proven, a lack of dietary knowledge could also be seen as a possible reason for some of the poor dietary decisions the study participants made. This could especially be due to the fact that Thabazimbi's DM community did not have access to a resident dietician for almost a decade; subsequently limiting their chances of appropriate and sustainable medical nutrition therapy (MNT). More than one third (37.10%) of the study participants have never consulted a dietician for T2DM-related diet therapy. Dieticians are known to meaningfully contribute to diabetes care by means of the dietary education of the patient with DM.^{59,60}

One could continue to hypothesise (once again without any proof as it wasn't a study objective) that some of the poor dietary decisions of participants could have been due to non-adherence towards their dietary prescription. For years it has been recognised that non-adherence rates for chronic illness regimens and lifestyle changes are around 50%.¹¹⁸ As a group, individuals with DM are especially prone to substantial regimen adherence problems.¹¹⁹ Research has also shown that adherence to one regimen area may be unrelated to adherence in other regimen components.¹¹⁹⁻¹²¹ For instance, research identified better adherence towards medicine use than to lifestyle adaptations.^{74,122} In other studies, adherence rates of 65% were reported for dietary habits¹²⁰ but only 19% for exercise.¹²¹ To improve on DM dietary adherence, it is imperative to understand why non-adherence arises. The literature regards it helpful to consider demographic, psychological, and social factors, together with health care provider, medical system, and disease- and treatment- related factors.¹²³ The Academy of Nutrition and Dietetics also specifically recommend that nutrition education and counselling be sensitive to the personal needs and cultural preferences of the individual, as well as to their readiness and ability to make the necessary changes. According to the Academy of Nutrition and Dietetics: "Research documents the benefits of dieticians addressing these challenges and improving outcomes in people with diabetes."⁶³

4.3.2 Key findings of the dietary assessment questionnaire

When evaluating and interpreting the results of each question on the dietary assessment questionnaire, both positive and negative findings were made. Most participants had regular eating habits, made good choices when it came to dairy consumption and sweetening agents, and did not overindulge on fruit (in various forms). The presence of regular eating habits (breakfast, lunch and supper) is good as it assists with more appropriate carbohydrate (CHO) distribution throughout the day. Similar results were found in the previously mentioned Limpopo study where more than 90% of participants ate breakfast, lunch and dinner.¹¹³

Less optimal dietary decisions were in turn made with regard to snacking frequency, breakfast and main meal carbohydrate quality and quantity, and the quality and quantity of snacks. Many of the participants were found to snack excessively throughout the day, which is worrisome as it could contribute greatly to fluctuating blood glucose levels. As mentioned, snack quality and quantity was also mostly far from optimal, consequently worsening the matter. Because breakfast and snacks are known to be predominantly CHO rich, and the main meal often contain substantial and/or multiple sources of CHO, it is important to address the CHO quality and quantity thereof. The ADA regards the monitoring of total CHO intake as a key strategy in achieving glucose targets.³² In turn, a Taiwanese RCT that investigated the association between changes in macronutrient intake and glycemic measures discovered an independent correlation between a reduction in CHO intake and improvements in HbA1c results ($p < 0.001$). The lowering of CHO consumption thus improves glycemic status.⁶²

Merely acceptable dietary decisions were made with regard to the other components (take-away, bread, vegetable and beverage intake) of the dietary assessment, thus indicating additional areas in need of improvement. The factors that contributed to a lower average mark for each of the dietary components under discussion were as follows: Take-away intake was either too frequent and/or the CHO load was excessive. Refined breads and large amounts of CHO-containing beverages were often ingested, and insufficient vegetables were consumed and/or vegetables were candied or consumed savoury with potatoes. The latter is unfortunate as whole vegetables can be of great value to the individual with DM. Vegetables are valuable sources of fibre and bulk and inhibits energy intake through the stimulation of satiety, they also have a lower CHO content than fruit or grains, and is fairly cost effective.¹²⁴ The Japanese Elderly Intervention (JEI) trial is an apt illustration of the significant role vegetables can play in the management of DM. The study aimed to clarify the relationship between the amount of vegetables ingested and HbA1c levels in elderly male Japanese T2DM patients. The investigators identified significant decreases in HbA1c %, triglycerides and waist circumference with an increase of total vegetable intake. Significant decreases of HbA1c levels were specifically detected

in participants with a total vegetable intake of $\geq 150\text{g/day}$. In addition, there was a significant decrease of triglyceride levels in participants with a total vegetable intake of $\geq 200\text{g/day}$. HbA1c levels also showed a lowering tendency with the increase of green vegetable intake. Furthermore, there were significant decreases of BMI, triglycerides and waist circumference reported with the increase of green vegetable consumption. The intake of grains, sweets and alcoholic beverages were also found to increase when total vegetable intake decreased. The JEI study concluded that a total vegetable intake of $\geq 200\text{g/day}$, and green vegetable intake of $\geq 70\text{g/day}$ is associated with improved HbA1c and triglyceride control.¹²⁴ It is important to note that during the JEI trial, intakes of vitamins A, C and E increased significantly with the increased vegetable intake. The authors subsequently proposed that sufficient intakes of these vitamins might be one of the reasons for the positive effects of vegetables on HbA1c % and other metabolic outcomes.¹²⁴ This deduction was made since blood concentrations of vitamins A, C and E have been reported to be significantly lower in DM patients than in healthy individuals.^{125,126} Other DM studies have similarly reported that a semi-vegetarian diet lowers fasting glucose,¹²⁷ and that a vegetarian diet¹²⁸ reduces HbA1c % more than a diet in compliance with ADA guidelines.¹²⁹

4.3.3 Comparison of the dietary habits of the post-prandial glucose (PPG) groups

When the two PPG groups were compared with regard to their dietary habits, the only significant difference established was the main meal CHO quality and quantity of each group. The good PPG group was found to have made significantly ($p=0.04$) better decisions (controlled portions of mainly unrefined, low GI carbohydrates) than the poor PPG group. This finding suggests that the choice and portion size of the main meal's carbohydrates has an important role to play in the glycaemic control of people with T2DM attending private health care practices in Thabazimbi. The beneficial effect of a low GI diet has also been pointed out in a meta-analysis evaluating the efficiency of low GI diets for people with DM. The investigators reported that low GI diets can significantly improve glycaemic control in individuals who are not optimally controlled. Low GI diets were also found to lower HbA1c percentage by 0.4%. This percentage decrease is seen as clinically significant, and is even comparable to the decrease achieved with medications for people with newly diagnosed T2DM.⁷⁰ It is thus plausible that the poor PPG group would benefit from addressing the quality of the CHO intake at their main meal. It would also be to their benefit if the total amount of CHO ingested at a time be reduced, as CHO load has a direct effect on the extent of glycaemia.³² Although not significant, the p-value obtained after comparing the PPG groups with regard to their choice of fruit form (fresh/canned/dried), was fairly close to the level of significant difference. This indicates another area of potential difference between the dietary habits of the two groups. Once again the difference is associated with the quality of the fruit i.e. refined (sugar-coated / canned in syrup) vs. unrefined (whole and unprocessed).

