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A FAMILY BASED INTERVENTION TO MANAGE TYPE 2 DIABETES IN PATIENTS FROM LOWER SOCIO-ECONOMIC BACKGROUND

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A thesis submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in fulfillment of the requirements of the degree of Doctor of Philosophy

Johannesburg, 2011

DECLARATION

I hereby declare that this thesis submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg, is my own original work. It has not been submitted to any other institution of higher education for any degree.

_____ 2011

N. Mshunqane (9512761M)

DEDICATION

In memory of my late parents:

Mrs Nophumele Ida Mshunqane

and

Mr Nkqayi Zandisile Mshunqane

To my life partner and our kids

Chester S Mhlanga: Tsatsi, Somila and Temave

ABSTRACT

Background

The quality of care in the management of type 2 diabetes has a significant impact on glycaemic control and quality of life of patients. Recent research in developing countries aiming to establish the factors that influence the quality of care of patients with type 2 diabetes has shown that poor adherence to medication and resistance to behavior change is associated with poor glycaemic control, development of complications and increased health care utilization in patients with type 2 diabetes. Factors contributing to quality of care have been thus far stated as the willingness of a patient to take control of the disease, good communication between the clinician and the patient to improve the patient's understanding and environmental factors. Environmental factors include the socioeconomic status and health system which determine health care utilization. There has been an improvement in the models of care for type 2 diabetes in which the use of diabetes self-management education strategies as described by the National Standards of Diabetes Management is the most recommended worldwide. South Africa has also adopted some of these strategies and drew guidelines for the management of type 2 diabetes in South Africa which are contained in National Health Policy document published in 2007. This study aimed to establish the effects a family based intervention which used diabetes self management education strategies in the management of type 2 diabetes in patients from poor socioeconomic backgrounds.

Objectives

The objectives of this thesis were:

1. to determine the demographic background (including socio-economic status (SES)) of patients with type 2 diabetes from lower socio-economic at Dr George Mukhari hospital.
2. to determine the availability of diabetes education programmes at Dr George Mukhari hospital.
3. to assess the appropriateness of the existing diabetic education programmes at Dr George Mukhari hospital.
4. to determine the level of knowledge of patients from lower socio-economic backgrounds with type 2 diabetes at Dr George Mukhari hospital about the management of the disease.
5. to determine the effects of a family based education and exercise intervention on the control of the levels of random blood results on the following parameters:
   i. HbA1c
   ii. Blood glucose
   iii. Lipogram
6. to determine the impact of a family based education and exercise intervention on the health related quality of life of patients with type 2 diabetes at Dr George Mukhari hospital.

7. to determine the factors that affect the management of diabetes in patients with type 2 diabetes at Dr George Mukhari hospital.

Four studies were conducted to address the above seven objectives. The steps below were followed in sequence to answer the specified objectives as described below:

Methods

Two preliminary studies were conducted to develop a knowledge questionnaire and to test the validity and reliability of a developed knowledge questionnaire and an internationally validated health related quality of life tool, (DIMS). To answer objectives 1 and 2, stated above, a qualitative approach where data were collected using focus groups and in-depth interviews was used. This approach was explored to establish the opinions of both patients and the management team regarding the medical management and services provided to treat patients with type 2 diabetes. A total of 10 patients and 13 members of the management team took part in the study. Qualitative survey methodology was followed to interpret the data. Five themes emerged from the qualitative data and these were used to develop a quantitative tool, a diabetes knowledge questionnaire which was used in the study population. Following this approach, a quantitative approach was used to determine the validity and reliability of a developed diabetes knowledge questionnaire and an internationally standardised Diabetes Impact Measurement Scale (DIMS). A total of 25 participants with type 2 diabetes took part in this study. Participants were selected from the clinic using a sample of convenience and they answered both questionnaires one after another. Cronbach's α coefficient was used to test the internal consistency that is the homogeneity of the questionnaire items. The test-retest reliability of the questionnaires was assessed by calculating the intraclass correlation coefficient (ICC). The two valid and reliable questionnaires were used to gather demographic characteristics of patients with type 2 diabetes consulting at Dr George Mukhari Hospital.

To answer objectives 3 and 4, as stated above, a cross sectional descriptive study, where a total of 135 black participants with type 2 diabetes, aged between 28 to 70 years were recruited from a population with type 2 diabetes consulting at Dr George Mukhari hospital. Participants were selected using simple random sampling. Both the knowledge questionnaire and DIMS were administered to all participants at the same time to establish the demographic characteristics. Descriptive statistics were used to interpret data. Findings of this study were used as needs analysis for interventions that are needed to address the problems of this population. To answer objectives 5, 6 and 7, as stated above, a prospective single blinded randomized controlled trial was used. A total of 135 patients with type 2 diabetes were randomized into three groups after determining their demographic data. The family supported group which selected a family member who was called once a month also engaged in a

home walking and education programme plus the usual care given at the hospital; the no family supported group, only had education and home walking plus the usual care given at the hospital; and the control group, only got the usual care given at the hospital. Patients' baseline characteristics and health status were determined using a diabetes knowledge questionnaire and the Diabetes Impact Measurement Scale (DIMS). The intervention lasted for six months and there was a further six months follow up during which time there was no intervention. All outcome measures were evaluated at baseline, after six months of intervention and after 12 months (six months of no intervention).Data were collected from August 2008 – February 2010. Groups were compared using an ANOVA. A multivariate logistic regression analysis was done to establish the effects of the intervention.

Results

Five themes emerged from the patients' and the professionals' focus groups. These were knowledge through health communication, education, behaviour change, support and patient-centered approach. These themes guided the domains of the developed knowledge questionnaire.

Cronbach's α coefficient for all standardized items for the knowledge questionnaire, ranged between 55% and 69%, (95% Ci, 0.54 ; 0.69), indicating good validity. Intraclass correlation coefficient ranged between 69 % and 71%, indicating good reliability.

The total score for DIMS ranged from 0. 62 to 0.71 for Cronbach's α coefficient and 0.63 to 0.70 for intraclass correlation coefficient also indicating good validity and reliability. The results of the cross sectional study to determine demographic backgrounds showed that there were more females than males diagnosed with type 2 diabetes. Female patients with type 2 diabetes consulting at Dr George Mukhari hospital were obese and male patients are overweight. All participants came from lower socioeconomic backgrounds and were sedentary. Education levels showed that participants had low schooling levels, (the majority of patients had a grade 11). The knowledge scores showed that there were diabetes education programmes, however these programmes were not appropriately conducted when comparing them to the guidelines recommended by the National Standards of Diabetes Self-Management Education Strategies and the South African National Health Policy. All participants had poor glycaemic and poor health related quality of life. These results showed poor quality of care at Dr George Mukhari hospital. A randomized control trial showed that groups were similar at baselines, ($p>0.05$). Following the six months intervention, the knowledge scores improved significantly in all groups but better in the family supported group. Health related quality of life also improved compared to baseline. Blood pressure and resting pulse did not change. The distance walked improved significantly at six months and 12 months compared to baseline, ($p<0.05$) but there were no significant differences between groups. There were significant improvements in total cholesterol, and LDL-C, after 6 months and again after 12 months in all groups, but better in the family supported group,($p<0.05$). Health related quality of life; HDL-C and triglycerides not significant statistically even

though the results on symptoms of the health related quality of life improved after the six months intervention compared to baseline. The findings of the multivariate logistic regression showed that group1 (family support) had a reduced risk of poor glycaemic control (OR= 0.58), whilst group 2 (no family group) showed a higher risk of poor glycaemic control (OR=1.1). Again for random blood glucose, similar effect was also confirmed, group 1 showed a reduced risk of poor glycaemic control (OR=0.64) and group 2 showed a higher risk of poor glycaemic control (OR=1.5). These results were not significant statistically.

Conclusion

The results from the qualitative approach showed that despite the psychosocial problems that were raised by patients when diagnosed with type 2 diabetes, participants did not think of diabetes as a lifelong disease that needs understanding and control. Therefore it is important to reinforce the understanding of these patients through health communication, encourage behaviour change by encouraging physical activity and adherence to recommended diet. Individual patient's environmental backgrounds should be considered because patients are unique. These results were used to design a diabetes knowledge questionnaire that was used to gather demographic data.

Reliability study showed that the developed knowledge questionnaire and DIMS were good and reliable questionnaires to use in patients with type 2 diabetes consulting at Dr George Mukhari hospital. The demographic study suggested that patients with type 2 diabetes consulting at Dr George Mukhari hospital had poor glycaemic control and poor health related quality of life; this indicated poor quality of care. The randomised control trial showed that a 12 months family based intervention improved knowledge, distance walked and lipids except HDL-C and triglycerides in patients with family support. This intervention showed that this intervention can improve self-care behaviours and its effects can be sustained for 12 months.

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LIST OF ABBREVIATIONS

ADA	-	American Diabetes Association
ACSM		Advocacy, Communication and Social Mobilization
ANOVA	–	Analysis of Variance
B.W	–	Body Weight
BMI	–	Body Mass Index
CDC	-	Center for Disease Control and Prevantion
CHD	-	Coronary Heart Diseases
CAD	-	Coronary Artery Diseases
Cl	–	Confidence Interval
Dias BP	–	Diastolic Blood Pressure
DIMS	–	Diabetes Impact Measurement Scale
DSME	–	Diabetes Self-Management Education
FFA	-	Free Fatty Acids
F	–	Female
GRP	–	Group
HbA1c	–	Glycosylated Haemoglobin
HDL	–	High Density Lipoprotein Cholesterol
HRQOL	–	Health Related Quality Of Life
IDF	-	International Diabetes Federation
IGT	-	Glucose Tolerance Test
LDL	–	Low Density Lipoprotein Cholesterol
M	–	Male
m	–	Meters
PTB	-	Pulmonary Tuberculosis
RPE	–	Rate of Perceived Exertion
6MWT	–	Six (6) Minute Walk Test
sd	–	Standard Deviation
SEMDSA	-	Society for Endocrinology, Metabolism and Diabetes of South Africa
SMBG	-	Self monitoring of blood glucose
Sys BP	–	Systolic Blood Pressure
WHO		World Health Organisation
WHR	–	Waist-Hip Ratio
Yrs	–	Years

CHAPTER 1

1. INTRODUCTION

1.1 BACKGROUND

Diabetes mellitus is a chronic disease and requires continuing medical care (American Diabetes Association, ADA, 2002). It is one of the top five leading causes of death in most developed countries but predictions for future increases in prevalence in developing and industrialised countries is a major healthcare crisis, (Bjork et al, 2003). It is estimated that by the end of the 20th century, a total of 151million persons worldwide were affected with diabetes, (Engelgau et al, 2003). This rate is alarming because diabetes is not just a burden to individuals and society but an economic burden. Type 2 diabetes is more common among females than males at the age 50 years and above, and is a common problem in both older and younger adults, (Cagle et al, 2002). Although about 20% of all individuals over 65 years of age have diabetes mellitus, a large number of these individuals are asymptomatic and unaware of their condition, (Amini, 2008; Van Rooijen, 2004).

1.1.1 Classification

The literature indicates that amongst the four classifications of diabetes there are two main types of diabetes mellitus, (Cagle et al, 2002; ADA, 2002; WHO, 2002; Anderson, 1981):
Insulin dependent diabetes mellitus (IDDM) or type 1diabetes mellitus usually referred to as juvenile diabetes mellitus because it occurs predominantly in children and young adults. It is characterized by autoimmune pancreatic beta cell destruction and absolute insulin deficiency. It will not be discussed further.

Type 2 or non-insulin dependent diabetes mellitus, occurs in middle and older ages with the majority of patients being overweight. Insulin resistance, usually with relative insulin deficiency is a major characteristic of this type of diabetes, (Ossei et al, 2003). The condition is characterized by hyperglycaemia, relative or absolute insulin deficiency, (Joshi, 2008; Ogunbanjo, 2006; Lebovitz, 1999).

1.1.2 Risk Factors of Type 2 Diabetes

The three most important risk factors in the pathogenesis of type 2 diabetes in older adults are a sedentary lifestyle, poor dietary habits and changes in body composition which result in overweight and obesity, (Boutayeb and Boutayeb, 2005). Obesity is associated with insulin

resistance and type 2 diabetes mellitus. The major contributing risk factor for cardiovascular disease is dyslipidaemia. Dyslipidaemia results in decreased high density lipoprotein cholesterol levels and elevated triglyceride levels, (Hossain et al, 2007; Raal et al, 2006; Elasy et al, 2004). In some cases there are elevated low density lipoprotein (LDL) also known as "bad" cholesterol levels which is associated with coronary heart disease, (Nesto, 2008; Chapman, 2007). Further, Chapman (2007) reported that observational studies have demonstrated a significant and independent association between low levels of HDL-cholesterol and increased risk of premature mortality. These studies have shown that men with HDL-C levels less than 0.9mmol/l were 3.6 times more likely to die of cardiovascular death, 4.1 times more likely to die from a coronary event and 1.9 times more likely to die from any cause compared to those with HDL-C levels more than 1.4mmol/l. Similarly, studies conducted in the sub-Saharan African (SSA) countries have shown that the prevalence of dyslipidemia varies across the regions of SSA and that there were high levels of dyslipidemia among patients with type 2 diabetes, (BeLue et al, 2009).

Physiologically, insulin is responsible for regulation of adipose fat content enhancing free fatty acid uptake and triglyceride synthesis by the muscle and liver. Lack of insulin results in increased blood sugar levels and fat deposits inside the walls of the small blood vessels, resulting in hypertrophy of the tunica media of the blood vessels, especially when there is sustained hypertension. This results in micro vascular diabetes complications like blindness and ischaemia, (Hajer et al, 2008).

1.1.3 Factors influencing adherence to treatment recommendations

There are several environmental factors that influence adherence to management of type 2 diabetes. These include the individual's lifestyle, health beliefs, attitudes and social networks, (Nelson et al 2007; Norris et al 2001; Samuel-Hodge 2000).

To address overweight and obesity as contributing factors to the pathogenesis of diabetes mellitus, it is important to understand more about an individual's motivation to lose weight, predictors of weight loss as well as their intention to lose weight (Hawkins et al, 2001). Reports by Norris et al, (2001) suggest that the optimal management of diabetes mellitus requires that we understand the lifestyle, beliefs, attitudes, family and social networks of patients being treated rather than concentrating on individuals. In addition, Greenhalgh et al (1998) described the three levels of cultural behaviour as:-

- what people say they do,
- what they are observed to do and
- the underlying belief system which drives that behaviour.

Anthropologists describe culture as a learned behaviour passed from one generation to the next by a process of enculturation and this is the reason why individuals need to be addressed either as part of a family or as part of the group to which they belong, (Spector, 1991). Culture comes from each society and gives people many of their unconscious attitudes, preferences, beliefs and health behaviours, (Taylor et al, 2003). The national centre for cultural competence in primary health care describes mental health as an integral part of primary care, (CDC, 2004). The differences among people of different backgrounds affect their health beliefs and behaviour as well as expectations of both patients and service providers. The delivery of high quality primary care that will be cost-effective requires providers to have an understanding of the socio-cultural background of patients, families and their environments, (Brown et al, 2002a). To improve the quality of services and primary care outcomes, it is important to analyse the differences that arise as a result of cultural factors such as nationality, ethnicity, acculturation, language, religion, gender and age as well as those attributed to family origins and individual experiences (Greenhalgh, 1998).

The difference between belief and knowledge is that knowledge is improved with intellectual study whilst belief is affected by culture or experience, (Ratanasuwan et al, 2005). Taylor et al (2003) emphasize the importance of involving family and the background environment of the individual for a holistic approach to disease management. They further explain that without understanding the background we can only treat the illness and not the person.

1.1.4 Type 2 diabetes and Quality of life

Diabetes falls together with hypertension and cardiovascular diseases in a group referred to as “chronic diseases of lifestyle”. Implicit in this name is the fact that lifestyle factors play a big role in these diseases. Chronic diseases of lifestyle are often characterized by the onset of complications which are disabling in nature and can be a major cause of morbidity and mortality, (Gill et al, 2009; Alberti et al, 2007a). Health related quality of life is also becoming increasingly important to measure the impact of a disease on patients’ health holistically and the response to treatment, (Westaway et al, 2009; Shobhana et al, 2003).Quality of life scales measure the effect of an illness and its management on an individual as perceived by that individual, hence quality of life assessment is not expected to provide detailed measures of symptoms of disease. It is designed to assess the effects of disease and health interventions on the patient’s sense of well-being.

1.1.5 Management strategies

The overall goal of diabetes mellitus management is to help individuals with diabetes and their families gain the knowledge, life skills, resources and support needed to achieve optimal health (International Diabetes Federation and WHO, 2004). For this goal to be successful a multidisciplinary team effort is required. Health care professionals and the people affected by type 2 diabetes, such as patients with type 2 diabetes, their families and their community should work together, (Funnel, 2009; Cagle et al, 2002; Fisher and Weihs, 2000).

The management of type 2 diabetes should address the goals of management as set out by the International Diabetes Federation and WHO, 2008. Physical activity, appropriate diet and knowledge through diabetes self-management education strategies, (DSME) are the cornerstones for effective diabetic therapy, (Funnel et al, 2009; Norris et al, 2002). Potential benefits of exercise in diabetes management include increased insulin sensitivity and possibly increase in glucose tolerance, improved cardiovascular fitness, a sense of well- being, agility and improved lipid profiles. In both type 1 and type 2 diabetes mellitus, hyperglycaemia is better controlled if the patient participates in regular exercise (Ogunbanjo, 2006; Bopp et al, 2006).

Regular exercise changes the lipid fractions in a favorable direction, thus resulting in reduced blood pressure. Exercise increases insulin sensitivity by the stimulation of glycogenolysis and glucose uptake by the exercising muscle, thus reducing insulin levels in the blood (Sigal et al, 2004). There is also an improvement in cardiopulmonary fitness and this is associated with a decreased incidence of coronary disease in patients with diabetes, (Nelson et al, 2002). Exercise may also affect the musculoskeletal system and possibly reduce the risks of falls and fractures in older adults with diabetes. Aerobic activities at 50-70% maximum heart rate or VO_2 max, starting with a 5-10 minute warm up and concluding with a 5-10 minute cool down period for a period of 30 minutes are recommended (Sigal et al, 2004). Physical activity will help to improve glycaemic control and weight reduction, (Woelever et al, 2000). It is well known that diet together with physical activity decrease the complications that patients with diabetes suffer from, such as kidney diseases, eye problems and the risk of cardiovascular sequelae.

A major goal of nutritional management for diabetes care is to improve glycaemic control by balancing food intake with endogenous/exogenous insulin levels. The major focus for the treatment of patients with type 2 diabetes as well as those individuals with impaired glucose tolerance or impaired fasting glucose should be on food portions and weight management (Klein et al, 2004).

Education programmes have become the best methods of facilitating self-management in the management of type 2 diabetes, especially when patients understand the role played by improvement of their knowledge in the disease process, (Keyserling et al, 2002; Jack et al, 2004 and Wens et al, 2008). It is important to consider the individual patients' values and preferences when the education is aimed at facilitating behaviour change, (Keyserling et al, 2002; Brown et al, 2005). For behaviour to change it is important to consider the psychological preparedness of the individual to change, as well as how the individual interprets his health beliefs through the Health Belief Model (HBM), (Hazavehei et al, 2007). There are two theories that work hand- in- hand with the HBM and they determine the likelihood of an individual to perform a specific behavior. These are:-

- The theory of reasoned action, and
- The theory of planned behaviour, (Glanz et al, 1997).

These theories will not be discussed further but their impact on how individuals with type 2 diabetes interpret their health beliefs through the HBM will be related. Hazavehei et al (2007), describes the six components of the HBM as follows:

- perceived susceptibility- in this study this refers to the level of susceptibility to type 2 diabetes
- perceived severity- in this study this refers to perceived seriousness and consequences of type 2 diabetes
- perceived benefits- in this study this refers to perceived benefits when following appropriate action such as education advice on the management of type 2 diabetes
- perceived barrier- in this study this refers to perceived challenged for action to prevent type 2 diabetes
- cues of action- in this study this refers to behaviour change for controlling type 2 diabetes.

There are two studies that have been conducted in South Africa which focused on the management of type 2 diabetes. As a consequence of the results that were gathered from both studies, it became evident that there is still a need to develop an intervention which will involve family members and measure the role of family support in the management of type 2 diabetes.
The study by Mshunqane et al (2004) was conducted in a rural region of the Free State, South Africa. The results of this study showed good glycaemic control, reduction in measures of obesity and improvement in exercise capacity equally in patients with type 2 diabetes whether exercising under supervision or unsupervised. The study by van Rooijen et al (2004) showed that urban black women with type 2 diabetes had little knowledge about their disease and they

had a sedentary lifestyle. Their attitude showed dependency on health professionals. Patients who were involved in relaxation exercises improved their HbA1c significantly after three months, compared to a control group.

From the two studies it is clear that there is still a need to develop an intervention that will encourage individuals to take responsibility for their own health rather than depending on health professionals. This will ensure a holistic approach and should facilitate behavior change, (Taylor et al, 2003; Ratanasuwan et al, 2005).

Changes over time in terms of the continued escalations in the burden of disease have shifted the focus and emphasis of public health from health protection measures that were used to retard the progression of infectious diseases, towards health promotion policies and practices, targeting individual behaviours and lifestyle risk factors, (Mbanya and Ramaya, 2006). The reviewed literature shows that there is a global increase in the prevalence of type 2 diabetes over the last century. This rise in type 2 diabetes prevalence has caused a major shift t in the burden of disease from infectious diseases such as pulmonary tuberculosis (PTB) and HIV to chronic diseases of lifestyle such as diabetes, hypertension and coronary heart diseases (CHD) but with CHD being the leading cause of death when compared to other chronic diseases.