A few dietary assessment questions were found to be answered significantly differently by the two PPG groups, thereby shedding additional light on the behavioural and dietary differences between the groups. The good PPG group's snacking frequency was more appropriate when compared to the poor PPG group. The majority of participants in the good PPG group made acceptable (59%) and excellent (16%) decisions, whilst the majority of the poor PPG group made poor (54%) decisions. By limiting excessive snacking the good PPG group could have had less fluctuating blood glucose values and subsequent better blood glucose control. Both groups however made predominantly poor (63% vs. 58%) dietary decisions when it came to snack quality and quantity, but the group with good PPG control made almost twice (34% vs. 19%) as much excellent dietary decisions when compared to the group with poor PPG control.

When evaluating the CHO quality and quantity of the main meal, most (77%) of the poor PPG group obtained a poor mark opposed to only 47% of participants in the good PPG group. In addition the good PPG group made more acceptable (25% vs. 15%) and excellent (28% vs. 8%) dietary decisions than the poor PPG group.

The group with good PPG control more frequently (72% vs. 62%) made excellent dietary decisions when it came to sweetening agents than the poor PPG control group. The latter also made more poor (35% vs. 6%) dietary decisions compared to the good PPG group. A 2012 scientific statement from the American Heart Association (AHA) and ADA concluded that there is inadequate data to determine conclusively whether the use of non-nutritive sweeteners (NNS) lessens added sugar or CHO intake. The evidence reviewed by the AHA and ADA did however suggest that when used wisely, NNS could enable reductions in added sugar consumption.⁷² When looking at the current study results the frequent use of NNS was associated with good PPG control and reductions in added sugar intake.

It is thus evident that appropriate snacking frequency, main-meal CHO quality and quantity, sweetening agents and snack quality and quantity is associated with good PPG control in this study.

4.4 PHYSICAL ACTIVITY LEVEL

Half of the study participants had a sedentary/low activity level (AL), whilst the other half had a active/moderately active AL. This high prevalence of inactivity amongst study participants is disturbing, as regular exercise is associated with improved glycaemic control, reduced cardiovascular risk factors, weight loss and improved well being.⁸⁷⁻⁸⁹ Two large prospective observational studies (n=2196 and 25-year follow-up; n=2316 and 27-year follow-up) reported that all-cause and cardiovascular mortality risk was 1.7–6.6 times higher in low-fit vs. high-fit men with T2DM, with the fittest men presenting the lowest risk.^{91,92} A 2001 meta-analysis of 14 controlled studies (11 randomised and 3 non-randomised)

reported that structured exercise interventions of at least 8 weeks' duration lowers HbA1c levels by an average of 0.66% ($p < 0.001$) in individuals with T2DM, even with no significant change in weight.¹³⁰ A more recent meta-analysis of exercise and T2DM concluded that exercise significantly reduces visceral adiposity, improves glucose control (-0.6% HbA1c), and reduces triglyceride levels, also in the absence of significant weight loss.¹³¹

In 2003 the International Physical Activity Questionnaire was administered (as part of the World Health Survey) to a representative sample of South Africans. The survey established that less than one third of South Africans met the American College of Sports Medicine and Centers for Disease Control's recommendation for health-improving physical activity (30 minutes of moderate exercise on most, but preferably all days of the week), and that almost half (46%) were reportedly inactive.¹³² The prevalence of inactivity among study participants is thus in accordance with that of the average South African. However, when compared to international data, the study population is more active than the average American DM patient. Just 39% of American adults with DM are regarded as physically active.¹³³

The ADA and SEMDSA recommends that individuals with DM do aerobic exercise (rhythmic, repetitive and continuous use of the same large muscle groups for at least ten minutes at a time), at a moderate intensity (50–70% of maximum heart rate), for at least 150 minutes per week. The 150 minutes should be spread over at least three days per week with no more than two successive days without exercise. People with T2DM should also do resistance training (exercise requiring muscle strength to work against a resistance load) at least twice per week.^{32,93}

4.5 DIETETIC CONSULTATION

Almost all of the participants indicated that it was necessary for an individual with DM to consult a dietician for appropriate MNT. However, only 63% of participants actually consulted a dietician for the dietary management of DM.

Almost 60% of participants who consulted a registered dietician (RD) had ≥ 3 MNT sessions. This is in line with the Academy of Nutrition and Dietetics' recommendations for the nutrition care process of DM.⁶³ The academy recommends that the initial series of MNT sessions should consist of 3-4 visits with a RD. The RD thereafter determines whether additional MNT sessions are needed. In addition to the above, at least one annual follow-up session is recommended.⁶³ However, when looking at the average DM disease duration (10 years) of participants and the average number of MNT sessions (4.28) completed with a RD, it is evident that annual follow-up sessions with a RD are not taking place.

What is also of concern is the 31% of participants who only had one MNT session with a RD. The most probable reason for the poor follow-up rate is possibly inaccessibility to a dietician in the past.

The Academy of Nutrition and Dietetics formulated the above mentioned recommendations following a extensive literature overview. They found 8 studies that evaluated the efficiency of diabetes MNT at 3-6 months. These studies reported reductions in HbA1c % (-0.25% to -2.9%) after individual MNT sessions (ranging from 1-5) or a series of 10-12 group sessions were employed.^{61,134-140} Studies found reporting on efficiency of MNT from 6-12 months reported a variety in the number and type of MNT sessions that lead to improved outcomes. From there the conclusion that the dietician has to decide whether additional MNT sessions are needed.^{134,135,137} Multiple studies were also found reporting on the sustained improvements in HbA1c % at 12 months and thereafter when a dietician provided follow-up visits ranging from monthly to 3 sessions annually.^{61,134-140}

4.6 GLYCAEMIC CONTROL

Only 47% of study participants had a HbA1c <7%. Hence, the poor long-term glycaemic control of the other (53%) participants is of concern. Worse HbA1c results [HbA1c >7%; 63.73% (n=181)] were however seen in the previously mentioned SA Limpopo study.¹¹³ More recent local data in turn suggest that more than two-thirds of South African T2DM patients have an HbA1c% above 7%.¹⁴¹ When looking at international data it is also evident that T2DM is not a particularly well-managed disease as less than 50% (similar to the present study) of patients are achieving glycaemic targets; even in more developed countries.¹⁴²

Slightly more than half of participants were found to have good PPG control, however 45% of participants still had poor PPG control. This is of concern as the contribution of PPG to overall blood glucose control increases as the HbA1c value decreases - indicative of the importance of strict PPG control when aiming for an optimal HbA1c.⁴¹ Research done by Monnier et al. showed that PPG contributed to $\pm 70\%$ of the HbA1c level when the HbA1c was <7.3%.⁴² Raised post-challenge (2 hour oral glucose tolerance test) glucose values have also been linked to increased cardiovascular risk in certain studies, and some measures of vascular pathology (e.g. endothelial dysfunction) are adversely affected by post prandial hyperglycaemia.⁴⁰ The continued poor glycaemic control of predominantly half of the study population will thus be detrimental (if not already) to their health. Large controlled clinical trials found a significant decrease in the development and/or progression of DM related microvascular complications when stricter diabetes management was implemented.^{18,19} Stricter glycaemic control is therefore urgently required.

Female participants were found to have better (but not significantly better) long (HbA1c %; 7.14% vs. 7.74%) and short-term (average PPG; 8.25mmol/l vs. 9.35mmol/l) glycaemic control than men. This is a surprising finding as female study participants were found to be more obese than their male counterparts and they also had significantly ($p < 0.01$) more visceral adipose tissue when compared to men.

4.7 CORRELATION TESTING

A significant negative association was found between glycaemic control (both for HbA1c % and PPG) and percentage dietary compliance. The better the dietary compliance of the participants, the lower their HbA1c % and PPG were. This demonstrates the significant role nutrition plays in the glycaemic control of people with DM attending private health care practices in Thabazimbi. A RCT that assessed the effect of dietician-led management of DM on glucose control in adult T2DM patients, also found that those in the dietician-led intervention group (with subsequent better dietary habits) had significantly greater improvements in their HbA1c % than the routine care control group.⁶²

Interestingly enough none of the other variables (BMI, waist circumference, activity level and dietetic sessions) were found to influence the HbA1c control of the study participants. Given the high prevalence of obesity, especially abdominal obesity, and inactivity amongst the group it would have been expected that both of the latter would be significantly associated with poor glycaemic control.^{76,84,96} Also, considering the role the dietician played in the above mentioned study, it was anticipated that glycaemic control in the present study would be significantly better as dietetic contact increased.

Additional correlation testing revealed that the number of dietetic (MNT) sessions that participants completed was significantly associated with their percentage dietary compliance. The more contact participants had with a dietician, the better their dietary compliance was. This finding is of great significance as the study also discovered a significant association between percentage dietary compliance and glycaemic control (HbA1c % and PPG). This study thus shows that if individuals with DM spend enough time with RD's, it could potentially contribute to better dietary compliance and subsequent better glycaemic control. The above mentioned expectation that glycaemic control would improve as dietetic contact increased is therefore now proven. These findings are also present in the literature as numerous studies have shown sustained improvements in HbA1c at 12 months and longer when a RD provided follow-up visits ranging from monthly to 3 sessions per year.^{61,134-140} As previously mentioned, RD's are known to meaningfully contribute to diabetes care plans by means of the dietary education of the patient with DM. Dietary education has been found to improve both anthropometric measures and glucose control.^{59,60}

Ozcelik *et al.* assessed the relationship between glucose control and effective DM education by using a knowledge and awareness questionnaire in patients with T2DM. The participants who received diabetes education were found to have higher knowledge and awareness scores compared to the control group (24.0 ± 4.0 vs. 16.8 ± 5.37 ; $p < 0.0001$) as well as lower HbA1c results (6.5% vs. 8.5%; $p < 0.0001$). There was furthermore a strong negative correlation between the knowledge and awareness score and HbA1c result ($r = -0.8101$, $p < 0.0001$), as well as between the knowledge and awareness score and fasting glucose ($r = -0.6524$, $p < 0.0001$). The investigators therefore concluded that the higher the knowledge and awareness score, the more efficiently glycaemic control can be achieved.¹⁰²

Wilson *et al.* in turn tested the relative efficiency of clinical nutrition education (CNE) when provided by a RD compared to an educator from a different discipline (non-RD). Those individuals who received CNE from a RD or from both a dietician and non-RD had the greatest as well as significant ($p < 0.0001$) improvements in HbA1c levels (-0.26 and -0.32) compared to those who received CNE from a non-RD only or no CNE at all (-0.19 and -0.10). The study thus shows that for CNE to be effective it should be delivered by a RD or health care team including a RD.⁶¹ It is thus of no surprise that the ADA recommend that a RD, experienced in the field of DM, be the leading role player in providing nutritional care.³²

Lastly, the association between DM disease duration and glycemic control (both average HbA1c % and average PPG) was also investigated by the study. However, only PPG control was found to have a significant positive association with DM disease duration. The longer DM was present in the individual, the worse PPG control became. This was to a certain degree anticipated as research has shown that lower regimen adherence can be expected when a health condition is chronic.¹¹⁸

4.8 HYPOTHESIS TESTING

The group with good HbA1c control had significantly ($p = 0.01$) better dietary habits than the group with poor HbA1c control. Similar results were also seen between the PPG groups, as the good PPG group had significantly ($p = 0.04$) better dietary habits than the group with poor PPG control. It is thus evident that dietary habits have a significant role to play in both the long- and short term glycaemic control of people with DM attending private health care practices in Thabazimbi. This finding is supported by the Lifestyle Over and Above Drugs in Diabetes (LOADD) study which investigated the degree to which intensive evidence based dietary advice is able to effect blood glucose control. The intervention group received intensive individualized dietary advice for six months; whilst both groups continued with their usual medical surveillance. Improvements occurred in most measures of the intervention group, with minimal changes in the control group. After the investigators adjusted for age, sex, and baseline

measurements, the difference in HbA1c percentage (-0.4%) between the two groups at six months was highly significant ($P=0.007$). It is thus evident that intensive dietary advice (contributing to better dietary habits) has the potential to significantly improve blood glucose control in individuals with uncontrolled T2DM, this despite optimised medicinal treatment.⁷⁵

A Malaysian prospective trial ($n=100$) in turn evaluated the efficacy of a 12-week dietician-managed MNT intervention amongst individuals with uncontrolled T2DM. MNT intervention was in the form of individualised dietary counselling, administered on a one-to-one basis by the same dietician over a 12-week period. All participants received their MNT intervention at baseline after which it was emphasized at week 4 and then again at week 12. At week 12 the post-MNT results indicated a significant reduction in fructosamine levels ($p<0.001$) and HbA1c % ($p<0.001$). Waist circumference ($p<0.05$), HDL-cholesterol ($p<0.05$), dietary intake and nutrition knowledge scores ($p<0.001$) were also all significantly improved from baseline. This study is thus also an apt illustration of what better dietary habits can achieve in the uncontrolled T2DM patient.¹⁴³

None of the other lifestyle components (BMI, waist circumference and activity level) as well as the extent of dietetic contact were found to play a significant role in the glycaemic classification (good vs. poor) of participants.

All null-hypotheses, except for one, were thus not rejected:

1. H_0 There is no difference between the anthropometric status of participants with good versus those with poor HbA1c control – not rejected.
2. H_0 There is no difference between the dietary habits of participants with good versus those with poor HbA1c control – rejected ($p=0.01$)
3. H_0 There is no difference between the activity level of participants with good versus those with poor HbA1c control – not rejected.
4. H_0 There is no difference between the number of MNT sessions completed with a dietician of participants with good versus those with poor HbA1c control – not rejected.