Persistent increases in the prevalence of type 2 diabetes have indicated a need for public health interventions to prevent diabetes complications (Shaw et al*,* 2006). According to the report from the 19th World Diabetes congress in Cape Town,2006, the trends of chronic diseases show a strong relationship to lifestyle factors like smoking, poor dietary habits and/ practices, physical inactivity and alcohol consumption. There is also a strong relationship between the individuals' health behaviours and their surrounding environmental factors, such as poverty and education, (Ramachandran et al*,* 2002). Type 2 diabetes as a chronic disease needs evidence based interventions, (ADA, 2002; Bryne et al, 2000). The principles of evidence based medicine (EBM) as defined by Akobeng (2005), work on integrating the best research evidence with clinical expertise and considering patient's values. This approach aims at improving quality of care and patients' knowledge for lifelong learning.

Literature about the management of type 2 diabetes shows that there is a gap in the scope of knowledge of type 2 diabetes mellitus management because of cultural variations and attitudes to ill health and disease as well as adhering to a healthy diet and lifestyle modifications. Social structures like poverty affect lifestyle modifications, (Taylor et al, 2003). Certain barriers to

health care are interrelated and common among historically oppressed people e.g. low income or lack of health insurance, (CDC, 2004). As a result of this gap, the epidemic of type 2 diabetes mellitus and obesity is gradually increasing in Southern Africa. Type 2 diabetes mellitus was common in developed countries but because of the increase in westernization even developing countries are now carrying this burden. It is therefore important to do the following in order to bridge the gap:

- Design an intervention that is meaningful for the affected population in terms of their environmental backgrounds, so as to control further escalation of the disease. In this study the influences of family backgrounds will be evaluated to see if they play a role in healthcare.
- Incorporate “information giving” and family support to promote behaviour change. Again it will be determined in this study whether empowering both the family and the patients or only the patient will improve an individual’s glycaemic control.
- Evaluate the importance of encouraging family member is involvement through phone calls, once a month in the management of type 2 diabetes.

Family support has a strong relationship with improvement of disease management outcome, (Ogunbanjo, 2006; Fisher et al, 2000b). They describe the role of the family as the primary social context of disease management because of the following reasons:

- Disease management behavior takes place at home.
- Food preparation, exercise and health monitoring are influenced by the family than a patient.
- Stress that is related to tight blood glucose control is influenced by family stress, and marital satisfaction.
- Health-related beliefs, which are supported by culture and ethnicity, are also influenced by family.
- The family represents the patient’s personal relationships and has supportive influence on patient behavior, health and well-being. This is achieved by reduction of symptoms of depression and improvement in morale as well as disease management behavior, (Wen et al, 2004).

Similarly findings of the qualitative study conducted by Chesla et al, (2003) on African Americans, showed that high family coherence suggested a world view that life is meaningful and manageable and is positively associated with general health, in contrast to this, unresolved family conflicts about diabetes were related to depressive symptoms.

Telephone calls have also been reported to improve quality of care by enhancing adherence to disease management regimes and improving glycaemic control, (McMahon et al, 2005; Piette et al, 2001).

This thesis attempts to establish whether a difference exists in the effects of family support and patients with no family support on lowering HbA1c by 1% after 6 months of a randomized control trial intervention. This study will further examine the impact of demographic, socioeconomic and behaviour modification practices (adherence to medication, changing dietary practices and exercises) on changes in an individual's health related quality of life.

1.2 PROBLEM STATEMENT

The alarming increase in the prevalence of type 2 diabetes in developing countries, South Africa included, raises a concern especially with all the advances in research technology. There is currently no research done on the optimal way to encourage self-care management in patients with type 2 diabetes in South African tertiary hospitals. The available evidence is mainly from developed countries and may not be relevant to a South African population because of the existing different cultural and the difference in socioeconomic backgrounds. The prevalence of poverty especially in developing countries as compared to developed countries affects the quality of care resulting in mortality and morbidity. An audit study conducted in one of the provinces in South Africa (Free State province), showed that there are millions of rands that are spent on day to day medication and this excludes costs on hospitalisation as a result of type 2 diabetes complications. It is therefore important to conduct this study in South Africa to contribute to the control of type 2 diabetes and improve quality of care.

1.3 RESEARCH QUESTION

- What are the effects of a family based education and exercise intervention in improvement of glycaemic control and health related quality of life in patients with type 2 diabetes?

1.4 AIM

The aims of this study were to:

- determine the effects of a family based education and exercise intervention in maintaining normal glycaemic control in patients with type 2 diabetes.
- determine the effects of a family based education and exercise intervention on health-related quality of life in patients with type 2 diabetes.

1.5 OBJECTIVES

The objectives of this study were:-

- to determine the demographic background (including socio-economic status-SES) of patients with type 2 diabetes from lower socio-economic backgrounds at Dr George Mukhari hospital.
- to determine the availability of diabetes education programmes at Dr George Mukhari hospital.
- to assess the appropriateness of the existing diabetic education programmes at Dr George Mukhari hospital.
- to determine the level of knowledge of patients from lower socio-economic backgrounds with type 2 diabetes at Dr George Mukhari hospital about the management of the disease.
- to determine the effects of a family based education and exercise intervention on the control of the levels of random blood results on the following parameters:
  i. HbA_1c
  ii. Blood glucose
  iii. Lipogram
- to determine the impact of a family based education and exercise intervention on the health related quality of life of patients with type 2 diabetes at Dr George Mukhari hospital.
- to determine the factors that affect the management of diabetes in patients with type 2 diabetes at Dr George Mukhari hospital.

1.6 RESEARCH SITE

The study was conducted at Dr George Mukhari hospital, formerly known as Ga-Rankuwa hospital in South Africa. The hospital is situated 37 km north of Pretoria in a township called Ga-Rankuwa. It falls under Gauteng province but used to be under Northwest province because it is situated in the demarcation area of Bophuthatswana region. Ga-Rankuwa was proclaimed a township by Proclamation 448 of 1965 and was established to accommodate people who were displaced from the city centers to the borders of the homelands. The hospital was renamed “Dr George Mukhari” by the Gauteng premier in 2003, after 10 years of South African democratic governance, (Limpopo Leader 12). This was after a death of an African dedicated local doctor who used to provide free medical services to people with financial difficulties, (Limpopo leader 16).

Dr George Mukhari hospital is an academic hospital for the University of Limpopo-Ga-Rankuwa campus, formerly known as MEDUNSA (Medical University of Southern Africa). It is the second largest referral hospital in South Africa with 1550 beds. It accommodates all fields

of medicine and has 23 clinical departments. It has approximately 82 full-time and 37 part-time specialists who are dual employed by the hospital and university. It provides services for patients from six of the surrounding townships (Mabopane, Soshanguve, Mamelodi, Atteridgeville, Temba, Lethlabile and Winterveld) including Ga –Rankuwa which has 14 zones, (Limpopo leader 16).

1.7 JUSTIFICATION OF THE THESIS

The interrelationship between the environmental factors or social structure and health is poorly understood though is evident in the healthcare system. Diabetes poses a huge economic burden on the health system worldwide and this includes South Africa. Most diabetes expenses result from hospitalization of patients due to the long-term complications of diabetes such as renal failure and cardiovascular diseases. It is unclear whether the escalation is enhanced by environmental factors or the quality of care given to patients with type 2 diabetes. The literature has indicated that obesity is the major contributing risk factor of type 2 diabetes in South Africa, (Steyn, 2006). They further explain that this is mainly influenced by culture and current societal trends that are characterized by sedentary lifestyles and fast food options that encourage overeating unhealthy food. Whittemore et al, (2004), added that it is therefore difficult to maintain individual lifestyle change, hence the expansion from an individual to community is strongly advocated to prevent the increasing prevalence of obesity and type 2 diabetes.

This thesis seeks to determine whether a family based intervention facilitates blood glucose control. In this approach the results of patients with family support will be compared to those patients with no family support at baseline, six (6) and 12 months post intervention.

1.8 OUTLINE OF THE THESIS

A mixed methodology approach was used to answer the objectives of this thesis as mentioned above. Below is a flow diagram showing an outline of the two phases.

1.8.1 **Outline of the Mixed Methodology Approach**

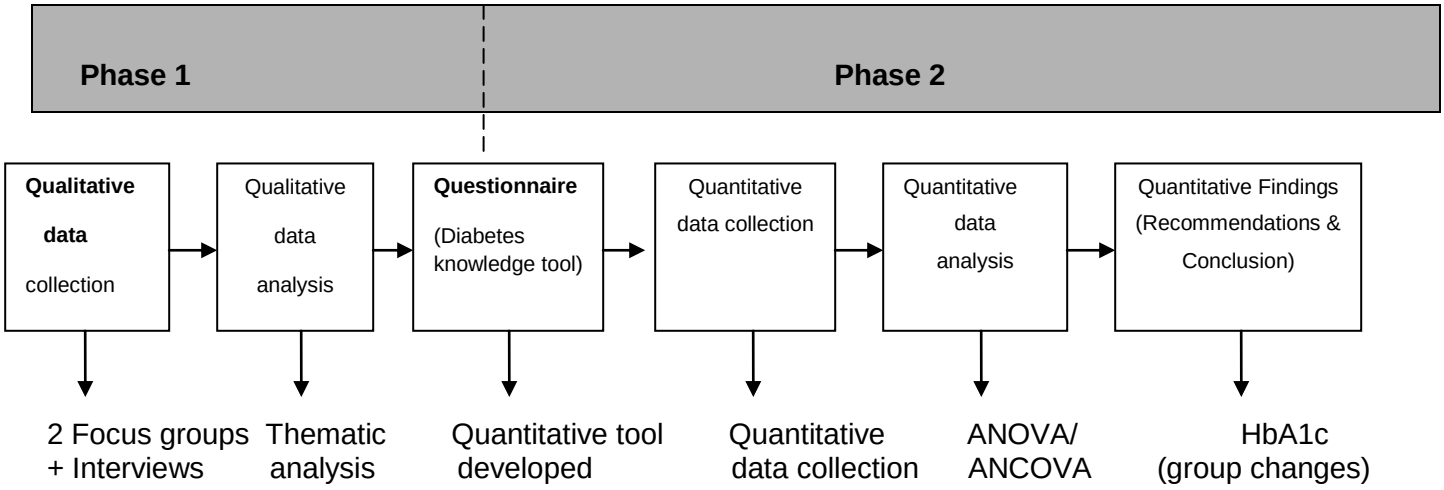

Figure 1.1: Diagram Showing Mixed Methodology Approach Used In This Study

Four studies were conducted to answer the seven objectives of this thesis.

Below is a flow diagram showing an overview of all the studies conducted.

1.8.2 An Overview of the Studies Conducted to answer all Objectives of the Thesis

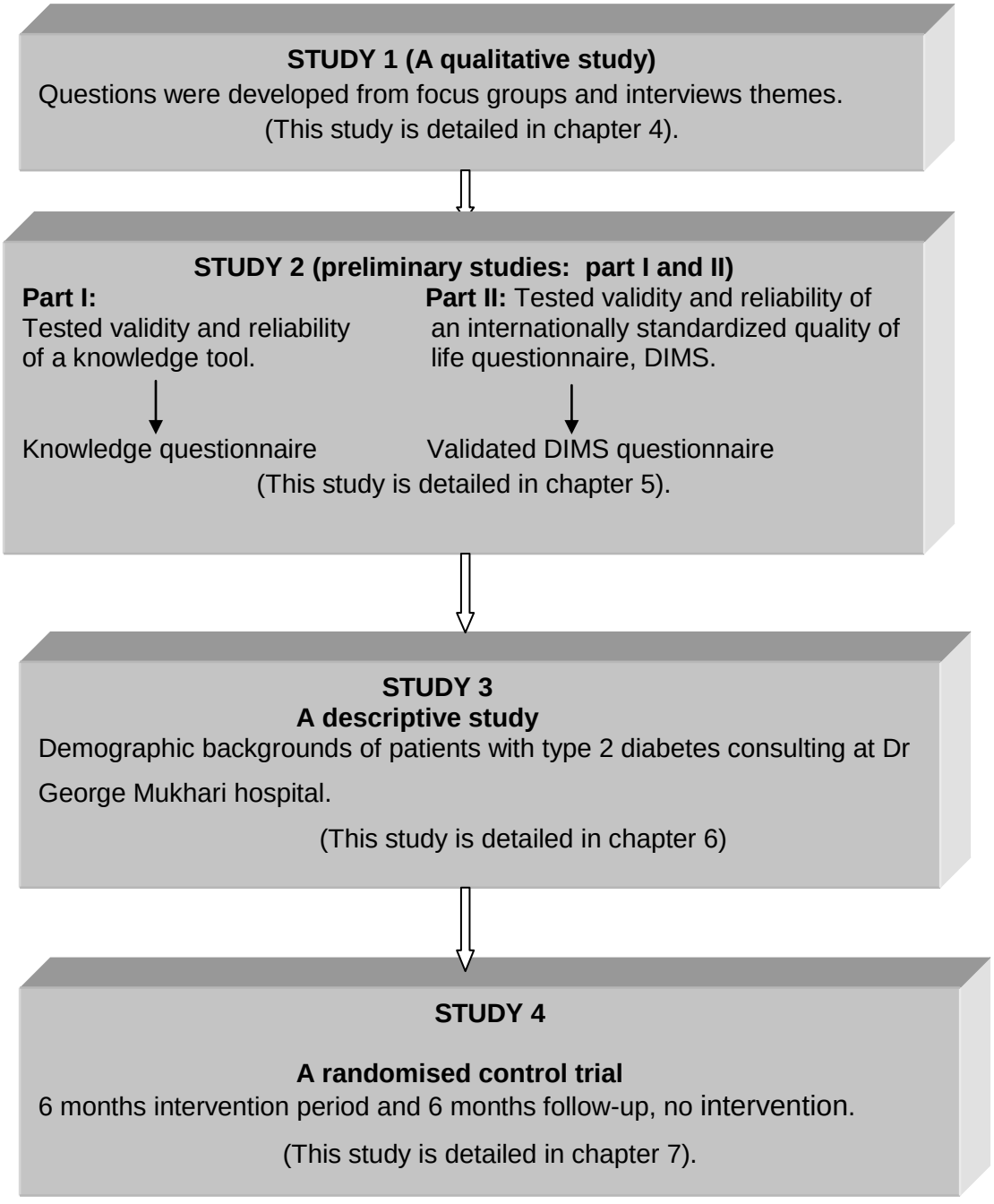

Figure 1.2: A flow Diagram Showing an Overview of the Studies Conducted in this Thesis

CHAPTER 2

2. LITERATURE REVIEW

2.1 INTRODUCTION

For the purposes of this study, the literature pertaining to the pathophysiology of type 2 (or non- insulin dependent) diabetes mellitus; prevalence and burden of type 2 diabetes; mortality and morbidity; quality of care; and effects of self-care management, family support and adherence to glycaemic control in patients with type 2 diabetes is reviewed.

2.2 DIABETES MELLITUS

Diabetes mellitus is a common and costly medical illness which is psychologically and behaviourally demanding, (Ciechanowski et al, 2001). They further debate that 95% of its management is conducted by a patient hence collaboration between the patient and provider may improve patient adherence and health outcomes. It is characterised by varying degrees of failure to store and metabolise carbohydrates with consequent hyperglycemia (increased levels of glucose in the blood), (ADA, 2002). Diabetes mellitus was a rare condition in Sub-Saharan Africa before the 1990's except for South Africa where the prevalence of diabetes was reported to be higher than 1.4 percent between 1959 and 1985, (Mbanya and Ramaiya, 2006).

According to recent literature type 2 diabetes is most common in the elderly population and it constitutes 95% of the population with diabetes in which 5% is diagnosed with type 1 diabetes, (Van Rooijen et al, 2004). Type 2 diabetes is characterized by insulin resistance and pancreatic beta cell defect. Insulin resistance is induced by obesity and beta cell dysfunction and results in relative insulin deficiency, (Younis et al, 2004; Zimmet, 2003). Elasy et al (2004), added that impaired glucose homeostasis is accompanied by varying degrees of abnormalities in insulin action, secretion and hepatic glucose production. Genetic factors which relate to each patient's family history and lifestyle factors such as food practices, a sedentary lifestyle and being overweight also play an important role in the aetiology of type 2 diabetes.

The causes of insulin resistance can be influenced by impaired beta cell function, circulating insulin antagonists and target tissue defects in insulin action (ADA, 2011; Elasy et al, 2004). Abnormal beta cells cannot fully compensate resulting in relative insulin deficiency and hyperglycaemia, (Stewart, 2004). Insulin deficiency results in failure of glucose transport into muscles and adipose tissue and liver. A resultant failure to convert glucose to glycogen in the liver and to modulate hepatic gluconeogenesis leads to a rise in blood sugar levels. Insulin also

normally stimulates the transport of amino acids into muscle and their synthesis into proteins. Insulin deficiency thus results in impaired protein synthesis and an accelerated rate of amino acid catabolism. Insulin controls lipolysis via enzymes. The fall in insulin levels therefore results in increased lipolysis and an increase in plasma free fatty acids (FFA), which in turn contribute to insulin resistance (Hajer[1] et al, 2008; Kolovou et al, 2004; Elasy et al, 2004). Type 2 diabetes co-exists with hypertension because hyperglycaemia causes abnormalities in central and peripheral structure of blood vessels, resulting in inflammation and stiffness of blood vessels, (Stewart, 2002).

Type 2 diabetes is a group of syndromes which results in abnormally high levels of glucose in the blood, (Mohan et al, 2007; Mbanya and Ramiaya, 2006). The body becomes unable to control the use and storage of glucose. Blood glucose is important for supplying the body with energy for metabolic needs. Insulin is normally released into the blood stream in response to rising levels of glucose. The high levels of glucose in the blood as well as syndromes which make up type 2 diabetes affect many of the body's normal processes of storing and breaking down glucose stores as they are needed by the body resulting in hyperglycaemia. The persistence of hyperglycaemia results in the development of acute complications even before the disease can be diagnosed.

The disease causes damage to the walls of blood vessels, such as occlusion of coronary arteries due to fat deposits resulting in atherosclerosis with micro-vascular complications. There is also damage to large diameter blood vessels including those that supply kidneys, with macro-vascular complications,(WHO, 2009). Macro and micro-vascular damage starts early before the symptoms of the disease become evident hence type 2 diabetes is referred to as a silent killer. The elevation of triglyceride levels and reduction in high density lipoproteins (HDL or good cholesterol) also result in the onset of coronary artery disease (CAD). The syndrome is also known as “The Deadly Quartet” because it is composed of four (4) deadly components, impaired glucose tolerance, hypertension, abdominal obesity, and dyslipidaemia, (Raal, 2006). Dyslipidaemia and increased cholesterol levels are associated with a high prevalence of coronary and peripheral artery diseases, which are responsible for a large percentage of blindness, limb amputations, heart diseases and stroke.

The prevalence of type 2 diabetes worldwide is augmented by the existence of the risk factors detailed below.

2.3 RISK FACTORS

The risk factors according to the National Programme for Control and Management of type 2 diabetes developed by the National Department of Health, South Africa and WHO (2007), include the following:

- Obesity (BMI ≥ 30kg/m^2)
- Physical inactivity or sedentary lifestyle
- Hereditary
- Western lifestyle
- Diet and pregnancy

The above risk factors have been mentioned worldwide to be responsible for the development of type 2 diabetes and its cardiovascular complications, (Hossain et al 2007; Glazier et al, 2006). The global increase in type 2 diabetes in developing countries in the East and Sub-Saharan regions is as a result of an emerging increase in the epidemic of obesity, (Hossain et al, 2007; Wild et al, 2004; Ossei, 2003). The increase in obesity was most common among urban middle-aged population but now it is affecting semi-urban and rural populations as well as the younger generation, (Alberti et al, 2004). In Africans, obesity in childhood has been observed to be the primary predictor for obesity in adulthood and this is expected to transpire in generations to come, (Ossei, 2003). The environmental factors of obesity in developing countries have been identified to be related to westernization which results in decreased physical activity and over consumption of cheap food. Globalization also contributes to the onset of obesity and type 2 diabetes because of a shift from traditional agricultural activities which are physically intense. These result in sedentary life styles, (Hossain et al, 2007). In South Africa obesity is found to be encouraged by over nutrition in particularly in urban adult women and its determinants include level of education and ethnicity, (Puoane et al, 2002).

Physical activity and weight control play an important role in type 2 diabetes prevention and management, because they reduce the risk of cardiovascular disease and overall mortality, (Christian et al, 2008). They further discussed that weight loss of as little as 2.25 kg to 4.5 kg, is sufficient to improve metabolic control. This means that patients will experience reduced diabetes related risk factors without achieving ideal body weight.

2.4 PATHOPHYSIOLOGY

The pathophysiology of type 2 diabetes mellitus is characterized by defects in both islet beta cell function (insulin secretion) and insulin action.

The impairment of islet beta cell function in type 2 diabetes mellitus is summarized as three manifestations:

- Absence of first phase insulin response to glucose, resulting in an overall delayed insulin secretor response to glucose. This can be because of decreased insulin binding to cellular receptors as a consequence of a reduced number of receptors resulting in decreased tissue glucose uptake and thus increased sugar levels in the blood (a minor factor).

- Decreased sensitivity of insulin response to glucose, such that insulin response to glucose is impaired and islet beta cell function is impaired resulting in hyperglycaemia. This is because of defective insulin action as a consequence of defects in the effector system beyond the level of insulin binding to cellular receptors resulting in increased blood glucose levels (a major site of insulin resistance).

- Decreased overall insulin secretor capacity, particularly in more severe and long duration type 2 diabetes (Joshi, 2006). This can be as a result of reduced sensitivity of the liver to the effects of insulin, which results in increased hepatic glucose production resulting in increased blood glucose levels (Levitt, 2008)

2.5 DIAGNOSIS OF TYPE 2 DIABETES

The development of type 2 diabetes takes place over a long period of time, (Cheng, 2005). It starts with insulin ineffectiveness and progresses to beta-cell dysfunction. For the diagnosis of type 2 diabetes the impaired glucose tolerance (IGT) test as stipulated by the ADA and WHO should be performed and a 2-h postprandial glucose level should be between ≥ 7.8mmol/l to < 11.1mmol/l, and impaired fasting glucose level of <6.lmmol/l are suggestive of type 2 diabetes, (Motala et al, 2008). Because the results of the two tests cannot replace each other and the impaired glucose tolerance test is difficult to implement as a screen test, a large population has been left undiagnosed, (Cheng, 2005). The use of HbA1c to diagnose type 2 diabetes was recommended in 2009 and the level of ≥6.5% is considered normal, (ADA, 2011).

2.6 PREVALENCE OF TYPE 2 DIABETES

"*The problems encountered by people with diabetes in Africa closely reflect those experienced by people with the condition in much of the rest of the developing world. While people with diabetes in many developed countries - with free access to an increasing range of modern diabetes supplies and analogue human insulins - strive for excellence in the control of their blood glucose levels, many people with the condition in African countries struggle every day with fundamental issues of survival",* (Frazer Pirie – page 1 ,World Diabetes Congress, 2006).

The prevalence of diabetes in Africa was rare between the years 1959-1980, with a prevalence rate that was equal to or less than 1.4%. In 1994, diabetes mellitus was estimated to have affected 3 million people on the African continent and the same number was estimated to double or triple in 2010. Epidemiological studies conducted in 1994, showed that the prevalence of type 2 diabetes was increasing worldwide and the highest prevalence was amongst emigrants from the Indian sub-continent in Fiji, South Africa, Tanzania, Mauritius and the United Kingdom, (Shera et al, 1995). In 2000, more than 151 million people in the world were diagnosed with diabetes, (Engelgau et al, 2003; Ramachandran et al, 2002). In 2001, the prevalence rate of type 2 diabetes was 3.6% in South Africa alone and this rate was reported to be influenced by urbanization, (Azevedo and Alla, 2008). The epidemic of type 2 diabetes is reported by researchers to be increasing in an uncontrollable rate worldwide, (Cheng et al, 2005). The remarkable increase in type 2 diabetes also caused an increase in the complications associated with the disease. As the prevalence of type 2 diabetes continued to increase regardless of the new technologies developed for the management of the disease, its impact also posed challenges to all healthcare professionals, (Faeh et al, 2007; Cheng et al, 2005). The prevalence rates show differences between urban and rural populations, with urban populations showing a higher prevalence of type 2 diabetes.

Studies conducted in the Middle Eastern Cresent; Sub-Saharan Africa and India, show that the prevalence of type 2 diabetes was expected to double in urban populations in developing countries, between the years 2000-2030. This projected increase in the disease was based on demographic change and the age group above 65 years, (Wild et al, 2004). The results of a prevalence study conducted in Mauritius for an 11 year period (1987-1998) at three different intervals and different stages of glucose intolerance in all ethnic groups showed a significant increase in the prevalence of type 2 diabetes at these different study intervals and in all age groups:- a 12.8% increase in 1987; a 15.2% increase in 1992 and a 17.9% increase in 1998. There were no significant differences between men and women, (Soderberg et al, 2005).

Estimates by WHO (2005) on prevalence of type 2 diabetes showed the following findings:

- 1994 = 89.6 million worldwide,
- 2000= 157.3 million worldwide,
- 2010= 2015.6 million worldwide,
- 2025= 300 million worldwide.

The uncontrolled escalation of type 2 diabetes was again reemphasized in the IDF, Africa region meeting, (December 2008, Kenya), where the latest estimates showed that 380 million people will be affected by 2025 in the developing regions of the world. It was also estimated that one person would die of type 2 diabetes every 10 seconds. The predicted prevalence rates in the African continent between the years 2007 - 2025 were estimated to increase from 3.1% to 3.5% from a total population of 747 million in 2007 to1088 million in 2025.

In 2004, the prevalence rates of type 2 diabetes in South Africa were estimated to be one million people diagnosed with diabetes and approximately the same number of undiagnosed individuals, (van Rooijen et al, 2004). In 2006, Rheeder and co-workers reported that the prevalence of type 2 diabetes varied between 3% and 28%. Thirteen percent prevalence was Indians in Durban and 28.7% prevalence were elderly coloured people in Cape Town. The prevalence of diabetes is reported to be lower in low socio-economic status groups in urban areas and higher in high socio-economic status groups. However the prevalence of long-term complications is higher in low socio-economic status groups than in high socio-economic status groups due to poor control of the disease, (Ramachandran et al, 2002). This continued increase in the prevalence of type 2 diabetes poses an economic burden worldwide causing the disease to be a public health problem.

2.7 ECONOMIC BURDEN OF TYPE 2 DIABETES

The management of type 2 diabetes, which accounts for 80-90% of the total diabetes population, is mainly by preventative and control programmes. The results of the epidemiological studies conducted in the year 2007, suggest that without effective preventative and control programmes, the prevalence will continue to increase, (Alberti et al, 2007a). Early intervention delays the progression of the disease and this benefits both, the patients, by increasing their quality of life and society by sustaining the economy. Long-term complications of type 2 diabetes, which result in negative economic impact and a human cost, can be delayed by prevention programmes, (Cheng, 2005). Studies conducted in America in 1997 as reported by the American Diabetes Association on cost involved in management of patients with type 2 diabetes, showed that the lifetime costs were estimated at $44.1 billion, (Caro et al, 2002).

Follow-up studies in 2000 showed an estimated cost of $1,700 for white men with a BMI of 30kg/m^2, and $2.100 for white women with the same BMI. An increase of BMI by 10 kg/m^2, treatment with oral drugs, diabetic kidney disease, peripheral vascular diseases and

cerebrovascular disease are associated with a 10% increase and a 60-90% increase in patients that were on insulin, have angina, and myocardial infarct.

End stage kidney dialysis increases the cost of hospitalization and medication 11 fold, (Brandle et al, 2003). Studies conducted from 1999-2002 based on records of medical aid payments also confirmed that long-term complications like coronary heart diseases, hypertension and depression but not HbA_1c, increased the cost of type 2 diabetes hospitalisation.

In South Africa, there is limited information on the cost of diabetes, but an audit conducted by Mollentze and Kining (2007), in a Bloemfontein provincial hospital-Free State during the period June 2005- May 2006 showed a total of R6, 471 million was used per annum to buy a volume of 1, 259- 460ml insulin; R1, 992 million was used to purchase 19 802- 144 Metformin tablets per annum; Gliclazide 80g tablets were R1.056 million per annum and Glibenclamide 5 mg tablets at a cost of R1.071 million per annum. A total of R12.26 million was spent on glucose lowering medication per annum and that excluded the cost of disposable syringes. Because of the economic implications of type 2 diabetes, the prevalence of poverty especially in developing countries as compared to developed countries affects the quality of care resulting in mortality and morbidity.

2.8 MORTALITY AND MORBIDITY

Type 2 diabetes is the fourth leading cause of death in South Africa and is rated the fifth leading cause of death in most developed countries, because of its cardiovascular complications, (Ossei et al, 2003; Bjork et al, 2003).

The acute complications are caused by hyperglycaemia and resultant occlusion of the walls of small blood vessels. The persistent hyperglycemia is responsible for serious damage to large and small blood vessels (chronic complications) together with various organs in type 2 diabetes such as retinopathy, nephropathy and neuropathy, (Caro et al, 2002). The World Health Organisation (WHO, 2009), estimated that more than 180 million people had diabetes and the number is likely to double by 2030. They also estimated that almost 80% of deaths occur in low and middle income countries. They also added that the reduced blood flow together with neuropathy increases the chances of limb amputation. They concluded that without urgent action, diabetes related deaths will increase by more than 50%.

The disease also leads to damage to large vessels resulting in severe diseases such as myocardial infarction, cerebral infarction and gangrene. These cardiovascular diseases are the

leading causes of both mortality and morbidity in patients with diabetes mellitus because of the damage to large and small vessels caused by the persistent hyperglycaemia. More than 50% of deaths in the diabetic population are from coronary heart diseases and 15% are caused by stroke (Wens et al, 2008; Ossei, 2003;). Acute complications such as hypoglycaemia, (results of missing a meal or too much alcohol consumption without food or inappropriate treatment) are also common and fatal.

Small vessels damage due to chronic complications of type 2 diabetes also affect the vessels that supply the reproductive organs especially in men resulting in erectile dysfunction, (De Berardis et al, 2005). Some patients develop this problem on initial diagnosis and some at a later stage. Erectile dysfunction impacts negatively on an individual's health related quality of life. This is further supported by the results of a study they conducted to evaluate the longitudinal changes in quality of life over a period of three years in patients with type 2 diabetes, showed different outcomes for patients at different stages of erectile dysfunction onset. Findings showed that patients who developed erectile dysfunction at baseline and those who developed it during the process of the study which involved a sample of 1, 456 participants, 34% reported frequent erectile problems at baseline and 13.2% (192 participants) developed erectile dsyfunction during the follow-up. The results showed worsening in health related quality of life using SF-36 in patients who developed erectile dysfunction at baseline and in those who developed during the follow up, a deterioration in all SF-36 dimensions and a worsening in depressive symptoms preceded the development of erectile dysfunction. The onset of erectile dysfunction was associated with a further marked worsening in physical functioning and social functioning on SF-36 subscales, as well as mental components scores. No change in health related quality of life was observed in those participants who did not develop erectile dysfunction at all.

The cause-specific mortality rates in sub-Saharan Africa and Bangladesh during the period 1999-2002 showed that in all the sites, mortality patterns were characteristic of rural populations living in poverty where there are high rates of deaths from infectious diseases, such as tuberculosis followed by HIV/AIDS, diarrhoea, respiratory infections and malaria. Diabetes and Cardiovascular diseases form lesser components of mortality and were mainly evident in Southern Africa and Bangladesh, (Adjuik et al, 2006). A South African report on causes of death as reported by Statistics South Africa, showed that between 1997-2007, diabetes had 6% of deaths reported on death notification forms and 2.1% deaths taken from medical records, (Bradshaw et al, 2010). The main challenge that was raised on both reports is absence of reliable information especially in developing countries because medical

personnel are rarely present to record the details of deaths and information on causes of death, (Bradshaw et al, 2010; Adjuik et al, 2006)

It can be concluded that chronic diseases with type 2 diabetes included are of long duration onset and are characterised by slow progression, (Westaway et al, 2009). Most of these chronic non-communicable diseases that are common are costly because of their acute and long-term complications, (Kalk et al, 2000). The progression of the disease affects each patient's general health and well-being as discussed below.

2.9 TYPE 2 DIABETES AND HEALTH RELATED QUALITY OF LIFE

Type 2 diabetes is often characterized by slow onset of complications which are disabling and can ultimately be a major cause of morbidity and mortality, (Westaway et al, 2009). Health related quality of life (HRQOL) is defined as the degree to which a participant's health status affects their self-determined evaluation of satisfaction, (Skinner et al, 2001). According to Hu and Meek, (2005), the domain "health" can be described interchangeably by the three concepts which are: health status, functional status and quality of life. They further added that the term "health" not only refers to the rates of disease and disability but also to the positive state of physical, mental and social well-being. They also added that in relation to chronic disease like diabetes, improved health related quality of life will lead to fewer hospital visits, and hospitalization thus reducing healthcare costs. They urged that health professionals should work hard in order to understand the impact of HRQOL on diabetes and its management.

A randomized, controlled, double-blinded study by Testa et al, (1998), showed that improved glycaemic control in patients with type 2 diabetes is associated with short-term symptomatic, quality of life and health economic benefits. This conclusion was supported by changes from baseline compared to 12 weeks. There were improved fasting blood glucose and $HbA1_{C,}$ levels with active therapy versus placebo. There were also improvements in HRQOL which resulted in higher retained employment, less absenteeism, greater productivity, fewer bed-days and fewer restricted activity days. All the above factors improved the health economic benefits. Redekop et al, (2002), stated that type 2 diabetes affects each patient's HRQOL negatively because it is a chronic disease and its management involves strict dietary restriction, daily self-administration of medications as well as the fact that it has long term complications. The results of a study conducted which looked at HRQOL and treatment satisfaction in Dutch patients with type 2 diabetes in the Netherlands showed that patients without complications had a slightly lower HRQOL than people of the same age in the general population. It was also

evident that, patients who were using insulin, were obese and had complications had a lower HRQOL independent of age and sex.

The levels of fasting blood glucose and HbA1c in this group showed a negative association with HRQOL even though there were no significant differences when using multivariate analysis, (Redekop et al, 2002). This finding is in contrast to the findings of Testa et al, (1998) who found that decreased levels of blood glucose were directly associated with improvements in HRQOL. They concluded that obesity and complications of type 2 diabetes were important determinants of HRQOL. This conclusion is supported by Hu and Meek, (2005), who also discussed that patients with chronic diseases always rate their health as poor and are less satisfied with their lives when they cannot perform their activities of daily living.

The increased epidemic of type 2 diabetes has resulted in a rise in micro-vascular complications such as loss of vision and ischaemic heart diseases even before the diagnosis of this disease. This results from vasoconstriction caused by hyperglycaemia, (WHO, 2002). The incidence of type 2 diabetes is rapidly increasing amongst the adult population making its impact on HRQOL to be a public health problem not only to patients but to families, employers, healthcare providers and tax payers, (Luscombe, 2000). This challenge has led to a demand for use of appropriate tools which can measure lifestyle factors such as physical and mental health as well as social and personal role functioning, (Luscombe, 2000). Quality of life scales are important because they measure the effect of illness and its management as perceived by that individual and are designed to assess the effects of a disease and its interventions on the patient's sense of well-being, (Westaway et al, 1999). In order to prevent or delay the complications of the disease that may result in mortality and morbidity as well as adverse effects on health related quality of life, it is important for patients with type 2 diabetes to be engaged in the interventions detailed below.

2.10 OVERVIEW OF INTERVENTIONS TO MANAGE TYPE 2 DIABETES

Type 2 diabetes is referred to as a chronic disease of lifestyle and hence its management should focus on the principles of the Chronic Care Model. This model focuses on patients' involvement and taking responsibility for their own health. The specific guidelines for the chronic disease management which need to be followed are designed to ensure patients understand and accept their condition, (Funnel et al, 2009; SEMDSA, 2009; Srinivasan et al, 2008). These guidelines include the patients' understanding on how to use medication; the importance of lifestyle modification for disease control as well as the role of family support,

(Savoca et al 2004).Drugs play an important role in increasing insulin secretion and reducing insulin resistance.

A hypocaloric diet results in weight loss thus improving insulin sensitivity and glycaemic control. Exercise programmes have long been included in the management of type 2 diabetes because of their beneficial effects on body weight reduction and hence reduction of cardiovascular complications associated with this condition (Kriska, 2000; Cheng, 2005; BeLue et al, 2009). All forms or kinds of support are important in the management of chronic disease. Patients with chronic diseases need support from family members so that they can understand and accept their condition. Support in terms of information giving is important for patients to understand the disease process and hence acquire better control. Material support in terms of adequate finances also helps patients to be able to get to their consultation clinics with ease and to be able to pay for their medication.

Patients need to eat the right amount of food for their normal body mass. A diet that is high in starch and fibre but low in saturated fats is recommended even though it is still questionable as to what the correct diet is, (van der Merwe et al, 2000). They need to engage in moderate low endurance type exercise for ± 20-30 minutes, three or four times a week in order to improve their cardiovascular health, (Mullooly and Kemis, 2005; Stewart, 2004;). Weight loss and adherence to their prescribed medication will also help to improve glycaemic control, (Nathan et al, 2008; van der Merwe et al, 2000). Patients with chronic diseases need support from their families, caregivers and communities in order for them to accept their condition, (Wens et al, 2005).

According to the national standards for diabetes self-management and WHO, the management of the disease should not only concentrate on lowering blood glucose levels but also on the other factors of the syndrome (multifactorial approach), (Funnel et al, 2009; International Diabetes Federation, 2009).

The subdivisions of the management strategies in order to address all components of the syndrome will be discussed below.

2.10.1 **Role of Exercise**

Physical activity is important in the management of type 2 diabetes as it reduces the incidence of obesity that is directly linked to type 2 diabetes, (Ossei, 2003; Nelson et al, 2002; van der Merwe et al, 2000).

Normal glucose levels are between 4-6mmol/l, (Anderson, 1981). During exercise there is an increase in glucose utilization due to a rapid depletion of muscle glycogen and a decrease in free fatty acid (FFA) concentrations thus increasing muscle sensitivity to insulin. This maintains normal levels of plasma glucose throughout the exercise. Blood glucose regulation during exercise in patients with type 2 diabetes differs from the normal. As peripheral glucose utilization increases with the onset of exercise, plasma insulin concentrations fail to decline and hepatic glucose production does not increase above the basal rate. This causes elevated blood glucose concentrations to fall towards normal levels (Stewart, 2004).

Hyperglycaemia in type 2 diabetes mellitus is primarily as a result of both hepatic and peripheral insulin resistance. Raised plasma glucose levels occur because of increased hepatic glucose production and diminished glucose utilization by the exercising muscles. Many patients with type 2 diabetes are hyperinsulinaemic, although insulin levels are relatively low compared with glucose levels. Since carbohydrates are stored as glycogen in muscle and liver; and fatty acids are stored mainly as triglycerides in adipose tissue and also in muscle, it is important to establish the effects of exercise on the breakdown of glycogen and triglycerides into energy substrates. To improve glycogen and lipid metabolism, exercise programmes should be encouraged in the management of these patients. Regular exercise is also generally recommended as part of the management of type 2 diabetes mellitus because it increases muscle sensitivity to insulin, so normalising plasma glucose levels, and reducing several risk factors for cardiovascular diseases such as excess weight, excess plasma lipoprotein levels and mild to moderate hypertension (Seitz et al, 2011; Nathan et al, 2009).

Exercise programmes reduce body weight and triglyceride levels by reducing fat mass and producing anti-atherogenic blood lipid agents. These reduce risk factors for coronary heart diseases which occur as a result of obesity and type 2 diabetes. When aerobic exercise is combined with diet, it reduces serum tryglicerides and increases HDL cholesterol (Stewart et al, 2004; Sigal et al, 2004; Di Loreto et al, 2003), because exercise training increases the ability of muscle tissue to take up and oxidize esterified fatty acids and increases the activity of lipoprotein lipase in the muscles resulting in decreased LDL cholesterol levels whilst increasing HDL cholesterol (Sigal et al, 2004) also found that physical training decreases intra-abdominal (visceral) fat (large amounts of abdominal fat are a risk for glucose intolerance) with no effect on body weight, (Longo-Mbeza et al, 2010). These results show that exercise programmes improve insulin sensitivity even when body weight remains constant (Christian et al, 2008;

Stewart, 2004). Thus regular exercise improves glycaemic control in patients with type 2 diabetes and this effect can be maintained over some time.

Improving glycaemic control is the most effective way of preventing diabetic complications. Regular exercise also plays a role in reducing obesity, precisely the intra-abdominal accumulation of fat increases the development of insulin resistance. The majority of patients with type 2 diabetes are overweight or obese. Obesity in these patients is related to abdominal type (android) fat distribution, which is frequently the factor in the hyperglycaemia of these patients (Hu et al, 2001). It has been postulated that the prevalence of obesity may be influenced by environmental factors such as socio–economic status, education and leisure time physical activity (Conn et al, 2007; Kriska, 2000; Russell et al, 1999). In addition many patients with type 2 diabetes do not follow exercise prescriptions because of poor motivation, low self-esteem and this contributes to the coexisting disease (Redekop et al, 2002).

Weight loss improves blood glucose control by lowering the liver's glucose production and increasing insulin sensitivity. Weight loss and a decrease in body fat percentage, in the absence of dietary changes have been observed in patients with type 2 diabetes following an exercises programme (Coleman et al, 2005; Clarke et al, 2001).

2.10.2 **Role of Diet**

According to standards of medical care for patients with diabetes the major goal for diabetes care is improvement of glycaemic control by balancing food intake with insulin level, (Shojana et al, 2006; Steyn, 2006; ADA, 2002). A 16 year follow-up cohort study, where 84,941 female nurses free of type 2 diabetes diagnoses; cancer and cardiovascular diseases at baseline was done to determine the importance of lifestyle on the development of type 2 diabetes. A low risk group in developing type 2 diabetes was defined according to a combination of the five variables listed below:

- BMI<25kg/m^2
- a diet high in cereal fibre and polyunsaturated fat and low in trans-fat and glycaemic load
- engagement in moderate to vigorous physical activity for at least 30 minutes a day
- no current smoking
- a consumption of not more than half a drink of an alcoholic beverage per day.

A total of 3300 new cases of type 2 diabetes were documented from this cohort. The new cases of type 2 diabetes were overweight/ obese, engaged in poor dietary practices and

lacked physical activity, (Hu et al, 2001). This was regarded as the first cohort in determining the influence of diet on type 2 diabetes.

According to a statement by the Canadian Diabetes Association on guidelines for the nutritional management of diabetes mellitus in the new Millennium, all people should receive nutritional counseling from a dietitian. It is also emphasized that people with diabetes should be encouraged to obtain optimal metabolic control by balancing food intake with physical activity. Studies on prevention and control of type 2 diabetes indicate that food is the main risk factor in increasing the epidemic of the disease, (Gill et al, 2009; Mitra et al, 2007; Kruger et al, 2005;). The reason being that the media is used to market cheap processed food and also it encourages sedentary life styles through computer games and play stations, (Levitt, 2008).

In addition weight loss can only be achieved when energy expenditure is greater than energy intake. There is a limitation to some dietary approaches such as very low-calorie diets because they lead to the development of complications like gallstones. Low–carbohydrate, high protein and high-fat diets have been recently demonstrated by five randomized control trials to achieve better glycaemic control with six months than at 12 months interventions, (Klein et al, 2004; Pastors et al, 2002).

2.10.3 Quality of Care for Type 2 Diabetes

Type 2 diabetes is a multifaceted, chronic disease and needs health care professionals to address it as such for good quality of care. Chronic diseases are largely (47% of the total burden of disease in 2002) the primary concern of healthcare systems throughout the world and healthcare leaders are facing a challenge in managing the quality of health services for these chronic diseases, (Epping-Jordan et al, 2004).