4.9 STUDY LIMITATIONS

The main limitation of the study is its descriptive nature. The scientific strength of some of the evidence is therefore limited. The analytical component of the study does however strengthen the findings. The smaller than anticipated study population and sub-group sizes is another limiting factor, as the probability of detecting significant results decreases as sample size decreases. Thirdly, dietary intake, activity level and number of DM-related MNT sessions with a dietician was self-reported and therefore could have been subject to under or over-reporting. The study population was also

heterogeneous with regards to recruitment site origin, education level, socio-economic status, ethnicity and age. These factors could possibly have influenced the study findings. Lastly, the potential failure of participants to adhere to the PPG testing protocol at home could also have impacted on the results.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSIONS

This study aimed to shed light on the association between glycaemic control and lifestyle habits in adults with T2DM attending private health care practices in Thabazimbi; and specifically attempted to identify the most common dietary and lifestyle changes participants with good glycaemic control made to better their glycaemic control. The role of the dietician with regard to optimal glycaemic control was also investigated with great interest. The study has successfully identified numerous significant findings that will direct the future management of patients with T2DM attending private health care practices in Thabazimbi.

Important findings made were as follows:

- The study sample was severely over-nourished. Most participants were obese and the rest were overweight. Almost all of the participants also had a substantially increased waist circumference. Female study participants were found to be more obese than their male counterparts and they also had significantly more adipose tissue around their waistline when compared to men. The anthropometrical findings of the study, especially those of the female participants, were thus found to be alarmingly far from the recommended healthy targets.
- Both long and short-term glycaemic control of participants were poor. Only 47% of study participants had an HbA1c <7% whilst 45% of participants had poor PPG control.
- Female participants had better (but not significantly better) long and short-term glycaemic control than men.
- PPG control (not HbA1c%) was significantly associated with DM disease duration. The longer DM was present in the individual, the worse PPG control became.
- The prevalence of inactivity amongst study participants was high. Half of the study participants were found to have a sedentary/low activity level (AL), whilst the other half had an active/moderately active AL.
- Almost all of the participants indicated that it was necessary for an individual with DM to consult a dietician for appropriate MNT. However, only 63% of participants actually consulted a dietician for the dietary management of DM.
- Of the participants who consulted a registered dietician, almost 60% had ≥ 3 MNT sessions.
- Thirty-one percent of participants had only one MNT session with a dietician.
- Annual follow-up sessions with a dietician are not taking place.
- The number of dietetic (MNT) sessions that participants completed was significantly associated with their percentage dietary compliance. The more contact participants had with a dietician, the better their dietary compliance was.

- The dietary compliance of the study participants was above average. Most participants had regular eating habits, made good choices when it came to dairy consumption and sweetening agents, and did not overindulge on fruit. Less optimal dietary decisions were however made with regard to snacking frequency, breakfast and main meal carbohydrate quality and quantity, and the quality and quantity of snacks. Just acceptable dietary decisions were made with regard to take-away, bread, vegetable and beverage intake, hence indicating additional areas in need of improvement.
- After comparing the two PPG groups with regard to their dietary habits, the only significant difference established was the main meal CHO quality and quantity of each group. The good PPG group was found to have made significantly better dietary decisions than the poor PPG group.
- Although not significant, the p-value obtained after comparing the PPG groups with regard to their choice of fruit form, was fairly close to the level of significant difference. Thus indicating another area of potential difference between the dietary habits of the two PPG groups.
- Four dietary assessment questions were found to be answered significantly differently by the two PPG groups. Conclusively, appropriate snacking frequency, main-meal CHO quality and quantity, sweetening agents and snack quality and quantity was associated with good PPG control.
- The group with good HbA1c control had significantly better dietary habits than the group with poor HbA1c control.
- Similar results were seen between the PPG groups, as the good PPG group had significantly better dietary habits than the group with poor PPG control.
- A significant negative association was also found between glycaemic control and percentage dietary compliance. The better the dietary compliance of the individuals, the lower their HbA1c % and PPG were.
- Hypotheses testing identified that none of the other lifestyle components (BMI, waist circumference and activity level) as well as the extent of dietetic contact were found to play a significant role in the glycaemic classification (good vs. poor) of participants.

In conclusion, this study showed that the longer DM was present, the worse PPG control became. Optimal dietary habits were found to have a significantly positive role to play in both the long- and short term glycaemic control of people with DM attending private health care practices in Thabazimbi. The choice and portion size of the main meal's carbohydrates has been identified to be the most important dietary role-player in the glycaemic control of this study population. This study also shows

that if individuals with DM spend enough time with a dietician, it could potentially contribute to better dietary compliance and subsequent better glycaemic control.

5.2 RECOMMENDATIONS

- It is recommended that both uncontrolled and newly diagnosed patients with DM be referred to a registered dietician for MNT. The patient with DM should be encouraged to attend at least 3 MNT sessions, after which the dietician should decide whether further immediate MNT is needed.
- Special attention should especially be given to the carbohydrate quality and quantity of the main meal. As appropriate snacking frequency, sweetening agents and snack quality and quantity also were identified as being associated with good PPG control, these dietary components should likewise receive adequate attention.
- Since the study identified that the longer DM was present, the worse PPG control became, it is recommended that all patients with DM attend at least one annual MNT session with their dietician to ensure optimal PPG control.
- The best evidence-based approach of evaluating the clinical significance of dietary and lifestyle adaptations in South Africans with DM, would be by performing a larger and better quality study. A large (population representative) lifestyle intervention RCT is therefore recommended.
- The DM population studied represented a heterogeneous group of patients. Future research could perhaps investigate various DM sub-groups (e.g. education level, socio-economic status, ethnicity, age etc.) in order to assist with the individualised approach towards MNT.
- Future research should also investigate the determinants of poor dietary compliance amongst individuals with T2DM

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ADDENDUM 1: Demographic questionnaire & anthropometric measurements

Patient no. _____

Date: _____

Gender:

Male	Female
------	--------

Age:

Disease duration: _____

Weight: (kg)

Measurement 1	Measurement 2	Measurement 3	Average

Height: (m)

Measurement 1	Measurement 2	Measurement 3	Average

Waist circumference: (cm)

Measurement 1	Measurement 2	Measurement 3	Average

BMI: (kg/m²)

**BMI category:
(1 - 8)**

**Waist circumference category:
(1 - 3)**

ADDENDUM 2: English Dietary Assessment Questionnaire

Patient no. _____

Date: _____

1. Indicate with "a X" in the relevant box which meals you have daily.

Breakfast	
Lunch	
Supper	

2. How many times a day do you eat between meals? _____

List the top 3 snacks on which you usually snack:

3. How often do you eat at restaurants/cafeterias, buy meals from shops or order food from a fast-food outlet for each of the following meals **per week**?