Parchman and Burge (2003) pointed out that most studies on quality of care for adults with type 2 diabetes in the primary care setting report poor adherence to existing guidelines for managing diabetes. They further debated that quality of health care is frequently determined by systems or processes rather than individual behaviour. In their study they found that continuity of care may influence provider and patient behaviours in a way that will improve quality, (Brown et al 2002c). Worldwide there are national standards that have been set to manage type 2 diabetes. Diabetic self-management education (DSME) is the critical element of care in order to improve patients' outcomes and these national standards are designed to define diabetes self-management education and assist diabetes educators at various settings to provide evidence based education, (Funnell et al, 2009), see Appendix VII. The national and

international standards support the use of patient centered approaches-“Make diabetes everybody’s business”. This is a plan of action as set by the diabetes strategy of Africa in 2006. The main goal of the strategy is to empower families and communities about the seriousness of diabetes. A study conducted in Kenya showed that quality of care in managing type 2 diabetes is affected because organised diabetes care is lacking within the existing healthcare delivery systems, skilled manpower is scarce and in areas where diabetes care is available, patients cannot access them because of distance and high cost of travel, (Otieno et al, 2003). This situation is similar in all developing countries where resources are scare.

In South Africa a policy was developed by the National Department of Health, Pretoria, in 2007 on “Quality in Health-care for South Africa”. Amongst the different issues that were discussed the most important for improving quality of care and also to address the principles of the national standards of diabetes self-management was “Targeting quality assurance interventions” and the four main targets of interventions for diabetes management were:

- **Health professionals**: there is a need to develop expertise to help clinicians modernize their practice through continuing medical education conferences.
- **Patients**: Multiple approaches are essential in order for practitioners to address patients’ perceptions and concerns.
- **The community**: There should be active community involvement in order to improve the overall health status.
- **The health service delivery system**: Managers need to modernize health care delivery systems in order to improve quality of care.

Even though there is a said policy the quality of care is still poor and the challenges are stipulated in the same policy document as:

- Lack of resources
- Underuse of services
- Inadequate diagnosis and treatment
- Variations in services
- Poor information
- Inadequate referral system
- Drug shortages
- Records not well kept and
- Poor delivery systems

The impact of these factors on quality of care and health systems can be clarified by the findings of a survey of hospital out-patient services for chronic diseases in Gauteng province. This study showed that none of the professional staff had received additional training in chronic disease management. Out of eight hospitals who responded, seven reported their services to be understaffed whereby on average, nurses managed 33 patients per day and doctors 53 with a mean consultation time of nine minute, (ranging from 4-20 minutes). Patients' attendance rates ranged from 25% to 75%. Management guidelines were not frequently used and there was little patient education with regards to self-care. There was also a low rate of hypertension and glycaemic control, (Kalk et al, 2000). Similarly, a study conducted in Soweto outreach programme for chronic diseases showed that primary healthcare teams are overworked, poorly supported, poorly educated and frustrated. Primary health-care nurses had poor knowledge concerning the management of chronic diseases using the chronic care model, (Katz et al, 2009).

2.10.4 **Diabetes Self-Management Education Strategies (DSME)**

Diabetes self-management education (DSME) training has been considered an important part of type 2 diabetes management since 1930 because it encompasses teaching patients to understand type 2 diabetes thus gaining skills, teaching them how to eat healthily and engage in physical activities, thus making a behaviour change, (Norris et al, 2001). Because of a rise in cultural and environmental risks to chronic disease such as unhealthy diet and physical inactivity, self-management strategies are recommended to improve life expectancy, (Coleman and Newton, 2005). DSME should be an ongoing process which facilitates skills, knowledge and the ability of patients with type 2 diabetes to sustain diabetic self-care, (Funnell et al, 2009; Jack et al, 2004). DSME is reported to be the best method of managing type 2 diabetes and is the process whereby patients become involved through self-management and education strategies. Patients with type 2 diabetes should be involved in order to get the best outcomes for optimum management of the disease.

Patients with type 2 diabetes should also be empowered with knowledge so that they can change their behaviours. It is important to re-emphasize these strategies until patients can understand them because patients believe only in what they understand, (Mulloly et al, 2005; Savoca et al, 2004). Millan-Ferro and Caballero (2007) showed that diabetic self-management education (DSME) is the primary method of care, especially for people with type 2 diabetes. These programmes are recommended because they aim to assist patients with acquiring necessary knowledge, learning skills, behaviour change as well as modifying their attitudes

towards the disease and its management. These lifestyle changes will improve clinical outcomes, health status and health related quality of life.

A literature search conducted by Millan-Ferro and Caballero, (2007) through Pub med in which ten publications with evidence on culturally orientated programmes were accessed, the following was learned:

- Longer duration interventions were necessary for good outcomes (lowering HbA1c).
- A nutrition- based curriculum was more likely to improve the lipid profile.
- Family orientation was important for educational programs.
- Randomised-control trials were rated important because their results represented characteristics of a population. Culturally orientated studies took into consideration factors such as multiple social, financial and cultural aspects in a target population that are likely to improve diabetic-related outcomes.

An overview by Bradshaw et al, (2007), South Africa on strengthening public health in South Africa supports the fact that there should be an assessment of the relative burden that is attributable to selected risk factors, and interventions should be selected, based on their effectiveness, cost-effectiveness, local applicability, appropriateness and their effects on health inequalities. The analytical framework of type 2 diabetes self-management education interventions is shown in Figure 2 below:

2.10.5 **Analytical Framework for Diabetes Self-Management Education Interventions (DSME)**

(Adapted from Jack et al, 2004)

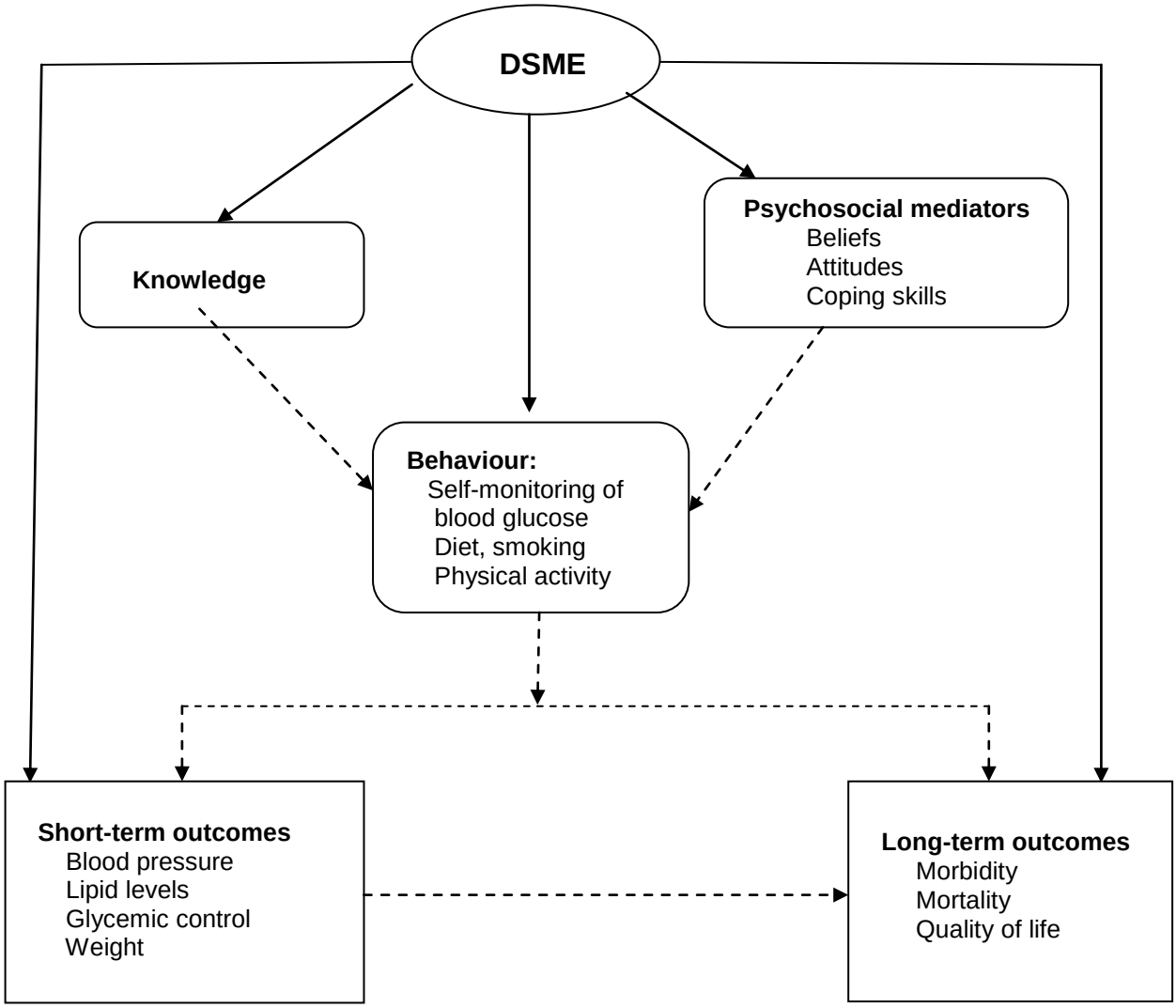

Figure 2.1: Analytical Framework for Diabetes Self-Management Education Interventions (adapted from Jack et al (2004))

The five components of DSME are described further below:

2.10.5.1 **Knowledge**

According to Glanz et al (1997), "Health education is the process of assisting individuals, acting separately or collectively, to make informed decisions about matters affecting their personal health and those of others". "Health behaviour is further described as referring to the actions of individuals, groups, and organization and to those actions' determinants, correlates and consequences including social change, policy development and implementation". This

means that health talks to patients should be goal directed and must not only address the individual but his/her community (people around him) as well.

Chronic diseases of lifestyle require an approach that focuses on primary health care by improving communication between patient and physician as well as identifying environmental problems from the patient's perspective, (Coleman and Newton, 2005). This means that there must be a good working relationship between patients, doctors, patients' families and communities in order to manage the disease. This relationship is referred to as a patient-centered approach. Patients' education should aim at enhancing personal control over day-to-day management in a way that will improve patients' quality of life, and discouraging the focus on curing the disease, (Sanden-Eriksson, 2000). This means that government, communities, service providers and patients with type 2 diabetes should work together to manage the disease, (National Department of Health policy, South Africa, 2007).

2.10.5.2 **Support**

Social support is very important in chronic disease management. This type of support makes the individuals or patients feel that they are cared for and this helps individuals to develop a sense of fulfilment within environments, (Westaway et al, 2005). The four dimensions of social support include: emotional or informational support, tangible support, affectionate support and positive social interaction. Socio-emotional and tangible support from family and friends are perceived important for patients with type 2 diabetes, (Westaway et al, 2005). This is because access to and utilization of medical services including hospital and nearby health care centres are related to socio economic status.

2.10.5.3 **Behaviour change**

According to the theory of reasoned action, for successful health education, it is important to determine the individual's behavioural intention which is determined by the patient's attitude towards performing that behaviour and his subjective norm associated with the behaviour (Glanz et al, 1997). This means that if patients strongly believe that there is a cure for their disease, it is very difficult to convince them that there is none unless one understands the attitudes and norms that drive that behaviour. Patients with positive beliefs will have positive attitudes towards behavioural change and will be motivated to comply and those with negative subjective norms will be less motivated and will resist behaviour change.

For successful type 2 diabetes management, individuals should pay more attention to food portions, weight control as well as engaging in exercises in order to improve their impaired

glucose tolerance and fasting glucose. This lifestyle modification will improve their glycaemic control (Mshunqane et al, 2004; Woelever et al, 2000,). Acceptance is the most important way of welcoming change, and patients need to be discouraged from using the information they are given to threaten themselves rather than improving their knowledge and lifestyle.

2.10.4.4 **Short and Long-Term Outcomes**

Short term outcomes such as reduction of blood pressure towards normal levels, weight reduction, lipid profile control and self- monitoring of blood glucose levels are achieved through DSME. Literature pertaining to how these effects are obtained has been discussed in sections above. Long-term outcomes such as morbidity, mortality and quality of life have been discussed under the interventions that delay the onset of type 2 diabetes complications.

2.11 **ADHERENCE TO TREATMENT REGIMES**

Green and Kreuter, (2000) justify that challenges with adherence are faced when patients compare themselves with others forgetting that each individual is unique and has his/her own limitations and abilities. They further state that patients need consistent encouragement about the benefits of their management in order to discourage them from negative thoughts. Glasgow et al (2001) describe barriers to diabetes self-management as occurring in a spherical pattern, where there are four components starting from the center to the outer shell as follows:

1. Internal factors- refers to physical
2. Psychosocial factors
3. External factors- refers to health systems
4. Cultural factors – this refers to the ability of an individual to change his/ her attitudes as influenced by his or her beliefs.

Non-adherence to medication or treatment regimens are reported to be influenced by psychological factors such as uncertainties about diagnosis, absence of symptoms, medication benefits, fear of side effects and complications of the disease, (Vermeire et al, 2008). They further debate that appropriate health beliefs such as perceived seriousness of the disease, impact of complications and perceived effectiveness of treatment results in better adherence.

Access to care and a good patient-physician relationship is also perceived to play a significant role in adherence to treatment. Other issues like depression, stress, alcoholism, and hypertension also affect adherence, (Grant et al, 2003). The language used for communication versus the patient's commonly used language is reported to affect adherence and this factor is also reported to be overlooked by clinicians because they tend to overestimate the abilities of patients. Schillinger (2002) states that common medical terms used at public hospitals such as

a stable blood pressure or instructions on medication dosage can be interpreted differently by different patients because of limited health literacy. In addition Nelson et al, (2007) concluded that even though veterans with poor diabetes control received appropriate medical advice, they still lacked motivation to make and maintain self-management changes. They further advised that targeted patient-centered interventions need to emphasise increasing self-efficacy and readiness to change. Below is the summary of the studies conducted between 2000 and 2009 outlining evidence on DSME strategies.

Table 2.9.4: Summary of Reports on Effects of DSME

Year	Data Source	Country	Study type	Sample size and study length	Results and Conclusion
2000	Samuel-Hodge et al	University of North Carolina-America	Focus group interviews. "Influences on day-to-day self-management among African-American women".	70 participants participated in 10 focus groups.	Three themes emerged from the focus groups which were:- spirituality; general life stress and multi-caregiver role and the third being diabetes impact which included feeling of dietary deprivation and fear about diabetes complications. They concluded that influences on diabetes self- management behaviours of this population may be best understood from a sociocultural and family context.
2001	Norris et al	Georgia	Systemic reviews of randomised control trials, using MEDLINE trials on Effectiveness of Self-management	Education resources information center; and Nursing and Allied health databases were used. A total of 72 studies were identified from 84 articles published between 1980 and 1999.	The results showed positive effects of self management training on knowledge, frequency and accuracy of self monitoring of blood glucose, self reported diet habits and glycaemic control in follow-ups <6months. Effects on lipids, BP and weight were variable. Longer follow-ups with regular reinforcement were sometimes effective in improving glycaemic control. Educational interventions that involved patient collaboration may be more effective.
2001	Piette et al	University of California	Systemic review a Randomised control trial. "Impact of automated calls with a nurse follow-up"	A total of 272 patients with type 2 diabetes. 12 months interventions using self care education telephone calls.	Results showed increased frequency of glucose self monitoring and foot inspections on experimental group. HbA1c levels showed clinical improvements but there were statistical improvements.
2002	Norris et al	Georgia	Meta-analysis " Self-management education"	A total of 31 studies out of 463 were included. Literature search was done from 1980-1999, using MEDLINE.	Results showed improvements in HbA1c, increases in contact time increased the effect; however the benefit declined after one to three months post intervention.
2002 (b)	Brown et al[b]	Texas	Literature reviews on "Cultural competence in diabetes self-management education".	A total of 256, randomly assigned participants. 12 months follow up.	DSME resulted in significant changes in HbA1c, knowledge, fasting blood glucose. Diabetes knowledge increased in both experimental and control groups.

Year	Data Source	Country	Study type	Sample size and study length	Results and Conclusion
2002	Keyserling et al	University of North Carolina	Randomized control trial. “Interventions to improve self-care behaviors of African-American women”	200 participants, 12 month follow up.	Diabetes knowledge improved and participants reported that they were satisfied with the intervention. There was a modest change in physical activity after 12 month intervention.
2003	Di Loreto et al	University of Perugia, Italy	Randomised control trial. “Counseling and the maintenance of physical activity”	A total of 182 participants were included in a 2 year follow-up intervention.	Results showed significant improvements in BMI and $HbA1_c$ in the intervention group, $p<0.05$. It was concluded that physicians can motivate most patients with type 2 diabetes to be engaged in long-term exercises.
2003	Epple et al	University of Arizona	Non-randomized study. “ The role of active family nutritional support”	A total of 163 participated in interviews regarding active family support on food.	Results showed that active family nutritional support is significantly associated with the control of triglycerides, cholesterol and $HbA1_c$.
2004	Jack et al	US	Understanding the environmental issues in Diabetes Self-management education research	Systematic Reviews a reexamination of 8 studies in community setting	All studies consistently reported on measurement of short-term outcomes. Four studies showed improvement in knowledge, family and peer support, as well as health behavior change in intervention groups.
2004	Van Rooijen et al	South Africa	Randomised control trial. “Effect of Exercise versus Relaxation on HbA1c in black females with type 2 diabetes mellitus”	A total of 158 participants were randomized to either exercise group or relaxation group. A. 3 months follow up.	There was a reduction of 0.39% HbA1c in the intervention group but there was significant difference between the intervention and control group.
2005	Brown et al	Texas	Randomised study. “Dosage effect of DSME for Mexican Americans.”	A total of 216 participants were randomly assigned to an extended 24h, education and 28h support versus a compressed 16h education and 6h support.	Both interventions showed statistical significance in reducing HbA1c and promoting improved metabolic control. Attending more sessions resulted in greater improvements in metabolic control.
2006	Shojania et al	Canada	A meta- regression-analysis.” Effects of Quality Improvement Strategies for type 2	A total of 66 trials were included using Medline and the Cochrane databases. Fifty were randomized control trials, 3	The results showed that most quality improvement strategies produced small to modest improvements in glycaemic control.

Year	Data Source	Country	Study type	Sample size and study length	Results and Conclusion
			diabetes on glycaemic control"	quasi-randomised trials and 13 controlled before and after trials.	
2008	Sacco et al	University of South Florida	Effect of a brief, regular telephone intervention by paraprofessionals for type 2 diabetes	Randomised control trial, 6 months follow up. 52 adults with type 2 diabetes.	The intervention increased frequency of exercise and feet inspection, improved diet reduced diabetes medical symptoms and lowered depressive symptoms. The intervention did not show significant improvements in HbA1c and BMI.
2009	Funnell et al	University of Michigan	National standards for DSME.	The emphasis on 5 guiding principles and 10 DSME standards of care.	The standards are responsible for improvements in knowledge, treatment strategies, educational strategies, psychosocial interventions and changing health care environments. The main purpose of DSME is to improve health status, clinical outcomes and quality of life.
2009	Lemmens et al	Erasmus University center	Professional commitment to changing chronic illness care: results from disease management.	52 Primary care professionals. 1 year follow up. Quasi-experimental design.	Professional significantly changed their system for delivering, namely self-management, support, decision support, delivery system design and clinical information system.
2011	Seitz et al	University of Zurich, Switzerland	Interventions in primary care to improve cardiovascular risk factors and HbA1c levels in patients with diabetes: A systematic review	Medline database from January 1990 to October 2008. Interventions were classified as professional if they concentrated on the effect on process of care; organizational, if they concentrated on effects on clinical and process of care outcome; patient-centered if they concentrated on effect on clinical outcomes.	Professional interventions seemed to improve clinical parameters such as HbA1c, cholesterol, LDL, and /or HDL, and blood pressure when combined with organizational interventions and patient- centered interventions.

2.12 SUMMARY OF THE REPORTS OF DSME

The main aim or objective across all studies is to show that different aspects of diabetes self-management education (DSME) improves knowledge, skills and glycaemic control in patients with type 2 diabetes. This is achieved by encouraging support from family; friends; healthcare professionals and church colleagues. There are four important components of DSME as described by Jack et al (2004), which are knowledge, behavior change, support (self-monitoring blood glucose, blood pressure control) and addressing short and long term goals (preventing mortality and morbidity) are important for better metabolic control. Studies which involved strict diet considerations for durations of three to six months showed improvements in blood glucose and HbA1c levels when compared to longer duration studies. It is reported that lipid improvements vary in interventions of more than six months but whether the improvement can be sustained for longer periods is still questionable. Interventions of longer durations result in greater improvements in metabolic control, (Brown et al, 2005).

The national standards for diabetes care also support the use of DSME as this improves knowledge, treatment strategies and social role fulfillment, (Funnell et al, 2009). There are national standards for management of type 2 diabetes that are released each year, but these standards never take into consideration the needs of different communities. Therefore the DSME strategies have been tested in different communities and they apply guidelines from the National Standards for Diabetes Care.

The studies summarized in table 2.9.4 above suggest that there is still a need for patient centered approaches, as it is clear that environmental factors play an important role in the prevalence of type 2 diabetes. The reviewed literature shows a wide variety of studies conducted ranging from single experimental studies to systematic reviews, which are characterized by different interventions, statistical methods, settings and outcomes. This makes assessing the effectiveness of specific interventions against others difficult. Findings of these studies show that DSME for more than six months empower patients with skills to change their behaviours and sustain good outcomes. Studies conducted on exercise or physical activity and diet show that low intensity exercise for durations of 30-45 minutes is effective in preventing the complications of this disease. Some studies indicated that family support is necessary for patients with chronic diseases for better acceptance and behavior change.

Although there are differences in the quality and type of studies in terms of the length of studies and how randomization was done, there is evidence that studies that are conducted for short durations result in significant change in HbA1c but the extent to which these results will be sustained is not known. In some studies participants were volunteers and there was no randomization, some were meta-analysis studies and some qualitative studies. In these studies, demographic characteristics have been used to predict and explain complex factors that contribute to variations in self-management behaviours and metabolic control. Culture is considered in these studies to define behaviours, attitudes, beliefs and practices by groups of people. These give a better understanding of the interactions and perceptions of different individuals with their communities, families and medical professionals, (Brown et al, 2002a).

Studies conducted in South Africa on management of chronic diseases in primary care setting between 2000 and 2009, indicate that the status of chronic disease management has not changed much in terms of resources, use of recommended guidelines and continued professional training. There is still a problem of lack of resources and professional staff training, which shows that the approach to the management of type 2 diabetes in this country should be designed according to what patients can use maximally to manage their disease. There is also a problem of lack of modern types of medication as opposed to developed countries. When all these barriers have been met, the quality of service delivery will improve. This shows that there is a need for restructuring of services for chronic diseases. Patients with chronic diseases need support from their families, healthcare professionals and their communities. Type 2 diabetes is every body's business and care needs to come from everybody.

Whilst the strategies of the DSME mentioned above have been used globally to manage type 2 diabetes, in the African setting especially in South Africa the use of family support to facilitate behavior change hence influencing glycaemic control seems to be less employed. This study is going to explore the effects of a family based intervention where education, physical activity and telephone calls will be implemented using the principles of DSME, (Jack el al 2004) on glycaemic control and health related quality of life after a six month intervention and again after six months follow up, during which time there was no intervention to evaluate the sustainability of the effects.

CHAPTER 3

3. OUTCOME MEASURES

3.1 INTRODUCTION

This chapter is aimed at providing a description of all instruments and tools that were used in the studies that are part of this thesis. It also provides justification for the selection of each tool.

3.2 QUESTIONNAIRES

Two questionnaires were administered to all patients who participated in the study.
Both questionnaires were tested for reliability and validity before they were administered to the study population.

QUESTIONNAIRE I: The Knowledge Questionnaire

According to Carey and Schroder (2002), knowledge is an important factor in the control of chronic diseases and it is believed to be a determinant of behaviour. A self-administered instrument was developed for this population using formative work from focus group discussions and interviews, item and factors analyses in order to assess knowledge needed for type 2 diabetes management and also to determine whether education programmes exist at Dr George Mukhari hospital. The development of this tool is described in chapter 4 and the validation and reliability is described in chapter 5.

The knowledge questionnaire was divided into three sections which also have subsections. The information described below was therefore recorded using this questionnaire:-

Section A: Demographic information

This section includes aspects such as age, gender, schooling, family support and settlement.

Section B: Socioeconomic status (SES)

A twelve item survey originating from a national probability sample of South Africans, residing in Soweto, developed and tested for validity and reliability by Westaway and Gumede, (2000), was used for this section. The twelve items covered the following sub headings:-_

1. Wall- which describes the predominant material of external walls of a house;
2. Floor- which describes the predominant material of the floor.;
3. Roof- which describes the predominant material of the roof;

4. Type of Housing-which describes the type of the house according to the municipality infrastructure;
5. Number of people living in the house hold;
6. Electricity: availability of electricity
7. Water supply: availability of water supply
8. Water supply: whether indoor or outdoor
9. Sanitation: availability of sanitation
10. Type of sanitation;
11. Total income per month;
12. Mode of transport to hospital. The results drawn from this tool gave an indication of the socio- economic status of the population.

This tool was considered appropriate for use in this population because of its origin, validity and reliability.

Section C: Knowledge

Four sub-sections which described knowledge, education, behaviour on exercise and behavior on food were included here.

Sub-section 1: Knowledge

This consists of 23 questions and the first three questions were not scored.

Only 20 questions gave a knowledge score about symptoms and management of type 2 diabetes.

Sub-section 2: Education

Includes information on education from the clinic and procedures done during the clinic day. It also includes information on each participant's emotions about type 2 diabetes.

Sub-section 3: Exercise behaviour

Participants were asked questions pertaining to their exercise behaviours and had to provide reasons for not participating in exercises.

Sub-section 4: Food behaviour

Participants were asked about their food choices and whether they were adhering to the recommended diet.

Questionnaire I is a valid and reliable tool with a Cronbach's alpha of 55% (95%CI: 55% to 60%) and intra-class correlation coefficient of 71% (95%CI: 69% to 71%), (see Chapter 5). The main purpose of developing this questionnaire was firstly to establish the existing education programmes (what is currently happening at the clinic), the appropriateness of the education programmes and to evaluate the outcomes of the intervention. Secondly, this tool was used to gather demographic information of all participants consulting at Dr George Mukhari hospital diabetes clinic, establish their level of knowledge regarding type 2 diabetes management and their views about the type of management they receive at this clinic.

QUESTIONNAIRE II

A literature search by, Luscombe (2000) using MEDLINE between 1985 through to February 2000 on development of measures and systemic evaluations of HRQOL, in individuals with type 2 diabetes showed that the most frequently used instruments to evaluate HRQOL were derived from the Medical Outcomes Study (MOS) mainly the SF-36 and SF-20. Follow up studies for one year showed that SF-36 was not a good measure of HRQOL in patients with diabetes because it showed no relationship between its scores and HbA1c. There was no good clinician-patient relationship when comparing scores on general health perceptions; mental health; energy; role functioning (emotional) and pain, as doctors reported higher scores compared to patients. DIMS showed a good patient-clinician agreement and good correlation with levels of HbA1c when compared to other scales.

The DIMS measures the health status of patients as they perceive it. The DIMS was originally developed by Hammond and Aoki, in 1992. It is widely used internationally because it is a valid and reliable tool that is useful in describing health related quality of life for patients with diabetes. It has four domains and a total of 44 items. The domains are: - symptoms; well-being; diabetes related morale; and social role fulfillment. Each domain has a reverse key that is designated by R. The reverse key gives the highest score to a less frequently occurring symptom. A high score indicates good quality of life and a low score indicates poor quality of life, (see Appendix VII).

A total score is measured as the sum of all the items in that domain and a higher score represents a better quality of life, (Tsai-Chung et al, 2006). Correlations between subscale and total scale scores ranged from 0.46 to 0.97.Cronbach's alpha for subscales and total score ranged from 0.60 to 0.94 and test-retest correlations for these ranged from 0.61 to 0.77.

The health related quality of life questionnaire (DIMS) is recommended because it is accurate and gives diabetic specific results of the quality of life. This questionnaire was used to evaluate the impact of type 2 diabetes on an individual's health related quality of life.

3.3 MEASURES OF OBESITY

The following anthropometric measurements were considered as important indicators of obesity.

BMI (Body Mass Index)

According to WHO, BMI or Quetelet index, gives a guide to a healthy weight range according to a person's height and weight. It is widely used to estimate the prevalence of obesity because it is easy to calculate. Even though BMI has been found to be useful in predicting the risk of cardiovascular diseases and type 2 diabetes, its results do not account for variations in body fat distribution and abdominal fat mass across populations, (Dalton et al, 2003). According to WHO, BMI assumes that the shortest man is about 1.58m tall.

It was developed between 1830 and 1850 by Adolphe Quetelet. It is defined as the individual's body weight (in kg) divided by the square of his or her height in meters (m^2).

The following references are recommended by WHO for diagnosis.

- $<18.5 kg/m^2$ = underweight
- $18.5 – 24.9 kg/m^2$ = Normal
- $25 – 29.9 kg/m^2$ = Overweight
- $30 – 34.9 kg/m^2$ = Grade I Obese
- $35 – 39.9 kg/m^2$ = Grade II Obese
- $> 40 kg/m^2$ = Grade III Obese (Morbidly obese)

Height

Height was measured in order to calculate the BMI

Body Weight

Body weight is considered an important measure of obesity because it provides an indication of each participant's mass in kilograms. Body weight together with height determined each participant's BMI.

Waist-Hip Ratio (WHR)

Waist-hip ratio (WHR) is used as an indicator of the health of a person and the risk of developing serious health conditions, (Dalton et al, 2003). People with more weight around the waist, “apple shaped” are more prone to risks of developing major diseases such as diabetes and cardiovascular diseases compared to people with “pear shaped” bodies. A WHR of ≤0.85 for women and ≤1.0 for men correlates with good general health, (Brook et al, 2001). WHR was determined as the ratio of waist and hip circumference.

WHR is used as a measurement of obesity, especially as an indicator of developing chronic diseases such as diabetes and cardiovascular diseases. According to Dalton et al, 2003, WHR> 1.0 in men and > 0.85 in women is classified as obese and individuals are at risk of cardiovascular disease and diabetes.

Table 3.3, below illustrates normal values of WHR for males and females.

Table 3.3: Normal Values of WHR for Men and Women

WHR	Men	Women	Classification
Normal	≤1.0	0.85	Healthy
High	>1.0	>0.85	Obese

The table above shows normal references for waist-hip ratio, (Dalton et al, 2003; Brook et al, 2001).

3.4 EXERCISE FITNESS LEVELS

The Six-Minute Walk Test (6MWT)

According to Enright (2003), a six minute walk test was chosen by the American Thoracic Society Pulmonary Function Standards Committee because it is easy to administer, it reflects activities of daily living and it is better tolerated by patients.

The 6MWT is preferred to other walk tests because it is self-paced which means that patients cannot push themselves beyond their individual endurance levels. The 6MWT has fewer contraindications, such as unstable angina. There should be a measured distance of not less than 20 metres where participants should walk repeatedly for six minutes. When performing the 6MWT, the individual’s rate of intensity of the exercise or activity, the rate of perceived exertion (RPE) as perceived by that individual should be checked, (Karavatas and Tavakol, 2005). The age-predicted maximum heart rate (80% [220-age]) should also be determined.

RPE

The Borg scale is a simple method of rating perceived exertion (RPE). It is commonly used by coaches to gauge athlete's level of intensity in training and competition. The most commonly used scale is a 15 point scale (6-20), (Bautmans et al, 2004), Enright (2003). The scale shows that there is a correlation between an athlete's rate of perceived exertion and their heart rate. In this study RPE was used as an indicator of exercise fitness where the resting pulse and resting blood pressure were used for cardiac stability, (van Rooijen et al, 2004).

Distance

For healthy individuals of the same age group, a distance range of 400 to 700m is considered normal, (Enright, 2003). For individuals with health related problems, a distance less than 400m is indicative of reduced exercise capacity. Arlsan et al (2007) in their study to determine the prognostic value of a 6 minute walk in patients with heart failure found that a distance ≤300m was a prognostic marker of subsequent death in patients with mild to moderate heart failure.

3.5 BLOOD CHEMISTRY

According to the WHO (2002), blood glucose concentration is the simplest indicator of the adequacy of carbohydrates metabolism of a patient. Blood glucose results only reflect the immediate carbohydrate metabolism but not a retrospective or prospective assessment. The continuous checking of blood tests is an integral part in the management of type 2 diabetes, because the results provide the evidence about self- monitoring of blood glucose, which can be good or poor, (SEMDSA, 2009; American Diabetes Association 2002). Blood tests that can be taken at any time of the day are referred to as random blood samples. These blood investigations are more convenient because patients can perform them at home when they feel the signs of the disease (signs of low or high sugar levels).

In this study random blood tests were carried out because the primary outcome was to to detect a clinically relevant lowering of HbA1c levels by 1% after 12 months following the six months intervention. The second reason was that the results of study three (chapter 6) that described the dermographic characteristics of all participants showed that a total of 99 participants (73%) were using insulin, within this group, 93 participants (69%) were using insulin + pills and six participants (4%) were using insulin only. It was difficult to get them to fast because they were injecting at home early before getting to the hospital and had to eat 30

minutes thereafter. Taking random bloods was the only solution to overcome a possible clinical bias when using fasting bloods.

The following random blood samples were taken for analysis:

- **HbA1c**: a measure of glycosaturated haemoglobin. This test gives a retrospective average level of blood glucose over eight to 10 weeks. It is important for monitoring blood glucose control, and it can be taken at any time of the day (WHO, 2002). It is recommended that this test should be carried out every three months or at least twice a year for a patient that is on follow-up diabetic medication to monitor the disease progress, (ADA, 2011). A systemic review by WHO experts (2011), concluded that HbA1c can be used as a diagnostic test for type 2 diabetes and 6.5% is a cut point for diagnosing diabetes. However the is no evidence on formal recommendation for levels below 6.5%.

  In addition to the above information, the international committee formed by experts from ADA, the European Association for the study of Diabetes and IDF also recommended that HbA1c test results of 6.5 % are indicative of diabetes and ranges between 5.7% to 6.4% are indicative of prediabetes (individuals at high risk of developing diabetes. HbA1c levels below 5.7% are normal. They further stated that in the event where HbA1c tests were not available or were gave inaccurate results because of pregnancy or disorders that affect the haemoglobin, other test such as random blood sugar tests can be used to confirm type 2 diabetes.

- **Random blood glucose**: The main purpose of using this test was to encourage patients to adhere to self monitoring of blood glucose (SMBG) guidelines, Patel et al (2007) and it is also a recommendation for all patients with type 2 diabetes in South Africa to perform regular self-monitoring of blood glucose, (Joshi et al, 2008) Previous studies have highlighted that patients exposed to use of a meter might achieve an increased sense of personal control over their disease, (French et al, 2008) This is facilitated by the observation of the positive impact of their behaviour on their blood glucose levels. In addition, Martin et al (2006), concluded that SMBG was associated with decreased diabetes- related morbidity and all- cause mortality after a 6.5 years follow up. This indicated that SMBG may be associated with better disease control or healthier lifestyle. Similarly, van Zyl (2006), reported that recent systemic reviews concluded that SMBG was associated with improvements of HbA1c of 0.39%. This information suggests that analysis of random blood glucose for the purposes of this study will not change the information

about HbA1c (which is the predictor of glycaemic control). SMBG also distinguishes among preprandial and postprandial hyperglycaemia and this provides an immediate feedback to patients about the effect of food choices and medication on glycaemic control, (Dailey, 2007).

Random blood tests also called simple glucose tests are taken regardless of when the patient last ate and it important to check blood glucose levels when a patient needs to take medication. When using this test for diagnosis, a level of 11.1mmol/l confirms diabetes, between 7.8-11.0 mmol/l is prediabetes and less than 7.8 is considered normal.

Dyslipidaemia is a common problem in patients with type 2 diabetes and it accounts for 50% of the population risk of myocardial infarction, (Raal et al, (2006) Solano et al 2006; Gregg et al, 2005;) . The international guidelines recommend that a five yearly screening is important. In South Africa, because of limited resources in the public sector, the screening test is done at least once yearly. Random blood tests are sufficient but in cases where total cholesterol levels are higher than 5mmol/l and triglycerides higher than 1.7 mmol/l, fasting blood tests are recommended, (Butler, 2009; SEMDSA, 2009).

The following random bloods for lipogram were investigated:

- **Cholesterol**
  i. Total cholesterol with ranges between 2.5 - 4.5 mmol/l.
  ii. HDL should be greater than 1.1mmol/l.
  iii. LDL should be less than 2.6mmol/l.

- **Triglycerides**: a measure of certain kinds of body fat which influences type 2 diabetes control, and should be less than 1.7 mmol/l.

Table 3.4 below, shows the normal values of glycaemic control, blood pressure and lipids as recommended by the Standards of Medical Care in Diabetes-2011 and the American Diabetes Association:

Table 3.4: Normal Blood Levels

Glycaemic control	**Normal values**
HbA1c	<7.0%
Blood glucose (before a meal)	5.0-7.2 mmol/l
Blood glucose (after a meal)	< 10.0 mmol/l
Blood pressure	<130/80mmHg
Lipids	
LDL	< 2.6 mmol/l
HDL	>1.1 mmol/l
Triglycerides	<1.7 mmol/l

The table above shows the normal blood values as recommended by the Standards of Medical Care in Diabetes-2011 and American Diabetes Association.

These bloods are determinants of glycaemic control and were used in this study not only as a confirmation of diagnosis and its extent but to assess whether the intervention caused a change in the control of patients with type 2 diabetes.

The outcome measures detailed in this chapter will be used in studies three and four which are aimed at answering all the objectives of this thesis.

CHAPTER 4

4. STUDY I: QUALITATIVE APPROACH-PRELIMINARY STUDY

KNOWLEDGE OF PATIENTS OF TYPE 2 DIABETES vs PERCEPTIONS OF THEIR MANAGEMENT TEAM ABOUT MANAGEMENT OF THEIR DISEASE.

(As a basis for the development of a tool to measure knowledge and attitude)

4.1 INTRODUCTION

This chapter describes how qualitative data from focus group discussions and interviews were used to develop a quantitative tool, namely the knowledge and attitude questionnaire described in Chapter 3.

4.2 FOCUS GROUP DISCUSSIONS

Focus group interviews are among the most widely used research tools in the social sciences. The “focused group interview” as focus groups were originally called, originated in the office of radio research at Columbia University in 1941 when Paul Lazarsfeld invited Robert Merton to assist him in the evaluation of audience response to radio programmes. In this study, members of a mass- media studio audience listened to a recorded programme and were asked to press a red button when they heard anything that evoked a negative response- anger, boredom, or disbelief and to press a green button whenever they had a positive response. These responses and their timing were recorded on a polygraph-like instrument. At the end of the programme the audience was to focus on the positive and negative events they recorded and discuss the reasons for these reactions. The focus group interviews began from then, (Stewart and Shamdasani, 1990).

According to Berker and Bryman (2005) focus groups are discussions that are organised to explore a specific set of issues and involve some kind of collective activity. They are indicated when a researcher wishes to explore peoples’ experiences, opinions and concerns. Focus group discussions are viewed by most researchers as generating rich data because respondents rise to challenges and defend views. The individuals are selected because they have certain characteristics that are common, in relation to the topic of the focus group (de Vos et al, 2002).

The discussions should be carefully planned and designed to obtain perceptions in a permissive, non-threatening environment. The interview should be guided by a facilitator or moderator. The moderator asks questions and always guides the audience to focus on the topic (de Vos et al, 2002; Stewart and Shamdasani, 1990). Focus groups produce real-life ideas and opinions in social environments. Focus group questions should be open-ended to allow the subject enough time to comment, explain and to share experiences on the issues under discussion. Questions should be more general at the beginning and become more specific and focused as the group continues (Berker and Bryman, 2005).

According to Krueger (1994), focus groups should consist of about 8-12 participants even though smaller sizes of between 6-9 participants are also accepted. Focus groups with specialised participants are usually best accomplished by smaller groups. This allows an in-depth discussion of the topic as well as observation of naturally occurring interactions (Berker and Bryman, 2005; Kitzinger, 1995).

Focus groups are used for the following reasons:

- As a self- contained method in studies in which they serve as principle sources of data.
- As a supplementary source of data in studies that rely on some other primary method.
- Are used in multi-method studies that combine two or more means of gathering data (de Vos et al, 2002).

In summary, focused group interviews should be free-flowing, relatively unstructured and easy to conduct without direct input from the researcher. However the results cannot be generalized since the sample is not randomised. Focus groups are not appropriate for testing hypotheses because of the small sample size, so the results cannot be generalized. (Berker and Bryan, 2005; de Vos et al, 2002; Strauss and Corbin, 1990)

4.3 THE PURPOSE OF THE STUDY

The main aim of conducting the focus groups was to develop a knowledge and attitude questionnaire which was used to address objectives 1 and 2 of the thesis, which were:

1. To determine the demographic background (including socio-economic status (SES)) of patients with type 2 diabetes from poor socio-economic backgrounds at Dr George Mukhari hospital.
2. To determine the availability of diabetes education programmes at Dr George Mukari hospital.

Before answering the objectives of the main study, the following specific objectives for the two focus groups which aimed to develop a knowledge questionnaire were identified:

- firstly to establish what patients with type 2 diabetes think about the various opinions that they are given by the management team about the medical management of their disease.
- secondly, to establish how health care professionals (management team) feel about the services given to patients with type 2 diabetes.

4.4 METHODOLOGY

Two focus groups were conducted to answer the specific objectives of the study mentioned above. The format shown below for the design and use of the focus groups was followed as recommended by (Stewart and Shamdasani, 1990).

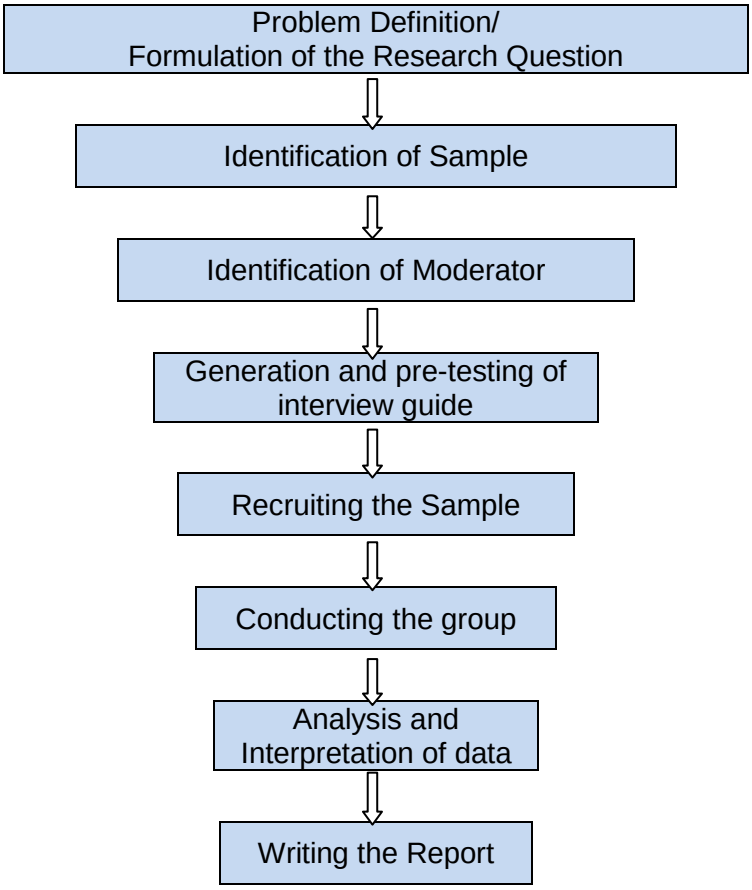

Figure 4.1: The Steps Followed when Conducting Focus Group Discussions

4.4.1 **Design**

A qualitative design was used.