Meal	Total number of restaurant/fast food meals per week	Examples of most common meal choice(s)
Breakfast		
Lunch		
Supper		

4. Indicate with "a X" the type of bread that you eat most of the time, as well as the amount eaten at a time.

Type of bread	"X"	Number of slices
White		
Best of both		
White low GI		
Brown		
Whole wheat		
Low GI whole wheat		
Low GI seed loaf		
Rye bread		
Other (please specify below)		

5. Do you have cereal/porridge for breakfast?

Yes	No
-----	----

If yes, mark the type(s) with “a X” and indicate the frequency and amount eaten per week.

Breakfast cereals and porridges	“X”	Number of times eaten per week	Amount eaten at a time (e.g. ½ cup or 1 cup)
High fiber cereal (All bran flakes/high fiber bran/shredded bran)			
Weet-Bix / Nutrific			
ProNutro: Flavoured			
Original			
Whole wheat			
Muesli: Roasted & flavoured			
Low GI			
Milo cereal			
Cheerio’s			
Corn flakes			
Ace instant maize meal			
Maize meal: Freshly prepared hot porridge			
Reheated porridge			
Cooked oats			
Instant oats sachets: Original			
Flavoured			
Maltabella			
Acidified maltabella			
Other:			

If no, what do you have for breakfast? Mark the appropriate block(s) with “a X”.

Fruit	
Yoghurt	
Bread	
Fried breakfast & toast/bread	
Leftovers	
Rusk(s)	
Nothing	
Other (please specify below)	

6. Indicate with “a X” the dairy products you regularly consume and indicate the frequency and amount eaten per day, per week or per month.

Dairy product	“X”	Number of times eaten per day/week/month	Amount eaten at a time
Milk (low-fat, full-cream & fat-free)			
Flavoured milk (Steri-stumpie/Nesquik)			
Cultured milk (Amasi)			
Sweetened yoghurt/drinking yoghurt			
Artificially sweetened yoghurt			
Plain yoghurt			
Other (please specify below)			

7. Indicate with “a X” the starches you regularly consume and indicate the frequency and amount eaten per day, per week or per month.

Type of starch	“X”	Number of times eaten per day/week/month	Amount eaten at a time
Tastic rice			
Other white rice			
Brown rice			
Wild rice			
Pearled wheat			
Pasta			
Durum wheat pasta			
Maize meal (lunch/supper only)			
Maize meal (cooled)			
Maltabella			
Acidified maltabella			
Samp			
Samp (cooled)			
Samp and beans			
Mashed potato/boiled potato			
Jacket potato			
Baby potatoes			
French fries/oven baked chips			
Sweet potato (with fat & sugar)			
Sweet potato (no fat & sugar)			
Butternut			
Other pumpkin (e.g. Hubbard)			
Butternut/pumpkin (fat&sugar)			
Other (please specify below)			

8. How many fruits do you eat at a time? _____
 9. How many pieces of fruit would you eat in total in a day? _____

10. Indicate with “a X” in which form(s) you most often eat your fruit.

Fresh fruit with skin (where possible)	
Fresh fruit – skin removed	
Canned fruit in syrup	
Canned fruit in fruit juice	
Fruit salad	
Dried fruit	
Other (please specify below)	

11. How many days per week do you eat vegetables/salad? _____
 12. How many different vegetables and/or salad would you eat in total in a day? _____

13. Indicate with “a X” in which form(s) you most often eat your vegetables.

Raw	
Steamed	
Cooked in a stew	
Cooked with sugar and fat (oil/butter/margarine)	
Cooked with onion and potato	
Salad	
Other (please specify below)	

14. Indicate with “a X” which of the following you use to sweeten beverages or food items.

Sugar (white/brown)	
Sweetener	
Both sugar & sweetener, alternating	
Honey	
Condensed milk	
Nothing	

15. If you use sugar/honey/condensed milk, how many teaspoons do you use per day? _____

16. Indicate with “a X” the beverages you regularly consume and indicate the frequency and amount ingested per day, per week or per month.

Beverage	“X”	Number of times ingested per day/week/month	Amount ingested at a time
Hot chocolate			
Milo			
Horlicks			
Nesquik			
Milkshake			
Smoothies			
Regular soda			
Diet soda (Coke zero/Sprite zero)			

Beverage	“X”	Number of times ingested per day/week/month	Amount ingested at a time
Fruit juice: 100% Sweetened			
Dairy fruit juice blend (Tropica)			
Squash (Oros/Tang)			
Diet squash (e.g. Low-cal)			
Other (please specify below)			

17. Indicate with “a X” the snacks you regularly consume and indicate the frequency and amount eaten per day, per week or per month.

Snack	“X”	Number of times eaten per day/week/month	Amount eaten at a time
Potato crisps (Simba/Lays/Niknaks)			
Popcorn: Salted Sweetend			
Plain/salted crackers (salticrax/creamcrackers)			
Whole wheat crackers (crackermate lite’s/provita’s)			
Rice cakes			
Corn thins			
Cracker bread Plain/whole wheat			
Ryvita’s			
Rusks: White / Diabetic / Whole wheat / Muesli / Nutri-rusks			
Biscuits/cookies			
Cake/baked pudding			
Muffin (Type:)			
Scone			
Tart			
Sweets (soft/hard boiled)			
Chocolate			
Breakfast bars			
Sugar-free chocolate (Canderel)			
Regular ice-cream			
Diabetic ice-cream			
Other (please specify below)			

18. Have you ever consulted a dietician with regard to the dietary management of diabetes?

Yes	No
-----	----

If yes, how many session did you complete with him/her? _____

19. Do you think it is necessary that a person with diabetes consult a dietician?

Yes	No
-----	----

20. Tick the block that best describe your current activity level.

<p>1 - Sedentary/Low active - People who have occupations that do not demand much physical effort, who do not walk long distances, generally use vehicles for transportation, do not exercise or participate in sports regularly, and spend most of their free time sitting or standing.</p>	<p>2 - Active/Moderately active - People who have occupations that are not strenuous in terms of energy demands, but involve more energy expenditure than that described for sedentary lifestyles. Alternatively, they are people with sedentary occupations who regularly spend a certain amount of time partaking in moderate to vigorous physical activity.</p>	<p>3 - Very active - People who engage regularly in strenuous work or in strenuous leisure activities for several hours.</p>
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PAL category:
(1 – 3)

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ADDENDUM 3: Afrikaans Dietary Assessment Questionnaire

Pasiënt nr. _____

Datum: _____

1. Merk met “n X”, in die relevante blokkie, die maaltye wat u daagliks nuttig.

Ontbyt	
Middagete	
Aandete	

2. Hoeveel keer per dag eet u tussen maaltye? _____

Lys die top 3 versnaperinge waaraan u gewoonlik peusel:

3. Hoe gereeld eet u uit by restaurante/kafeterias, koop u etes by winkels of bestel u wegneem etes vir elk van die volgende maaltye **per week**?