4.4.2 **Focus Groups Participants**

Selection of Focus Groups Participants

Selection criteria for the study included patients with type 2 diabetes for at least one year, between thirty to sixty five years of age (Patients' focus group). Participants for the patient focus group were recruited from the outpatient diabetes clinic at Dr George Mukhari, (DGM) Hospital, South Africa, after a twenty minute talk about diabetes. Twenty patients with type 2 diabetes volunteered to participate and gave their telephone numbers for follow-up reminders. Only ten participants were randomly selected to participate in the study. Healthcare professionals were selected based on their expertise in the chronic disease management, working in community settings (public health) or working directly with patients with type 2 diabetes. One moderator for each group was identified, (Stewart and Shamdasani, 1990; Krueger, 1994). All participants volunteered to participate in this study and gave their consent. There were no incentives provided. Participants were allowed to withdraw at any time if they wanted.

4.4.3 **Sampling Method**

A sample of convenience was used.

4.4.4 **Sample Size**

A total of 23 individuals participated in this study. The patients' focus groups discussion was formed by 10 patients with type 2 diabetes. The professionals' focus group discussion was formed by eight (8) healthcare professionals which were a doctor; two professional nurses; two physiotherapists involved in community based rehabilitation; two physiotherapists involved in chronic disease management including type 2 diabetes and a dietician. There were interviews conducted and the following professional participated: a doctor (professor specialized in endocrinology) working in a referral clinic; a professional nurse working in a poly clinic; a pharmacist; a traditional healer and a faith healer. The traditional healer and a faith healer were included because patients use them and this results to delay in consulting western medication.

4.4.5 **Ethical Considerations**

The Committee for Research for Human Subjects at the University of the Witwatersrand (WITS) granted ethical clearance, ethical form no M060955 and a signed consent form was

obtained from all patients who volunteered to participate in the study. The CEO of the hospital also gave written consent, the sister in charge and the staff members at the diabetic clinic were fully informed about the study, (See Appendix III).

4.4.6 **Formulation of Questions**

Questions for the two focus groups were formulated according to the reviewed literature on focus group discussions, so that the purpose and the objectives were addressed, (Krueger, 1994; Stewart and Shamdasani, 1990). The two focus groups were asked different questions. The reason for this difference was that, the patient focus group was held mainly to explore patients' ideas as well as information they are given about their disease and understanding of its global management strategies. However, the professional focus group was conducted mainly to establish how they feel about the services given to patients with type 2 diabetes at the public hospital, (Stewart and Shamdasani, 1990).

The interview questions were designed such that the language was easy to understand. The first questions were on general knowledge and towards the end of the session, they focused on management strategies as well as factors affecting adherence, (Krueger, 1994). Questions for the patient focus group were pre- tested on a sample of three staff members with type 2 diabetes working at Dr George Mukari hospital. Questions for the professional focus group were tested on three professionals working with chronic diseases.
This exercise was done to check the quality and appropriateness of the questions.

All the participants who took part in the pre-testing of questions were not included in the main focus group discussions, (Stewart and Shamdasani, 1990).

4.4.7 **Invitation Letters**

Invitation letters were sent four weeks before the date of the focus group discussions. Patients were reminded by telephone/e-mail two weeks prior to the date and again called two days before the date. The purpose of a focus group discussion was explained to the patients and health care professionals, in the invitation letters and again prior to the discussion sessions, (Becker and Bryman, 2005; Stewart and Shamdasani,), (see Appendix I).

4.4.8 **Process of Focus Group Discussion**

The patients' focus group included 10 patients with type 2 diabetes and was conducted at Dr George Mukhari (DGM) diabetes clinic seminar room. The professionals' focus group included

eight health care professionals. The discussions were conducted for 1hr 30min in the morning. Both the moderator (professional nurse) and a research assistant were present. Five patients were recruited from the Diabetes Support Group at DGM hospital and another five patients were recruited from the clinic. Their telephone numbers were kept for follow up calls to remind them about the date of the focus group, (Krueger, 1994; Strauss and Cobin, 1990).

Both focus group discussions were tape recorded and the process of tape recording was previously practiced on a conversation of two people before the focus groups (see Appendix III). A free-flowing discussion was encouraged during the focus group discussions and the moderator followed a pre-planned script with questions that were selected to address the objectives of this study, a guide of questions is included in appendix 1.

In-depth interviews were conducted for health care professionals who could not attend for various reasons. These were the endocrinologist, pharmacist and nurse working in poly clinic. These interviews were also tape recorded. Field notes were kept by the moderation during the discussion.

4.4.9 **Transcription of the Tapes**

This was done following all the interviews. Three different people transcribed each tape. The researcher checked that the transcripts were the same. The transcripts were read a number of times and checked with the field notes to get a feel of what was being said. The transcripts from the professional focus group were given to two other colleagues who were part of the focus group discussions to check. The transcripts from the patients' focus group were given to one participant and the moderator of the group to check. The transcripts from the interviews were given back to each participant to check. There were no changes made in all the transcripts. Transcripts were checked back and forth and concepts or ideas in both focus groups and in depth interviews with the endocrinologist, traditional healer, pharmacist, faith healer and a professional nurse in polyclinic were identified.

4.4.10 **Themes**

The data were categorized into concepts and thereafter into categories by the researchers, using axial coding. The data from the categories were then grouped into themes, (Strauss and Cobin, 1990; Becker and Bryman, 2005; de Vos et al, 2002). Themes were developed from each focus group following all the responses through using a vertical and horizontal approach, across the groups and these were checked for consistency by an independent coder who had

experience in qualitative research. Themes with similar meanings were then grouped together and a questionnaire was developed from this grouping, (Krueger, 1994; Stewart and Shamdasani, 1990; Strauss and Cobin, 1990). The field notes were used to check all of the above.

4.4.11 **Trustworthiness**

An independent coder was appointed to confirm whether coding was done properly and to confirm the themes (Bailey, 2007). The coder was not involved in the focus group discussions. A copy of the research protocol, the two focus group responses and the interviews were provided. A meeting was arranged with the coder to discuss the themes, and there was 90% agreement on the themes that were developed. The independent coder was selected because of his familiarity with qualitative research.

4.5 **RESULTS**

Results of all responses are presented in tables.

Table 4.5 (a-c) below illustrates the codes, categories and themes developed from the focus group discussions and the in-depth interviews.

Table 4.5(a): Patients' Responses (n=10), Categories, Sub-Themes and Themes

Coding	Categories	Sub- theme	Theme
Knowl	**Knowledge** **-Causes** (Insulin resistance- secretion and action, family history, pregnancy, stress, unhealthy eating, overweight and physical inactivity) **-Complications** (heart problems, impotence, kidney problems, stroke, amputations, blindness, foot problems, non-healing wounds) -educate people close/around to you about these signs. **Management** – stop fatty food - take medication - exercise - stop eating sweets	-causes -complications - management	Knowledge
Contrl	**Control** -eat properly -take medication -avoid getting angry -avoid heaters -weight control **Behavior change** -no cure but control stop smoking and drinking -eat properly -avoid fatty foods and sweets (take small amounts of everything in community gatherings) -exercise	Acceptance -the disease is not curable - the disease can be managed by lifestyle changes.	Behavior change

Coding	Categories	Sub- theme	Theme
F	**Fear** - affects you mentally - death sentence - thought of complications - learn to live with it - self responsibility (I told myself it's about my life) **Stigma** -community response -avoidance by people signs of increased or decreased sugar levels.	Negative thinking (paranormal belief)	Fear
Supp	**Support** - tell people around you - believe better with support - what am I going to eat? - where am I going to get money to buy food?	- emotional support - material support - informational support	Support
Awareness prog	**Awareness programs** - public education - campaigns - radio and T.V shows	Patients need:- - information - education - material support	Education programmes

The following themes were developed from categories: - knowledge, behavior change, fear, support and education programmes.

Summary of all themes:

- Behaviour change
- Knowledge
- Support at three levels (emotional, material and information)
- Education programmes (information support)

Table 4.5(b): Professionals' Responses (n=8), Categories, Themes and sub-Themes

Coding	Category	Sub-theme	Theme
Knowl	**Knowledge** - understand disease and risk factors, management (how and when to take medication) and benefits. - understand the role of healthcare professionals. - education on food - power of word of mouth		Health communication
Socio-econ	**Socio- economic issues** - patients' affordability (difficult to change what the patient can afford) - environmental factors (assess each family's relationship with food)	Affordability	Environmental factors.
Ad	**Adherence** - knowledge about food - medication (don't take medication when feeling well) - seeking for a cure (some patients will consult for traditional medicine first and western medicine later)	Lifestyle changes	Western medicine and traditional medicine/ (Behavior change)
Cult	**Cultural issues** - weight control (African image of women vs man) - food portions for men	Culture	Culture and health

Coding	Category	Sub-theme	Theme
Supp	**Support** - african men don't cook -educate the person preparing food - educate each family closely especially young generation.	Support	Information support
Behav contrl	**Behaviour change** - control of food portion - weight control (patients should be asked if willing to lose weight and how) - exercises - bio-psychosocial approach	Lifestyle change	Health Behaviour change
Limit Res	**Limited resources in public sector** - contact time with the patient is limited - no time to listen to patients' problems - patients develop attitudes towards health professionals.		Patient-doctor interaction
Biopsych Appr	**Bio-psychosocial approach** -work holistically - modify activities of daily living with patients' environment - empower young generation - accommodate patients' beliefs (don't be judgmental)		Patient centered approach

The following themes were developed from categories: - health communication, environmental factors, western medicine versus traditional medicine, culture and health, information support and patient- doctor interaction.

Summary of all themes:

- Behaviour change
- Health communication (knowledge)
- Health and culture
- Patient- doctor interaction
- Patient- centered approach

Table 4.5(c), below shows the responses from in-depth interviews of other: professionals, (n=5).

Table 4.5(c): Responses from In-Depth Interviews of Other Professionals, (n=5)

Coding	Category	Sub-theme	Theme
Und	Understanding - epidemic - metabolic syndrome (asymptomatic yet sick) -chronic disease models -cultural issues of concern - explain the importance of taking medication at specified times)	No cure but control	Knowledge
Stig	Stigma - weight loss and HIV - avoidance by people around		Behaviour change
Compl	Compliance - adherence to medication - behaviour control (accept that there is no cure but control)	Self responsibility	Compliance/ Behaviour change
Qual care	Quality of care -no access to newer medicine - hospital short staffed -long hospital queues. -limited time with patients (less information given)	Limited public sector resources	Availability of human resources.
Rapp	Rapport - tell the truth about the disease -spend time and listen to patient's problems (this develops trust). - continuity is a problem (drs & nurses rotate)	Limited public sector resources	Availability of human resources.

Coding	Category	Sub-theme	Theme
B	Beliefs -patients respect their religious beliefs even if is not allowed medically. - weight loss a problem - start by consulting other expects and come to hospital with complications.	Lifestyle change	Health belief systems and Indigenous knowledge system (IKS)
Tm Wk	Team work -Drs, traditional healers, faith healers should come together to help the patient. -nurse based intervention		Education programs and patient centered approach

The following themes were developed from categories: - knowledge, behavior change, availability of human resources, health belief system and education programmes.

Summary of all themes:

- Behaviour change
- Health communication
- Availability of human resource
- Education programmes
- Patient centered approach education programs.

The summary of all themes that developed from the two (2) focus groups and in-depth interviews (vertical and horizontal approach) are as follows:

1. Health communication (knowledge)
2. Behaviour change (which is influenced by fear and lifestyle changes)
3. Environmental factors (including socio economic status, health and culture)
4. Support
5. Patient-doctor interaction (patient centered approach)

Data from patients' and professionals' focus group discussions are also presented according to the Health Belief Model (HBM). This was done to clarify the patients' beliefs about their own health and to determine the barriers towards behaviour change. The Health Belief Model is described to be the useful and applicable framework for the planning and implementation of education programmes to encourage health behaviours, (Hazavehei et al, 2007).

Below is Table 4.5(d) which shows the responses of both patients' and professionals' focus group discussions presented according to the Health Belief Model (HBM).

Table 4.5(d): Patients' Responses Using the Health Belief Model (HBM)

Concept	**Definition: Type 2 diabetes**	**Application**
Perceived Susceptibility	-Pregnancy; Hereditary factors; stress; obesity; unhealthy eating; physical inactivity; hypertension. Professional focus group felt that westernization, physical inactivity and uncontrolled food portions increase the prevalence of type 2 diabetes.	Affects both males and females between ages of 30-65. Professionals felt that westernization affects both the young and old (20-65 years). Patients have to understand that the disease is a metabolic syndrome (**Theme:** Knowledge**)**

Concept	Definition: Type 2 diabetes	Application
Perceived Severity	Patients believe that the consequences of increased blood sugar levels are significant enough to cause complications and they should be avoided i.e. avoid getting angry, avoid heaters- (non-healing wounds), avoid sweets, avoid fatty foods. Professionals felt that patients do not have an understanding of the disease despite the talks that are given to them. They believe that patients consult other sources before western medicine (e.g traditional healers) because they are looking for a cure.	They believe that if the disease is not controlled by medication and behaviour change, this will lead to development of complications. Patients should understand that there is no cure but the disease can only be controlled by medication, exercise and following a proper diet. (**Theme:** Behaviour change)
Perceived Benefits	Patients believe that eating healthily, exercises, and taking your medication as prescribed as well as having family support will delay the disease complications. Professionals believed that weight loss, lifestyle modification and informational support by educating the spouses as African men do not cook. Patients also need material support as many of the patients miss their appointments because they lack funds for transport. They also need emotional support from family and friends.	Understanding that there is no cure for the disease but it can be controlled. There is a need to educate the person preparing food, friends and family. (**Theme:** Support)
Perceived Barriers	Patients identified their main barriers as acceptance, socio-economic status and avoidance by people around them (community). They always ask themselves the following questions after the diagnosis: - Why me? What am I going to eat? What are the people going to say about me? Where will I get money to buy food?	As individuals, they see the disease as a death sentence and a stigma especially losing weight with HIV epidemic. Support makes them feel better.

Concept	Definition: Type 2 diabetes	Application
	Professionals believed that patients' barriers included cultural issues, limited resources in public sector, attitudes towards health professionals, poor adherence and socio-economic issues.	Women would be resistant to losing weight because they want to maintain their image. Limited resources make doctors cut down the contact time with patients and they do not listen to patients' problems; this creates poor attitudes towards health professionals. Because the disease is a syndrome; patients do not see why they should take their medication regularly when they in fact do not feel sick. (**Theme:** Education)
Cues to action	Patients believe that, if they can be empowered more through educational programmes (Radios/T.V.), control can be better. They feel that there are fewer programs on diabetes awareness. Professionals believe that type 2 diabetes management should be nurse -based, more public education and patients should be told the truth about the disease management and the availability of human resources.	Diabetes needs to be treated like HIV- more knowledge should be given to people through campaigns and television (T.V) shows. A patient- centered approach. (**Theme:** Patient-entered approach)
Self-efficacy	Patients believe that change of behaviour is important for better control. Professionals believe more awareness about the disease and understanding how the patient feels is important.	They are confident that they will engage themselves in exercises and change their behaviours about food with support Nurse based intervention

The table above shows patients' responses from the focus group discussions using the Health Belief Model (HBM). It is clear that patients know the causes of the disease but they experience problems with behaviour change because there is stigmatization with the disease such as losing weight, as this is associated with HIV and AIDS in their communities. Patients need support in order to manage their condition well. Health professionals indicated that health communication (between the patient and a doctor) is important for better management of type 2 diabetes.

The figure below illustrates the convergence of the different themes that immerged from the focused group discussions and interviews.

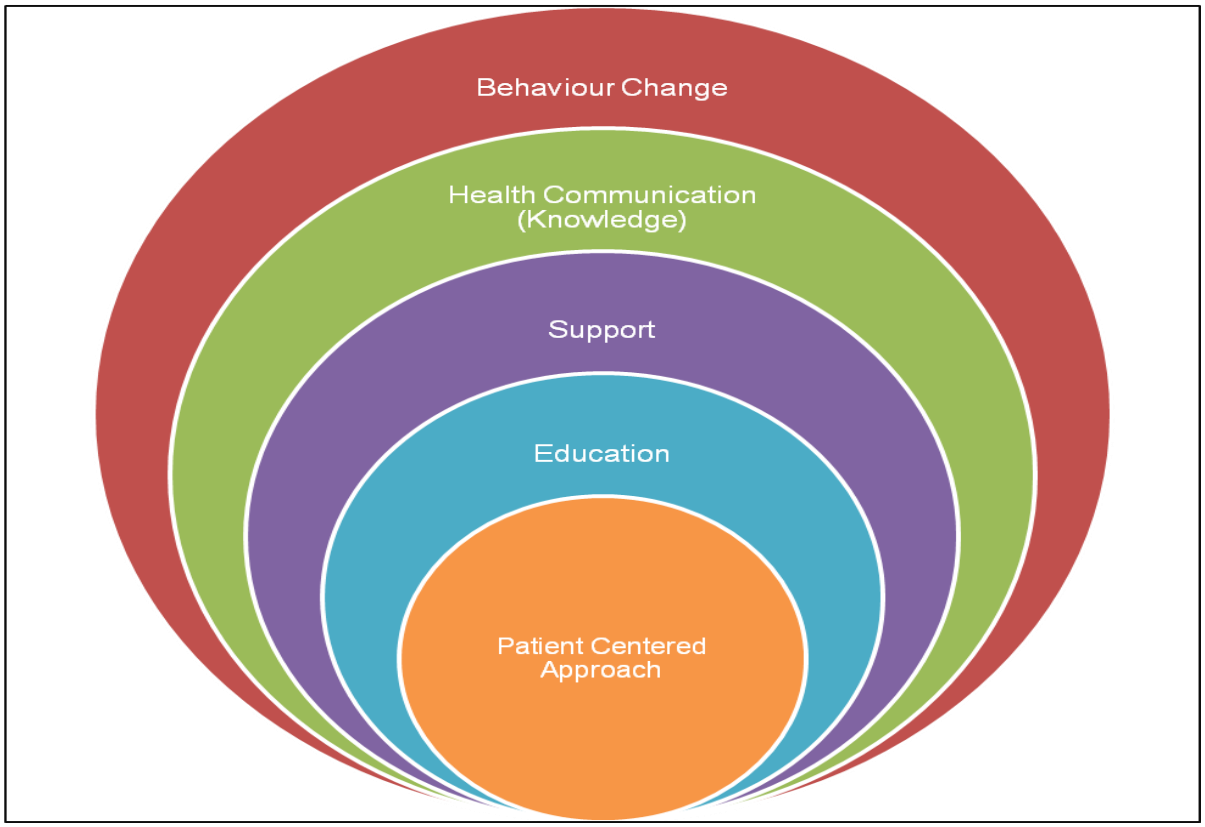

Figure 4.2: Convergence of the themes from the Qualitative Approach

4.6 DISCUSSION

4.6.1 Health Communication (Knowledge)

Chronic diseases of lifestyle require a sense of coherence management where patients, the doctor, family and community work together to manage the disease. Patients' education should aim at enhancing personal control over day-to-day management in a way that will improve their quality of life, rather than focusing on curing the disease, (Joshi, 2008; Jack et al, 2004; Wagner, 2001). This means that government, communities, service providers and patients with type 2 diabetes should work together to manage the disease. Successful chronic disease management is dependent on effective, systematic and interactive communication between patients and service providers as well as the health system with which they make contact.

This approach focuses on primary care by improving communication between patient and physicians as well as identifying environmental problems from the patient's perspective, (Coleman and Newton, 2005). Knowledge emerged as the main problem in the management of type 2 diabetes by patients and healthcare professionals. Patients showed the importance of knowledge in how they interpreted the diagnosis of type 2 diabetes. The knowledge component of type 2 diabetes management according to the healthcare professionals in this study included participants' understanding of types of food, food portions and appropriate times that food should be eaten. In this study some patients knew about the recommended food practices but because of socioeconomic barriers, such as a lack of finances, they were unable to acquire the right kind of food. Some of the challenges to dietary adherence are avoiding favourite foods, selecting healthful alternatives, time management, (patients find it difficult to plan food with insulin or oral medication) and social support (as most women prepare food for their families), (Savoca et al, 2004). Patients need to eat the right amount of food for each individual's normal body mass, i.e high starch and fibre but low in saturated fats (there is still a gap as to what is the correct diet), (van der Merwe et al, 2000). They need to engage in moderate low endurance type of exercises for ± 20-30 minutes three or four times a week in order to improve their cardiovascular health, (Mullooly and Kemis, 2005; Mshunqane et al, 2004;). Weight loss and adherence to their prescribed medication will also help to improve glycaemic control, (Nathan et al, 2008; van der Merwe et al, 2000).

In this study, patients showed an understanding of the causes and complications of the disease but most of them understood these negatively (as fears- as confirmed by participant 6 when asked about the reaction when diagnosed with diabetes: *"A death sentence, you think of*

the complications". Participant 10 - a 28 year old male; *"My family is gone" (when thinking about impotence)*. They lacked a sense of positive thinking, namely that managing the disease well with good control will delay the onset of complications. This is mainly influenced by lack of knowledge and perceived ideas about the disease process.

It is therefore clear that, to improve quality of care in this population, especially type 2 diabetes, a collaborative model of chronic disease management, which will include education and support, should be developed. Professionals on the other hand felt that patients should be encouraged to understand the meaning of chronic disease and its management as referring to medical interventions that can only control but not cure the disease, (Green and Kreuter, 2000). They also emphasized that patients should know that the disease is a syndrome; which means they need to treat the disease continuously even if they don't feel sick, as confirmed by participant 1; *Patients always come to consult medical help when complications set in because they say: "why do I have to take medication even though I don't feel sick".* This typifies a barrier to adherence to their management and this leads to poor disease control. A review on effects of quality improvement strategies for type 2 diabetes showed that interventions that involve patient education, case management and team changes improved glycaemic control especially when medications were adjusted without awaiting a physician, (Shojania et al, 2006)

4.6.2 **Education**

According to Glanz et al (1997), "Health education is the process of assisting individuals, acting separately or collectively, to make informed decisions about matters affecting their personal health and those of others". Health behaviour is further described as referring to the actions of individuals, groups, and organizations which are aimed at bringing about change whether social change or policy development. This means that health talks to patients should be goal directed and must not only address the individual but his community (people around him) as well.

In this study, patients reported that education programmes should be more public just like HIV education programmes. They felt that more awareness campaigns as well as radio and television education would also help to empower their care givers at home. This is confirmed by participant 4: "*What are people going to say about me when I lose weight"*. They went on to say that, one only knows about diabetes when one is diagnosed or there is someone with diabetes at home. Professionals also emphasized that diabetes education should be nurse-

based in order to improve knowledge and thus prevent complications. This supports the patients' suggestion of more awareness and education programmes for the public.

Professionals also added that patients should be told the truth about the lack of human resources in the South African public sector. The lack of human resources results in patients being given short consultation times and they also have to wait for long periods of time. This shortage may have a negative impact on patients' attitudes. This is confirmed by participant 4: "*We should explain to patients and listen more; don't be judgmental*". It is therefore important that behaviour should be evaluated individually and the Health Belief Model helps to bring clarity to individual health behavior (Glanz et al, 1997).

An impact on behaviour can only be made when the patient has a good understanding of the disease process (informational approach) as well as disease management. This is confirmed by participant 3: "*At work we were supplied with a "finger lunch" every time we have a meeting, now I have to change the way I eat-diabetic food is expensive".* Patients need to be encouraged to actively participate so as to "voice out" their fear and strengths about the management, (Green and Kreuter, 2000; Glanz et al, 1997). Interestingly in the professional group and in-depth interviews, cultural issues were considered to be the most challenging barrier to the management of type 2 diabetes (e.g, women in this population prefer not to lose weight because it is culturally unacceptable and the fact that losing weight stigmatizes them as being HIV positive). This happens because the community doesn't know much about diabetes but they know and have seen on television that people with HIV lose weight.

The above challenge supports the importance of considering an individual's integration of cognition, beliefs/values and practices as explained by the Indigenous Knowledge Systems Theory, (Durie, 2004). The system looks at behaviours that occur naturally regardless of the fact that the individuals are empowered in terms of education (this is also referred to as traditional science). Because of the diversities in beliefs and values with different ethnic groups, it is important to consider each individual's environmental factors through indigenous knowledge systems, (Helman and Purnell, 2006;Glanz et al, 1997;Spector, 1991).

4.6.3 **Behaviour Change**

Patients and professionals perceived behavior change as a barrier in terms of acceptance and this makes it difficult to control the disease ("What are people going to *say about me," "how am I going to live with this disease"),* as said by participant 4. The overall goal for the management

of type 2 diabetes is to help patients and their families gain knowledge, life skill changes, and the support needed to achieve optimal health (Woelever et al, 2000). The success of this management requires that health professionals understand the lifestyle, cultural beliefs, attitudes, family and social networks of the patients (Greenhalgh et al, 1998). They describe culture as a learned behaviour that is passed from one generation to another and that gives people different attitudes and beliefs.

According to the theory of reasoned action, for successful health education, it is important to determine the individual's behavioural intention which is determined by the patient's attitude towards performing that behaviour and his subjective norm associated with the behaviour (Glanz et al, 1997). This means that if patients strongly believe that there is a cure for their disease, it is very difficult to convince them that there is none unless one understands the attitudes and norms that drive that behaviour. Patients with positive beliefs will have positive attitudes towards behavioural change and will be motivated to comply and those with negative subjective norms will be less motivated and will resist behavior change.

For successful type 2 diabetes management, individuals should pay more attention to food portions, weight control as well as engaging in exercises in order to improve their impaired glucose tolerance and fasting glucose. This lifestyle modification will improve their glycaemic control (Mshunqane et al, 2004; Woelever et al, 2000). Acceptance is the most important way of welcoming change, and patients need to be discouraged from using the information they are given to threaten themselves rather than improving their knowledge (‘*You think of the disease as a stigma', 'You think of the complications'), as said by participant 2.*

Challenges are faced when patients compare themselves with others forgetting that each individual has his/her own limitations and abilities. Patients need to be encouraged always to "think out of the box" in order to discourage them from negative thoughts, (Green and Kreuter, 2000). Professionals felt that behaviour change also forms a barrier to disease management. "*Patients need to cut down their food portions, they also need to exercise; but they need to know what is regarded as sufficient exercise or physical activity and how much is sufficient?"* participant 3.

4.6.4 **Support**

Support is very important in chronic disease management. Patients need emotional support from family and friends *(Why me?),* participant 4. They also need material support *(Where am I going to get money to buy food?)*, participants 5 and 6. Low socio economic status makes it difficult to manage the disease. This is because access to and utilization of medical services including hospital and nearby health care centres are related to socio economic status (Polednak, 1989).

In this study both patients and professionals agreed that changing lifestyle e.g food choices needs sufficient finances and most patients struggle to meet these requirements because they do not have sufficient finances to cope with the specific food requirements.

Patients with type 2 diabetes also need informational support, *(You think of it as a death sentence especially when you think of the complications)*, participant 1. Support networks give patients strength and a sense of living, (Coleman and Newton, 2005; Schillinger, 2002).

Professionals felt that it is important to consider patients' environmental backgrounds because these will affect the outcome of the disease management. They emphasized that the relationship of each family with food will affect the individual. "*Each patient should be assessed individually, families are unique -it is very difficult to change what a patient can afford",* participants 4 and 5. Professionals also felt that it is important to give information to the wives, relatives or children of each male patient on how to prepare their food because black African men-culturally do not cook. This is thus a barrier to disease management.

4.6.5 **Patient Centered Approach**

In this study, the problem of limited time for consultation with the doctor was seen as one of the possible problems that could contribute to patients being non adherent in their management; "*Patients need more time so that they can ask questions and be asked by the doctor how they feel",* participant 9. This was felt more strongly by the professional focus group than by the patient group. Chronic diseases need optimal care therefore limited time given to patient's consultations make providing comprehensive care a challenge (Nelson et al, 2007).

"A bio-psychosocial approach is important for these patients", participant 3. *"We need to be accommodative, work holistically and work hand in hand with one another as a health team",* participant 4, 5 and 7. When using a patient- centered-approach health care providers can

provide care that is more effective over time. This approach helps to set goals collaboratively and explores patients' understanding of the disease and its treatment options.

4.7 CONCLUSION

The information collected in this study addressed the objectives of the study because both the patient's feelings about the disease and the professional were addressed in five themes which were consistent with literature. Both focus groups indentified gaps in the management of type 2 diabetes, which if they can be addressed the management of type 2 diabetes can improve. The five themes showed that it is important to reinforce knowledge of patients through health communication; encourage behaviour change through lifestyle modification with support and incorporate a patient-centered approach. Each patient's environmental background should be considered.

Chapter 5 below describes the preliminary studies that were conducted to develop a knowledge tool from the themes stated above. It will also describe the tests done to establish the validity and reliability of the tool.

CHAPTER 5

5. STUDY II: PRELIMINARY STUDIES

VALIDITY AND RELIABILITY TESTING OF A DEVELOPED KNOWLEDGE QUESTIONNAIRE AND THE DIABETES IMPACT MEASUREMENT SCALE (DIMS)

5.1 INTRODUCTION

This chapter gives a detailed description of the methodology followed in the preliminary studies conducted to address the specific objectives of this chapter, i.e objective 1 and 2 listed below:

Objective 1

- to develop and test the validity and reliability of an instrument to measure the level of knowledge in adult patients with type 2 diabetes.

Objective 2

- to test the validity and reliability of an international standardized questionnaire that measures health status in adults with type 1 and type 2 diabetes.

5.2 BACKGROUND

Diabetes is considered to be part of a group of diseases referred to as “chronic diseases of lifestyle”. This group of diseases is often characterized by the onset of complications which are disabilitating and can ultimately be a major cause of morbidity and mortality, (Cheng, 2005).

According to Coleman and Newton (2005), chronic diseases are responsible for 59% of deaths and 46% of the global burden of disease. Due to the severity of “chronic diseases of lifestyle”, there has been a demand for tools which can measure knowledge and lifestyle factors such as physical and mental health as well as social and personal role functioning, (Stewart et al, 1988). Quality of life scales are important because they measure the effect of illness and its management as perceived by that individual. These scales are also designed to assess the effects of a disease and its interventions on the patient’s sense of well-being, (Westaway et al, 2005; Stewart et al, 1988).

Teaching individuals with type 2 diabetes about how to manage their disease has been the important goal of diabetes management since 1930. “Healthy people 2010” also aimed at

increasing the knowledge of individuals with type 2 diabetes who received education from 40% to 60% in order to prevent acute and chronic complications, (Norris et al, 2001). Currently there are existing questionnaires that measure the level of knowledge for the general population, this knowledge tool is going to assess the levels of knowledge of patients consulting at Dr George Mukhari hospital. The use of the developed questionnaire is going to describe the problems experienced by patients with type 2 diabetes in managing their disease. We hope that when these problems are known, the quality of care will improve resulting in reduced patient attrition, (Paddock et al, 2000)

In South Africa, the main objective for diabetes and chronic disease management is to improve quality of life but there are few studies that concentrate on assessing the patient's sense of well-being and quality of life (Westaway et al, 2005). According to Westaway (2009), chronic diseases accounted for 37% of deaths in 2000 in South Africa. Currently there is no existing diabetes specific tool that is used in South Africa to measure the impact of type 2 diabetes on each patient's quality of life hence DIMS will be tested for validity

5.3 AIM

The purpose of this study was to establish the validity and reliability of an instrument to measure knowledge and an international validated questionnaire to measure health related quality of life (DIMS) in adult patients with type 2 diabetes which will be used to answer objectives one (1) to four (4) of the thesis mentioned in page 9.

OBJECTIVE 1: THE DEVELOPMENT AND TESTING VALIDITY AND RELIABILITY OF THE INSTRUMENT TO MEASURE KNOWLEDGE

5.4 DEVELOPMENT OF THE INSTRUMENT (KNOWLEDGE QUESTIONNAIRE)

5.4.1 Stage 1: Item Generation

To generate items that measure the important aspects of type 2 diabetes literacy, a knowledge questionnaire was developed from two focus group discussions and interviews (already described in chapter 4). Questions were identified from the five themes which emerged, viz:

- Knowledge/health communication
- Education/informational support
- Behaviour change/environmental factors
- Support at three levels (emotional, material and information)
- Patient centered approach

Themes were used as a guide to develop questions that addressed the following:

- knowledge in the form of health literacy: this included glucose monitoring, acute and severe complications, perceptions of general health or well being.
- education programmes available at the clinic: this included information taught, follow up.
- patients' behaviour towards food and exercise: this included physical activity knowledge as well as food practices.
- kinds of support available for each patient, patients had to mention the kind of support they had.
- quality of care at the clinic in relation to each patient's expectations, this included time commitment.

The instrument comprised of five (5) separate domains. All questions were developed and retained in specific domains using guidelines of developing questions for a knowledge questionnaire from Advocacy, Communication and Social mobilization (ACSM) and "A manual for health services researchers" (WHO, 2008; Francis et al, 2004). The developed questions were given to three participants of the patients' focus group as well as three of the professional group, to indicate those questions they believed captured both patients' as well as professionals' concerns about the management of type 2 diabetes.

Questions were considered meaningful if they were not leading, simple and understandable and were mentioned by at least two (2) participants in each focus group. Specific questions were kept in specific domains as indicated by the content validity ratings. After this process the researcher and the supervisor went through the list of questions and agreed that the selected questions would answer the objectives of the thesis after validation.

The following subsections were developed for easier scoring of the questions, viz: symptoms and complications of type 2 diabetes; education; emotions about diabetes; exercise behaviour, and food behaviour.

5.5 METHODOLOGY

5.5.1 Sample

A sample of convenience was used. The study population was selected from a group of patients who were receiving their diabetes treatment at Dr George Mukhari hospital out-patients diabetic clinic. These patients were randomly selected using simple computer generated random sampling.

5.5.2 Sample Size

A total of 25 patients with type 2 diabetes (10 males and 15 females) were selected from a larger population of patients at Dr George Mukhari hospital diabetes outpatient clinic. This is the group of participants who participated in study 1, described in chapter 4 previously. Each patient completed both questionnaires to answer objectives 1 and 2.

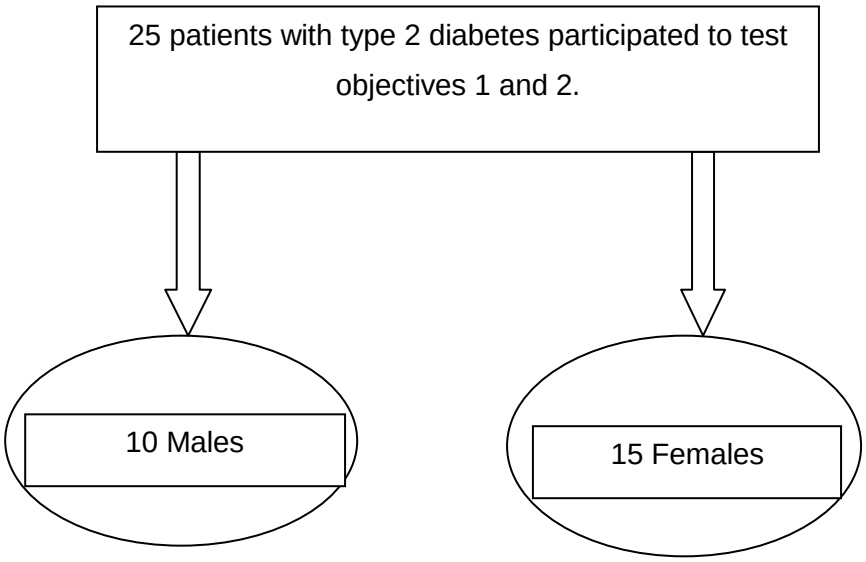

Figure 5.1: Distribution of Sample of this Study

5.5.3 Design

A prospective correlation study design was used. As part of this prospective study, all patients were given questionnaires and the same patients were enrolled for the second part, reliability (to test correlation), which was undertaken one week later.

5.6 ETHICAL CLEARANCE

The Committee for Research for Human Subjects at the University of the Witwatersrand granted ethical clearance, (ethical clearance certificate no M060955) to conduct the study and collect blood from patients with type 2 diabetes, (see Appendix III). In this study each patient

was given an information sheet and written consent form to obtain their permission to participate in the study which they had to sign. Each patient was allocated a reference number which was applicable to all forms used for data collection and blood specimens. The anonymity of patients was maintained in all stages of the research. All participants were free to decline at any-time during the course of the study without prejudice. A separate application to get permission to conduct the study at Dr George Mukhari hospital out-patient diabetes clinic was made through the CEO of the hospital, consent was granted, (see Appendix III). The sister in charge and the staff members at the diabetic clinic were fully informed about the study,

5.7 PROCEDURE

Two instruments, an instrument measuring knowledge and the other measuring the health status (DIMS and Knowledge) were administered to each patient, one after the other. A multilingual (professional nurse) research assistant was asked to administer the questionnaires. The diabetes outpatient clinic days at Dr George Mukhari hospital were on Mondays and Thursdays, weekly. The patients' addresses and telephone numbers (at least two contacts) were noted to facilitate follow up.

Patients who completed questionnaires on Monday for the first time were called back on Monday of the following week for a re-test and those who came on Thursday for their first test were called back the following Thursday for the re-test (a seven day interval). This period was considered long enough for the purposes of this study to prevent direct recall of answers. Patients were also asked to document the time it took them to complete each questionnaire. All patients who experienced problems (most patients had eye sight problems even though the font was 14) to complete their questionnaires were assisted by the research assistant.

5.8 STAGE 2: VALIDITY AND RELIABILITY OF A QUESTIONNAIRE

5.8.1 Validity

- **Face validity**

  Face validity refers to the scientific method of validity that gives a subjective judgment of measures on the surface, (Field, 2005). In this study face validity was obtained by asking patients to indicate whether the questions that were asked in the questionnaire were relevant to type 2 diabetes.

- **Language validity**

  The questionnaire was originally developed in English and was translated to two commonly spoken languages, which were Setswana and IsiZulu (back and forth translation), by professional translators from the department of Arts and Culture in the City of Tshwane. These translators were recommended by the University of Limpopo (Turfloop Campus) linguistic department. The questionnaire was translated from Setswana and IsiZulu back to English by two colleagues in the Department of Physiotherapy, University of Limpopo-Medunsa campus. The translation was done following guidelines as proposed by Beaton, (Hartvigsen et al, 2005). The two colleagues were chosen because their home languages were IsiZulu or Setswana, they worked in a community setting and they had good English skills. Four health professionals who were working at the diabetes clinic and were specialists in other chronic diseases also reviewed the questionnaire. We found this review fundamental for this questionnaire because the purpose of the questionnaire was to test knowledge of patients with type 2 diabetes consulting at Dr George Mukhari hospital regarding the management of the disease.

- **Content validity**

  This is also a subjective measure which asks whether the content of a measure covers the full domain of the content. It involves the use of experts in the field or individuals belonging in a target population, (Field, 2005). To assess content validity in this study, the questionnaire was administered to two members of the patients' focus group and two members of the health professionals' focus group to verify whether the questions captured what was raised as concerns. The four point Likert scale was used to finalise the questions in their organized sections and to measure satisfaction with questions. Responses 1 = very dissatisfied, 2 = dissatisfied, 3 = satisfied and very satisfied. The Likert scale was chosen because the content validity was used to establish the perceptions of the patients and professionals who would have been involved in focus group discussions. The four point Likert was scale also preferred because it is commonly used in patient satisfaction questionnaires, (Paddock et al, 2000).

Table 5.8, below illustrates the domains of the developed instrument.

Table 5.8: The Domains of the Developed Instrument (Knowledge Questionnaire)

(See Appendix VI)	Very Dissatisfied	Dissatisfied	Very Satisfied	Satisfied
I. Symptoms (questions : 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, and 17)				
II. Diabetes Education (**question : 18)**				
III. Emotions about Diabetes (**question : 19)**				
IV. Behaviour on Exercise (question : 20)				
V. Behaviour on Food (questions : 21, 22, 23, 24, 25, 26)				

Content validity of all questions in the developed knowledge questionnaire was assessed as indicated above. The questionnaire was rated good (satisfied) and relevant (none of the questions were rated as dissatisfied) by the health professionals and patients with type 2 diabetes. Some questions were reworded as a result of recommendations from content validity, (see Appendix VI, after piloting).

- **Internal consistency**

  Cronbach's α coefficient was used to test the internal consistency that is the homogeneity of the questionnaire items. Internal consistency was satisfied if Cronbach's α coefficient ≥ 0.70, and item (question) validity was satisfied if item-scale correlation achieved ≥ 0.40.

5.8.2 Reliability

The test-retest reliability of the questionnaires was assessed by calculating the intraclass correlation coefficient (ICC), (Portney and Waltins, 2000). An ICC above 0.75 indicates excellent reliability, an ICC between 0.4 - 0.75 indicate fair to good reliability, and an ICC below 0.4 indicates poor reliability. A p-value of less than 0.05 was considered significant.

5.8.3 Results

Each question was assessed separately first for item reduction (for factor analysis) and as domains using SPSS version 17.0. A range of 40- 70% was considered significant. Questions were deleted automatically by the system if they appeared on two or more factors or if they had a low correlation coefficient (< 0.40). A low correlation coefficient indicated difficult questions for patients. However questions were retained if they were considered clinically relevant and a

research assistant would then assist in explaining the questions when patients experienced problems.

A t-test was also used to confirm the results of the factor analysis for those questions that were deleted. A p value < 0.05 was considered significant.

5.8.3.1 **Factor analysis**

Factor analysis was done to establish whether the questions asked related well to constructs that this questionnaire intended to measure, (Field, 2005).

After content validation of questionnaire items, all items that address similar constructs were grouped together as factors and statistical analysis using SPSS was performed.

A total of 33 questions of the questionnaire constituted 60 items.

A total of six out of 60 questions were removed/reduced during factor analysis, p=0.000, confirming that these questions were too easy and leading. These were:

- <u>sub-questions 1 and 2:</u>

  1.1 Are you taking insulin injection and pills or pills only to control your diabetes?

  Injection □ Injection & pills □ Pills only □ Diet & Exercises □

  1.2 How would you rate your overall health?

  Excellent □ Good □ Fair □ Poor □

  2. Compared to one year ago, how would you rate your overall health?

  Good □ Fair □ Same □ Worse □

  The results of the content validity suggested that these questions should be interpreted descriptively as they give subjective perceptions or subjective evaluation. These questions were not scored as a result.

- <u>sub-questions 7 and 9:</u>

  7. If yes what do you do in this situation? Yes □ No □

  9. Do you keep your weight under control? Yes □ No □

  These questions were found to be interdependent with the preceding questions 6 and 8. These were not scored because if participants get question 6 correct, they would know the

answer to the next question. However the five questions were kept because they were relevant to type 2 diabetes education.

- sub-question 13:

  13. Which of the following are complications of diabetes?

  Blindness □ Foot Ulcers /unhealed wounds □ Renal failure □ Heart diseases □ Peripheral neuropathy □

  In this question peripheral neuropathy was removed because most patients would not understand an addition of two other complications in this question was made, (see Appendix VI, after piloting).

- sub-question 19:

  19. Indicate to what extent do the following statements stop you from exercising regularly?

  This question was rephrased because the results showed that it is assumed that patients with type 2 diabetes did not exercise, (see Appendix VI, after piloting).

- sub-question 33:

  It was also suggested that food preferences and frequencies should be preceded by questions to find out whether there was education on diet for type 2 diabetes. It was also suggested that daily and monthly should be added to food preferences, (see Appendix VI, after piloting). The developed questionnaire constituted five factors with the following items:-

  Factor 1: Symptoms, Complications and Management

  This factor mainly addressed the knowledge relating to the understanding of type 2 diabetes disease processes and it management. The knowledge score was deduced from this factor. The component questions were: 3,4,5,6,7,8,9,10,11,12,13,14,15,16,and 17.

  Factor 2: Diabetes Education at Dr George Mukhari Hospital

  This addressed the kind of education that is practiced at the diabetes outpatient clinic at the specified hospital. The component questions were: 18, 19, 20,21,22,23 and 24.