Ete	Totale aantal restaurant / wegneem / winkel gekoöpte etes per week	Voorbeelde van mees algemene maaltyd keuse(s)
Ontbyt		
Middagete		
Aandete		

4. Merk met “n X” die tipe brood(e) wat u meeste van die tyd eet, asook die hoeveelheid snye wat u op 'n slag eet.

Tipe brood	“X”	Hoeveelheid snye
Wit		
“Best of Both”		
Wit Lae GI		
Bruin		
Volgraan		
Lae GI volgraan		
Low GI saadbrood		
Rogbrood		
Ander (spesifiseer asb. hieronder)		

5. Eet u ontbytgraan/gekookte pap vir ontbyt?

Ja	Nee
----	-----

Indien ja, merk die tipe(s) met “n X” en dui asb. aan hoe gereeld en hoeveel u daarvan eet per week.

Ontbytgraan & pap	“X”	Hoeveelheid keer geëet per week	Hoeveelheid wat op ’n slag geëet word (bv. ½ koppie of 1 koppie)
Hoë vesel ontbytgraan (“All bran flakes/high fiber bran/shredded bran”)			
Weet-Bix / Nutrific			
ProNutro: Gegeur “Original” Volgraan			
Muesli: Gerooster & gegeur Lae GI			
“Milo” ontbytgraan			
“Cheerio’s”			
Graan vlokkies (“Corn flakes”)			
“Ace” kits meliemeel			
Mieliepap: Vars warm pap Afgekoel			
Gekookte hawermout			
Kits hawermout pakkies: “Original” Gegeur			
Maltabella Aangesuurde maltabella			
Ander:			

Indien nie, wat eet u vir ontbyt? Merk die toepaslike blokkie(s) met “n X”.

Vrugte	
Jogurt	
Brood	
Plaasontbyt & roosterbrood/brood	
Oorskiet	
Beskuit	
Niks	
Ander (spesifiseer asb. hieronder)	

6. Merk met “n X” die suiwel produkte wat u gereeld nuttig en dui asb. aan hoe gereeld en hoeveel u daarvan eet per dag, per week of per maand.

Suiwel produk	“X”	Hoeveelheid keer geëet per dag/week/maand	Hoeveelheid wat op 'n slag geëet word
Melk (lae-vet, volroom & vet-vry)			
Gegeurde melk (“Steri-stumpie”/Nesquik)			
Karringmelk (“Amasi”)			
Versoete jogurt/ “drinking” jogurt			
Kunsmatig versoete jogurt			
Ongegeurde/ “plain” jogurt			
Ander (spesifiseer asb. hieronder)			

7. Merk met “n X” die stysels wat u gereeld nuttig en dui asb. aan hoe gereeld en hoeveel u daarvan eet per dag, per week of per maand.

Tipe stysel	“X”	Hoeveelheid keer geëet per dag/week/maand	Hoeveelheid wat op 'n slag geëet word
Tastic rys			
Ander witrys			
Bruinrys			
Wilde rys			
Stampkoring			
Pasta			
Durum pasta			
Mieliepap (slegs middag-/aandete)			
Mieliepap (afgekoel)			
Maltabella			
Aangesuurde maltabella			
Stamp mielies			
Stamp mielies (afgekoel)			
Stampmielies & boontjies			
Kapokaartappels/gekookte aartappel			
Aartappel gekook met skil			
Baba aartappels			
Slap “chips”/oondgebakte “chips”			
Patat (vet & suiker bygevoeg)			
Patat (geen vet & suiker bygevoeg)			
Botterskorsie (“Butternut”)			
Ander pampoene (bv. Boerpampoene)			
Pampoene/botterskorsie (versoet)			
Ander (spesifiseer asb. hieronder)			

8. Hoeveel vrugte eet u op 'n slag? _____

9. Hoeveel vrugte sal u in totaal per dag eet? _____

10. Merk met "n X" in watter vorm(s) u die meeste van die tyd u vrugte eet.

Vars vrugte met skil aan (waar moontlik)	
Vars vrugte – skil verwyder	
Geblikte vrugte in stroop	
Geblikte vrugte in vrugtesap	
Vrugteslaai	
Gedroogte vrugte	
Ander (spesifiseer asb. hieronder)	

11. Hoeveel dae per week eet u groente/slaai? _____

12. Hoeveel verskillende groentes en/of slaai eet u in totaal per dag? _____

13. Merk met "n X" in watter vorm(s) u die meeste van die tyd u groente eet.

Rou	
Gestoom	
Gekook in 'n bredie	
Gekook met suiker & vet (olie/botter/margarien)	
Gekook met aartappel en ui	
Slaai	
Ander (spesifiseer asb. hieronder)	

14. Merk met "n X" watter van die volgende u gebruik om voedsel items of drinkgoed te versoet.

Suiker (wit/bruin)	
Versoeter	
Beide suiker & versoeter, afwisselend	
Heuning	
Kondensmelk	
Niks	

15. Indien u suiker/heuning/kondensmelk gebruik, hoeveel teelepeltjies gebruik u per dag? _____

16. Merk met "n X" die drinkgoed wat u gereeld nuttig en dui asb. aan hoe gereeld en hoeveel u daarvan drink per dag, per week of per maand.

Drinkgoed	"X"	Hoeveelheid keer gedrink per dag/week/maand	Hoeveelheid wat op 'n slag gedrink word
Warm sjokolade			
"Milo"			
"Horlicks"			
"Nesquik"			
Melkskommel			
"Smoothies"			

Drinkgoed	“X”	Hoeveelheid keer gedrink per dag/week/maand	Hoeveelheid wat op 'n slag gedrink word
Gaskoeldrank			
Dieet gaskoeldrank (bv. Coke zero/Sprite zero)			
Vrugtesap: 100% Versoet			
Suiwel vrugtesap mengsel (bv. Tropicana)			
Aanmaak koeldrank (bv. Oros/Tang)			
Dieet aanmaak koeldrank (bv. Low-cal)			
Ander (spesifiseer asb. hieronder)			

17. Merk met “n X” die versnaperinge wat u gereeld nuttig en dui 'n. aan hoe gereeld en hoeveel u daarvan eet per dag, per week of per maand.

Versnapering	“X”	Hoeveelheid keer geëet per dag/week/maand	Hoeveelheid wat op 'n slag geëet word
Aartappelskyfies (bv. Simba/Lays/Niknaks)			
Springmielies: Sout Soet			
Gesoute/ongesoute beskuitjies (bv. “salticrax/creamcrackers”)			
Volgraan beskuitjies (bv. “crackermate lite's/provita's”)			
Ryskoekies			
“Corn thins”			
“Cracker bread”			
“Ryvita's”			
Beskuit: Wit / Diabeties / Volgraan Muesli / “Nutri-rusks”			
Koekies			
Koek/gebakte poeding			
“Muffin” (Tipe:)			
Botterbroodjie (Scone)			
Tert			
Lekkers (sag/hard)			
Sjokolade			
Ontbytstafies (“breakfast bars”)			

Versnapering	“X”	Hoeveelheid keer geëet per dag/week/maand	Hoeveelheid wat op 'n slag geëet word
Suikervrye-sjokolade (Canderel)			
Roomys			
Diabetiese roomys			
Ander (spesifiseer asb. hieronder)			

18. Het u al ooit 'n dieetkundige gekonsulteer vir die dieetbehandeling van u diabetes?

Ja	Nee
----	-----

Indien wel, hoeveel sessies het u saam met hom/haar voltooi? _____

19. Dink u dit is nodig dat iemand met diabetes 'n dieetkundige gaan sien?

Ja	Nee
----	-----

20. Merk die blokkie wat u huidige aktiwiteitsvlak die beste beskryf.

<p>1 - Passief/Laag aktief – Mense met beroepe wat nie fisies van aard is nie, wie nie vêr ente stap nie, oor die algemeen voertuie gebruik vir vervoer, nie gereeld oefen of deelneem aan sport nie, en die meeste van hul vrye tyd spandeer deur te sit of te staan.</p>	<p>2 - Aktief/Matig aktief – Mense met beroepe wat nie uitputtend in terme van energie eise is nie, maar meer energie verbruik vereis as wat vir 'n passiewe leefstyl beskryf word. Alternatiewelik is hulle mense met passiewe beroepe wat gereeld 'n sekere hoeveelheid tyd spandeer aan matige tot intense fisiese aktiwiteit.</p>	<p>3 – Baie aktief – Mense wat gereeld uitputtende werk of uitputtende ontspanningsaktiwiteite vir verskeie ure lank doen.</p>
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Fisiese aktiwiteitsvlak kategorie:
(1 – 3)

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ADDENDUM 4: Home blood glucose monitoring template

Patient no. _____

Date: _____

Home glucose monitoring instructions:

- Use the blood glucose monitoring template below to record readings
- Wash hands before taking the measurement
- Measure post meal blood sugar levels two hours after commencing with the meal
- Record two breakfast, lunch and supper post meal glucose readings respectively, in the same sequence as specified in the table below

Date	Meal	Time of measurement (2 hours after you started to eat)	Post meal glucose measurement
	Breakfast		
	Lunch		
	Supper		
	Breakfast		
	Lunch		
	Supper		
		Average:	
		Group classification:	

ADDENDUM 5: English Consent Form

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

The association between glycaemic control and lifestyle habits in adults with type 2 Diabetes Mellitus in Thabazimbi, Limpopo Province.

REFERENCE NUMBER: S12/02/060

PRINCIPAL INVESTIGATOR:

Maryke Carstens

ADDRESS:

37 van der Bijl street

Thabazimbi

CONTACT NUMBER:

084 4163584

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

The aim of the project is to determine the association between blood sugar control and lifestyle habits in adults with type 2 Diabetes Mellitus living in Thabazimbi. The valuable region-specific data will not

only shed light on the behaviour of Thabazimbi's diabetic population, but will also be used to create awareness of the importance of the right lifestyle habits and glucose control with regard to long term health, as well as the role of the dietician in this process.

Participants will be recruited from four medical practices, one dietetic practice and a clinical research facility in Thabazimbi, Limpopo Province. The total number of participants needed for the study is at least 88 individuals.

Each participant's data will be collected separately on two different occasions, one week apart. Data collection will mainly take place at the investigator's offices (37 van der Bijl Street, Thabazimbi).

Visit one will consist of:

- Collection of basic demographic information (gender, age and disease duration)
- Measuring body weight, height and waist circumference
- Explanation of home glucose monitoring and recording

Participants will have to measure and record six post meal blood glucose values in the week between the first and second visit. If a participant is unwilling to use their own test strips or does not have a glucose monitor and/or test strips, it will be supplied by the investigator.

Visit two will consist of:

- Completion of a dietary assessment questionnaire
- Submission of the six post meal home glucose measurements

Why have you been invited to participate?

You have been invited because you are a patient diagnosed with type 2 Diabetes Mellitus, and have no current serious abnormality/illness or infection.

What will your responsibilities be?

You will have to attend two visits at Maryke Carstens's consulting rooms. The two visits will be one week apart and no longer than 60 minutes each. You must be willing to partake in the above mentioned activities at each visit. In the week between the two visits you will have to record six post meal blood glucose values. These values must be recorded on the template supplied at visit one.

Will you benefit from taking part in this research?

Not all participants, especially those with good blood glucose control, will directly benefit from taking part in this research project. However, all participants who were found to have poor blood glucose control due to poor dietary and lifestyle habits will be invited to a group nutrition education session.

This session will be held after the research data has been analysed, and will be free of charge and voluntary. The research data will thus mainly be used to better the diabetes care of future/other diabetes patients in Thabazimbi.

Are there any risks involved in your taking part in this research?

There is no risk involved in taking part in this research.

Who will have access to your medical records?

Privacy and confidentiality of participant information will be ensured at all times by using an anonymous approach. Names of participants will thus not be recorded. The participant's information will also be kept in a locked steel cabinet and only the investigator will have access to participant information.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study. There will be no costs involved for you, except for transportation costs, if you do take part.

Is there any thing else that you should know or do?

- You can contact Mrs. Maryke Carstens at 084 4163 584 if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by Maryke Carstens.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant:

By signing below, I agree to take part in a research study entitled: The association between glycemc control and lifestyle habits in adults with type 2 Diabetes Mellitus in Thabazimbi, Limpopo Province.

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.

- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*) 2012.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator:

I (*name*) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter.

Signed at (*place*) on (*date*) 2012.

.....
Signature of investigator

.....
Signature of witness

ADDENDUM 6: Afrikaans Consent Form

DEELNEMERINLIGTINGSBLAD EN –TOESTEMMINGSVORM

TITEL VAN DIE NAVORSINGSPROJEK:

Die verband tussen glisemiese beheer en leefstyl gewoontes in volwassenes met tipe 2 Diabetes Mellitus in Thabazimbi, Limpopo Provinsie.

VERWYSINGSNOMMER: S12/02/060

HOOFNAVORSER:

Maryke Carstens

ADRES:

Van der Bijlstraat nr. 37
Thabazimbi

KONTAKNOMMER:

084 4163584

U word genooi om deel te neem aan 'n navorsingsprojek. Lees asseblief hierdie inligtingsblad op u tyd deur aangesien die detail van die navorsingsprojek daarin verduidelik word. Indien daar enige deel van die navorsingsprojek is wat u nie ten volle verstaan nie, is u welkom om die navorsingspersoneel of dokter daarvoor uit te vra. Dit is baie belangrik dat u ten volle moet verstaan wat die navorsingsprojek behels en hoe u daarby betrokke kan wees. U deelname is ook **volkome vrywillig** en dit staan u vry om deelname te weier. U sal op geen wyse hoegenaamd negatief beïnvloed word indien u sou weier om deel te neem nie. U mag ook te eniger tyd aan die navorsingsprojek onttrek, selfs al het u ingestem om deel te neem.

Hierdie navorsingsprojek is deur die **Etiese Komitee vir Gesondheidsnavorsing aan die Universiteit van Stellenbosch** goedgekeur en sal uitgevoer word volgens die etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki en die Etiese Riglyne vir Navorsing van die Mediese Navorsingsraad (MNR).

Wat behels hierdie navorsingsprojek?

Die doel van die studie is om die verband tussen bloedsuiker beheer en leefstyl gewoontes in volwassenes met tipe 2 diabetes, wat in Thabazimbi woon, vas te stel. Dié waardevolle streek-spesifieke data sal nie net lig werp op die gedrag van Thabazimbi se diabete nie, maar sal ook gebruik word vir bewusmaking rondom die belang van die regte leefstyl gewoontes asook bloedsuiker beheer m.b.t. langtermyn gesondheid, asook die rol van die dieetkundige in dié proses.

Deelnemers sal van vier mediese praktyke, een dieetkunde praktyk en 'n kliniese navorsings eenheid in Thabazimbi, Limpopo Provinsie gewerf word. Die totale hoeveelheid deelnemers wat vir die studie benodig word, is minstens 88 individue.

Elke deelnemer se data sal afsonderlik tydens twee verskillende geleenthede, een week uitmekaar, ingesamel word. Data insameling vind hoofsaaklik by die navorser se spreekkamer plaas (Van der Bijlstraat nr. 37, Thabazimbi).

Die eerste besoek bestaan uit:

- Insameling van demografiese inligting (geslag, ouderdom en diabetes duurt)
- Meet van liggaamsgewig , lengte en middelomtrek
- Verduideliking van tuis bloedsuiker monitering en dokumentering

Deelnemers sal ses na-ete bloedsuiker waardes moet meet en dokumenteer in die week tussen die eerste en die tweede besoek. Indien 'n deelnemer onwillig is om hul eie toets strokies te gebruik of nie oor 'n bloedglukose meter en/of toets strokies beskik nie, sal dit deur die navorser verskaf word.

Die tweede besoek bestaan uit:

- Invul van die dieet evaluering vraelys
- Ingee van die ses na-ete tuis bloedsuiker metings

Waarom is u genooi om deel te neem?

U is genooi omdat u 'n pasiënt met tipe 2 Diabetes Mellitus is, en tans geen ernstige siekte toestand of infeksie het nie.

Wat sal u verantwoordelikhede wees?

U sal twee besoeke by Maryke Carstens se spreekkamer moet nakom. Die twee besoeke sal een week uitmekaar wees en nie langer as 60 minute elk duur nie. U moet gewillig wees om aan elk van die bogenoemde aktiwiteite, by die onderskei besoeke, deel te neem. In die week tussen die twee

besoeke sal u ses na-ete bloedsuiker waardes moet meet en dokumenteer. Die bloedsuiker metings moet gedokumenteer word op die templaar wat by die eerste besoek verskaf word.

Sal u voordeel trek deur deel te neem aan hierdie navorsingsprojek?

Nie alle deelnemers, veral nie die met goeie bloedsuiker beheer, sal direk baat by die deelname aan die navorsingsprojek nie. Alle deelnemers met slegte bloedsuiker beheer, sekondêr tot swak dieet en leefstyl gewoontes, sal egter genooi word na 'n groep voeding-opvoeding sessie. Die sessie sal na die navorsingsdata geanaliseer is gehou word, en sal verniet en vrywillig wees. Die navorsingsdata sal dus hoofsaaklik gebruik word om diabetes-sorg van toekomstige/ander diabetes in Thabazimbi te verbeter.

Is daar enige risiko's verbonde aan u deelname aan hierdie navorsingsprojek?

Daar is geen risiko's verbonde aan u deelname aan die navorsingsprojek nie.

Wie sal toegang hê tot u mediese rekords?

Privaatheid en konfidensialiteit van deelnemers se inligting sal te alle tye verseker word deur 'n anonieme benadering te volg. Deelnemers se name sal dus nie gedokumenteer word nie. Deelnemers se inligting sal ook in 'n geslote staal kabinet gebêre word en slegs die navorser sal toegang tot dié inligting hê.

Sal u betaal word vir deelname aan die navorsingsprojek en is daar enige koste verbonde aan deelname?

Nee, u sal nie betaal word om deel te neem aan die studie nie. Daar sal ook geen onkoste verbonde wees, behalwe vervoer onkoste, indien u deelneem nie.

Is daar enigiets anders wat u moet weet of doen?

- U kan Mev. Maryke Carstens kontak by 084 4163 584 indien u enige verdere vrae het of enige probleme ondervind.
- U kan die **Etiese Komitee vir Gesondheidsnavorsing** kontak by 021-938 9207 indien u enige bekommernis of klagte het wat nie bevredigend deur u studiedokter hanteer is nie.
- U sal 'n afskrif van hierdie inligtings- en toestemmingsvorm ontvang vir u eie rekords.

Verklaring deur deelnemer:

Met die ondertekening van hierdie dokument onderneem ek,, om deel te neem aan 'n navorsingsprojek getiteld: *Die verband tussen glisemiese beheer en leefstyl gewoontes in volwassenes met tipe 2 Diabetes Mellitus in Thabazimbi, Limpopo Provinsie.*

Ek verklaar dat:

- Ek hierdie inligtings- en toestemmingsvorm gelees het of aan my laat voorlees het en dat dit in 'n taal geskryf is waarin ek vaardig en gemaklik mee is.
- Ek geleentheid gehad het om vrae te stel en dat al my vrae bevredigend beantwoord is.
- Ek verstaan dat deelname aan hierdie navorsingsprojek **vrywillig** is en dat daar geen druk op my geplaas is om deel te neem nie.
- Ek te eniger tyd aan die navorsingsprojek mag onttrek en dat ek nie op enige wyse daardeur benadeel sal word nie.
- Ek gevra mag word om van die navorsingsprojek te onttrek voordat dit afgehandel is indien die studiedokter of navorser van oordeel is dat dit in my beste belang is, of indien ek nie die ooreengekome navorsingsplan volg nie.

Geteken te (plek) op (datum) 2012

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Handtekening van deelnemer

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Handtekening van getuie

Verklaring deur navorser:

Ek (naam) verklaar dat:

- Ek die inligting in hierdie dokument verduidelik het
- Ek hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.
- Ek tevrede is dat hy/sy al die aspekte van die navorsingsprojek soos hierbo bespreek, voldoende verstaan.
- Ek 'n tolk gebruik het/nie 'n tolk gebruik het nie.

Geteken te (plek) op (datum) 2012.

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Handtekening van navorser

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Handtekening van getuie