Factor 3: Emotions about diabetes

This addressed the extent to which type 2 diabetes has impacted on patients' emotions as described by individual patients. There was only one question (number 25) with seven sub questions.

Factor 4: Behaviour towards Exercise

This addressed the knowledge of patients about exercises, their behaviours with exercise and the reasons for not exercising if they were not exercising. The component questions were: 26, 27 and 29.

Factor 5: Behaviour towards Food

This addressed the knowledge of patients about diet in relation to type 2 diabetes, their behaviours with food as well as their food choices and food intake frequencies. They also had to give reasons for not adhering to the prescribed diets. The component questions were: questions 30, 31, 32 and 33.

- **Testing for validity**

  Cronbach's α coefficient for all standardized items ranged between 55% and 69%, (95% Ci, 0.54 ; 0.69), indicating good validity.

- **Testing for reliability**

  Intraclass correlation coefficient ranged between 69 % and 71%, indicating good reliability.

5.8.4 Scoring of the Questionnaire

For quantitative data, responses to knowledge questions were scored using the standard practice of scoring where items scores were added and their sums were standardised, (Hofstee et al, 1998). All questions were based on a simple "YES" or "NO" answer for the disease symptoms and four point ordinal as well as four point Linkert scales for rating their perception of health and emotions about their disease.

The first three knowledge questions, (see Appendix VI- section C) were not scored because they gave descriptive information. The total knowledge score was determined as means of 20 items; the items were scored as follows: a correct answer = 1 and an incorrect answer = 0. Therefore, a total knowledge score was calculated as total of all correct answers. The

percentage of the knowledge score was estimated by the mean score over items with a response multiplied by 20, as follows:

Response require to n items (n = 20)
Responded to n_1 items => mean = $\frac{\sum I_1 - I_{20}}{n_1}$

For a clinical relevant conclusion, the knowledge responses were categorized using the established conventions for rating health literacy, (Schillinger et al, 2002). Participants who scored 0 to nine (9) were classified as having inadequate knowledge; 10 to 12 as marginal; and 13 to 20 as having adequate knowledge.

5.9 DISCUSSION

The findings of objective 1 showed that 52 out of 60 knowledge questions correlated well. The language back and forth translation findings were satisfactory showing that the questionnaire is a valid tool to be used in patients with type 2 diabetes consulting at Dr George Mukhari diabetes out-patient clinic. The instrument had good validity using Cronbach's α coefficient and good reliability, using the intraclass correlation coefficient.

According to Jaarsma et al (2002), self-care behaviour which is facilitated by knowledge is an outcome to improve quality of life, reduce morbidity and also reduces health care costs. Coleman and Newton (2005) argued that its is important to improve health communication between patient and health care professionals and also to identify any environmental problems that may contribute to the outcomes of each patient's disease management as mentioned by the patient. Self-management education in chronic illnesses, type 2 diabetes included aims at improving knowledge for better understanding of the disease process, (ADA, 2011). Standards of Medical Care further explain that diabetes care needs many issues to be addressed beyond glycaemic control. It is therefore important to empower, clinicians, patients and other interested individuals with treatment goals and tools to evaluate the quality of care. Improving quality of care in type 2 diabetes management is important in order to prevent acute and chronic diabetes complications, (SEMDSA, 2009, Norris et al 2002). Therefore a knowledge questionnaire is an important outcome measure that will give feedback to health professionals and patients so that changes can be effected to better the quality of care. A reliable instrument for measuring knowledge about diabetes management in patients consulting at Dr George

Mukhari hospital is necessary to establish current knowledge and possible improvements with an intervention.

5.10 CONCLUSION

The developed knowledge questionnaire was successfully translated and validated.

It is a reliable and valid questionnaire that can be used in a population consulting at Dr George Mukhari hospital, (see Appendix VI, after piloting).

OBJECTIVE 2: VALIDITY AND RELIABILITY TESTING FOR DIMS

DIMS was used in this study to measure HRQOL for all participants with type 2 diabetes (refer chapter 3). Recent literature shows that DIMS is among the nine different reliable and valid instruments worldwide for measuring disease-specific HRQOL in patients with diabetes, DIMs was preferred over other Medical Outcomes Scales like the SF-36 or SF-20 instruments which also measure the quality of life, because adding to its high internal consistency for all scales and a good test-retest reliability, it also has high correlations of clinical status both by patients and clinicians, (Tsai-Chung et al, 2006; Luscombe, 2000).

5.11 METHODOLOGY

The methodology executed to test validity and reliability of the knowledge instrument was implemented as well to test validity and reliability of the DIMS.

5.11.1 Sample

The same individuals who participated in the development and testing the validity of the knowledge instrument also completed the DIMS.

Below is a flow diagram illustrating the number of patients with type 2 diabetes who participated in the study.

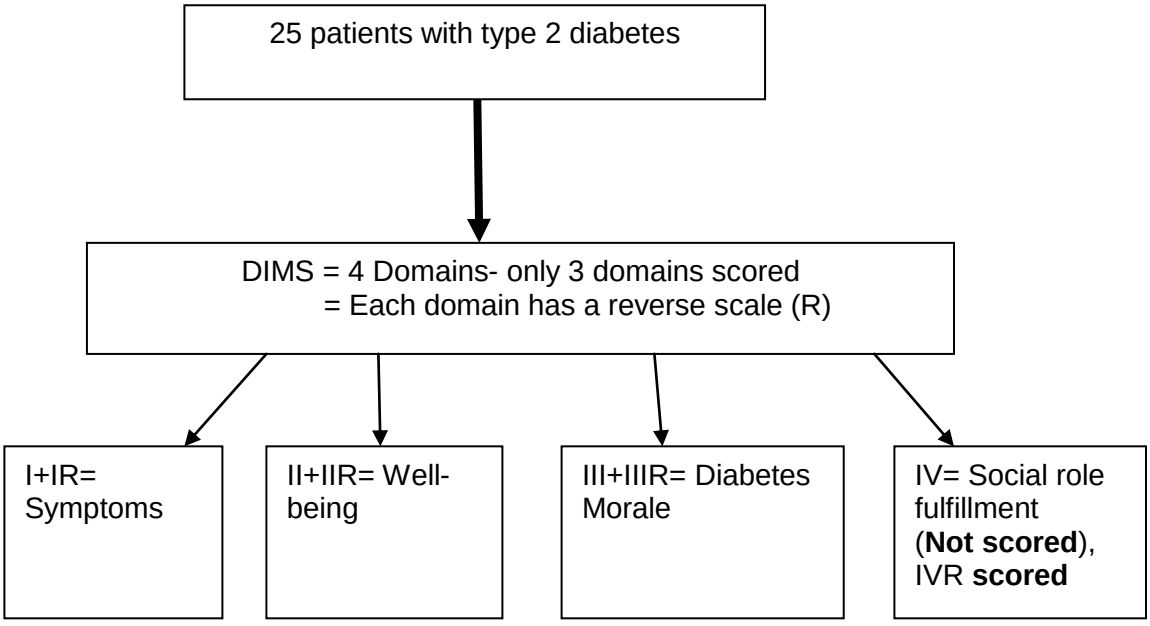

Figure 5.2: Flow Diagram Illustrating the Domains of DIMS

Domain IV (Social role fulfillment) is not scored because it has only one (1) question but the reverse scale of domain IV is scored.

5.12 VALIDITY

- **Internal consistency**

  This was assessed using Cronbach's α coefficient, consistency was satisfied if Cronbach's α coefficient ≥ 0.70, and item (question) validity satisfied if item-scale correlation achieved ≥ 0.40.

- **Face validity**

  This was obtained by asking patients to indicate in each questionnaire whether relevant questions about diabetes were being asked. All patients indicated that all questions were relevant to diabetes.

- **Language validity**

  This was assessed by back and forth (English-Setswana and English-IsiZulu) translation. Both Setswana and IsiZulu versions of the questionnaire were translated back to English. The back translation was done by health professional who speak Setswana and IsiZulu as their mother tongue and were working in the community for a better understanding of the application of medical terms.

- **Content validity**

  This was established by giving the questionnaires to ten health professionals, to rate whether the questionnaires were good and relevant for type 2 diabetes. One of them indicated that the questionnaire has negative questioning especially the reverse scale questions. They indicated that these would be tricky in Africa languages. To overcome this problem, a research assistant needed to be on standby to explain questions.

Table 5.12 below, illustrates how content validity was established for the DIMS.

Table 5.12: Content Validity for the Domains of DIMS

	Very Dissatisfied	Dissatisfied	Very Satisfied	Satisfied
I. **Symptoms** (questions : 5; 6; 7; 13; 17; 24; 26; 29; 37 and 38)				
IR. (**Reverse symptoms**) (questions : 1; 4; 9; 10; 21; 33; and 43)				
II. **Wellbeing** (questions : 2; 14; 18 and 41)				
IIR. (**Reverse wellbeing**) (questions : 8; 15; 27 and 32)				
III. Diabetes Morale (questions : 3; 11; 34 and 40)				
IIIR. (**Reverse diabetes morale**) (questions : 19; 20; 25; 28 and 44)				
IV. **Social role fulfillment** (questions : 12)				
IVR. (**Reverse social role fulfiment**) (questions : 23; 30; 31 and 35)				

Content validity of all questions in the DIMS was assessed as indicated above.

The questionnaire was rated good (satisfied) and relevant especially for assessing measures relating to type 2 diabetes.

5.13 RELIABILITY

The test-retest reliability of the questionnaires was assessed by calculating the intraclass correlation coefficient (ICC) as described in objective 1.

5.14 RESULTS

The results are presented in figure 5.7 and 5.8 as histograms and expressed as percentages achieved in each factor or items described.

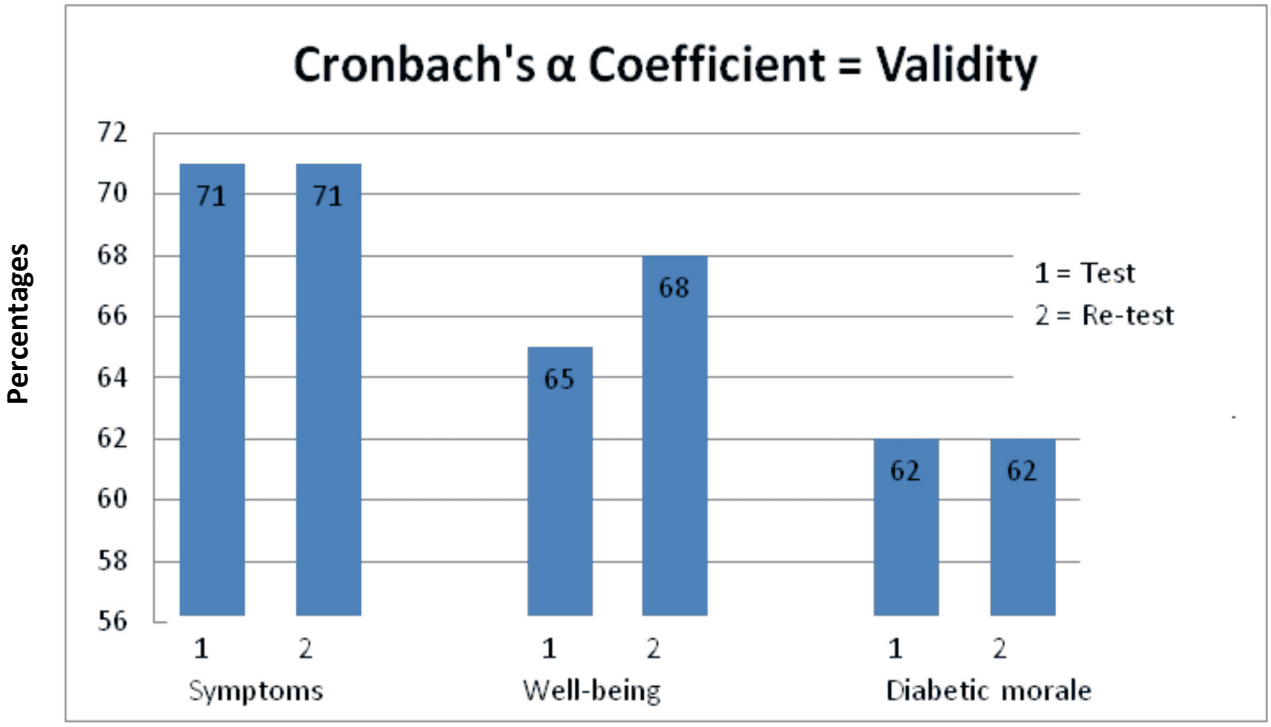

Figure 5.3: Internal Consistency of DIMS when using Cronbach's α Coefficient

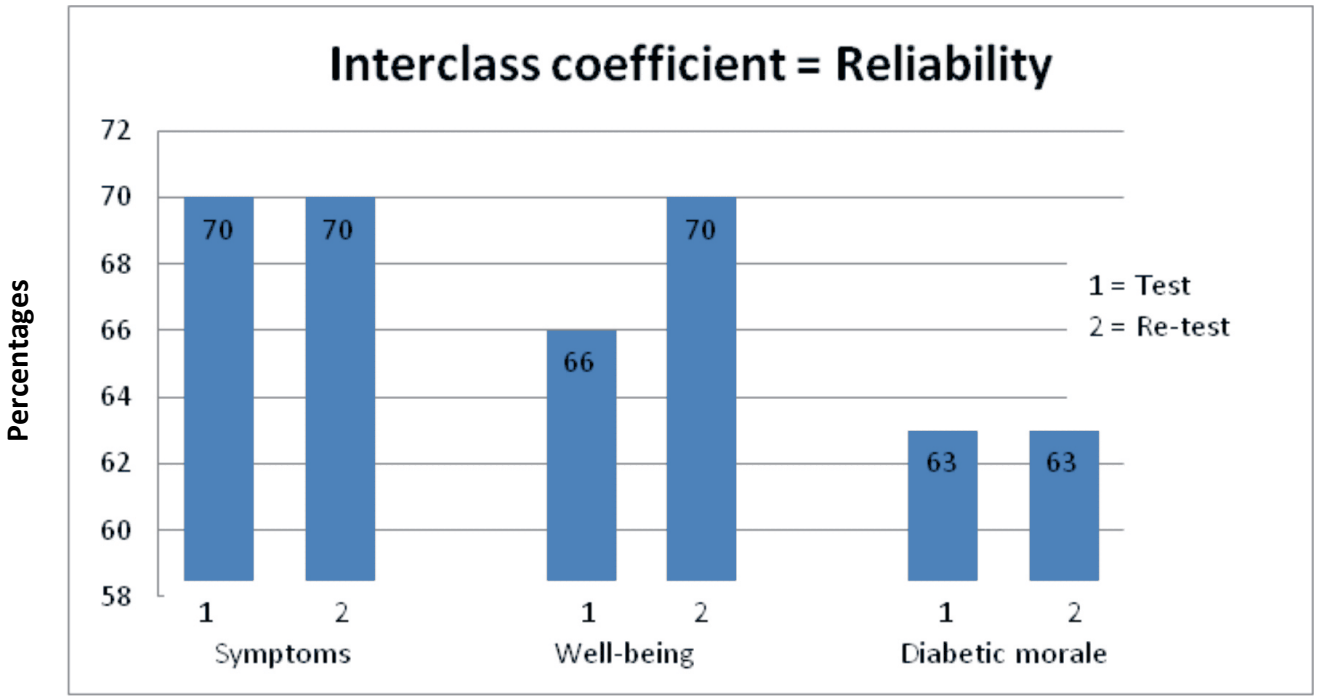

Figure 5.4: Reliability of DIMS when using Intraclass Coefficient (ICC)

5.15 DISCUSSION

Few studies in South Africa have assessed quality of life in patients with type 2 diabetes. Even though the DIMS has been validated in another population, (Hammond and Aoki, 1992) this study had to be undertaken to test the reliability and validity of this tool on patients with type 2 diabetes consulting at Dr George Mukhari hospital.

According to Luscombe, (2000), health related quality of life has become popular in medical care as an outcome measure for chronic disease. This outcome measure is important because chronic disease cannot be cured but can only be controlled. This means that even though diabetes cannot be cured, quality of life can still be improved provided the disease is well controlled. Further review by (Westaway, 2009) supports that chronic diseases are diseases of long duration and have a slow progression. These diseases account for 60% of estimated deaths worldwide. This study therefore assessed the reliability and validity of the impact of type 2 diabetes on patients' quality of life using an international standardized tool, the Diabetes Impact Measurement Scale.

Patients scored well in all domains except the reverse keyed values of diabetes-related morale 7%- 38% for the test and this value improved on re-test. A possible reason for this is the difficulty in understanding these questions in that there is no negative questioning in South African traditional languages. Another explanation could be the fact that the study population was poorly educated and those participants who did not ask for assistance might have experienced a problem in understanding these questions. When comparing the test to re-test results, this shows that patients scored 63% on re-test showing more understanding of the questions. The language used in the questionnaire was tricky for patients the first time but thereafter they understood it.

During factor analysis all questions were retained, ($p>0.05$) showing that all questions in each domain were valid and relevant. The Cronbach's α coefficient and Intraclass correlation coefficients were acceptable, showing that the tool is consistent and reproducible for use in the population consulting at Dr George Mukhari hospital. The total score ranged from 0.62 to 0.71 for Cronbach's α coefficient and 0.63 to 0.70 for intraclass correlation coefficient.

5.16 CONCLUSION

The DIMS is an acceptable health related quality of life questionnaire that can be used in patients with type 2 diabetes consulting at Dr George Mukhari hospital.

CHAPTER 6

6. STUDY III: DEMOGRAPHIC BACKGROUNDS OF ALL PARTICIPANTS

APPROPRIATENESS AND AVAILABILITY OF THE EDUCATION PROGRAMMES AT DR GEORGE MUKHARI HOSPITAL

6.1 INTRODUCTION

This study was conducted to determine the availability and appropriateness of the diabetes education programmes conducted at Dr George Mukhari hospital out-patient diabetes clinic.

The objectives 1 to 4 listed in chapter 1, page 9 of the thesis were addressed:-

Objective 1: to determine the demographic background (including socio-economic status-SES) of patients with type 2 diabetes from poor socio-economic background.

Objective 2: to determine the availability of diabetes education programmes at Dr George Mukari hospital.

Objective 3: to assess the appropriateness of the existing diabetic education programmes.

Objective 4: to determine the level of knowledge of patients from poor socio-economic backgrounds with type 2 diabetes about the management of the disease.

6.2 METHODOLOGY

6.2.1 Design

A quantitative descriptive cross sectional study design was undertaken using a population consulting at Dr George Mukhari hospital out-patient diabetes clinic. Information such as demographic characteristics, knowledge based on availability of education programmes, attitudes and behaviour towards exercise and food were captured. The knowledge score and health related quality of life questionnaires that were developed and validated in Chapter 5 were used to capture data for all patients diagnosed with type 2 diabetes and treated at Dr George Mukhari hospital out-patient diabetic clinic. Knowledge was compared to the glycaemic control of all patients and their health related quality of life.

6.2.2 Sampling Method

A sample of convenience was used.

6.2.3 Sample Size

A total of 135 patients, both males and females, diagnosed with type 2 diabetes, who were receiving their treatment at Dr George Mukhari hospital out-patient diabetic clinic participated in this study. All patients who fell between the ages of 28-70 years at the date of inception of this study were included using consecutive sampling. The known duration of the disease diagnosis was at least one year.

A total of 105 participants were required statistically with $\alpha=0.05$ and $\beta=0.10$ (90% power) to detect a clinically relevant lowering of HbA_1c levels by 1%, given a standard deviation of 1.41% between males and females. In consideration of a dropout rate of ±20%, an additional 30 participants were recruited, (Brown et al, 2005; van Rooijen et al, 2004).

6.2.4 Inclusion Criteria

The following inclusion criteria were used for the selection of the study participants:

- Patients with type 2 diabetes mellitus who agreed to participate in the study by signing a consent form.
- Patients aged between 28 – 70 years at the beginning of the study.
- Males and Females.
- Controlled blood pressure (BP), this means that patients should be on antihypertensive medication with Systolic BP not more than 150 mmHg and Diastolic BP not more than 90 mmHg at rest, (Pignone, 2010), or a BP not more than 130/80 not using antihypertensive medication, (SEMDSA, 2003; WHO, 2002;).
- No peripheral vascular diseases

6.2.5 Exclusion Criteria

- All patients with uncontrolled BP (BP above 150/90 at rest) or a BP more than 130/80 if not using antihypertensive medication.
- Amputations of the lower limbs
- Diagnosed ischaemic or peripheral neuropathy.
- Patients with any lesions of the lower extremities which may be aggravated with exercise.
- All patients who did not give consent to participate in the study.
- Patients with type 2 diabetes mellitus.
- Patients between 28 – 70 years.
- Males and Females.

- Controlled blood pressure (BP) meaning Systolic BP not more than 150 mmHg and diastolic BP not more than 90 mmHg at rest) for a patient who is on antihypertensive medication, (Pignone, 2010), or a BP not more than 130/80 not using antihypertensive medication, (SEMDSA, 2003)
- No peripheral vascular diseases

6.2.6 **Ethical Clearance**

The Committee for Research for Human Subjects at the University of the Witwatersrand granted ethical clearance, (ethical clearance certificate no M060955) to conduct the study and collect blood from patients with type 2 diabetes, (see Appendix III). In this study patients were given an information sheet and written consent form to obtain their permission to participate in the study which they had to sign. Each patient was allocated a reference number which was applicable to all forms used for data collection and blood specimens. The anonymity of patients was maintained in all stages of the research. All participants were free to decline at any-time during the course of the study without prejudice. A separate application to get permission to conduct the study at Dr George Mukhari hospital out-patient diabetes clinic was made through the CEO of the hospital and consent was granted, (see Appendix III). The sister in charge and the staff members at the diabetic clinic were fully informed about the study,

6.2.7 **Procedure**

Participants completed the two self- administered (the knowledge and HRQOL) questionnaires that were described in chapter 3.

The description of the study population is illustrated below:

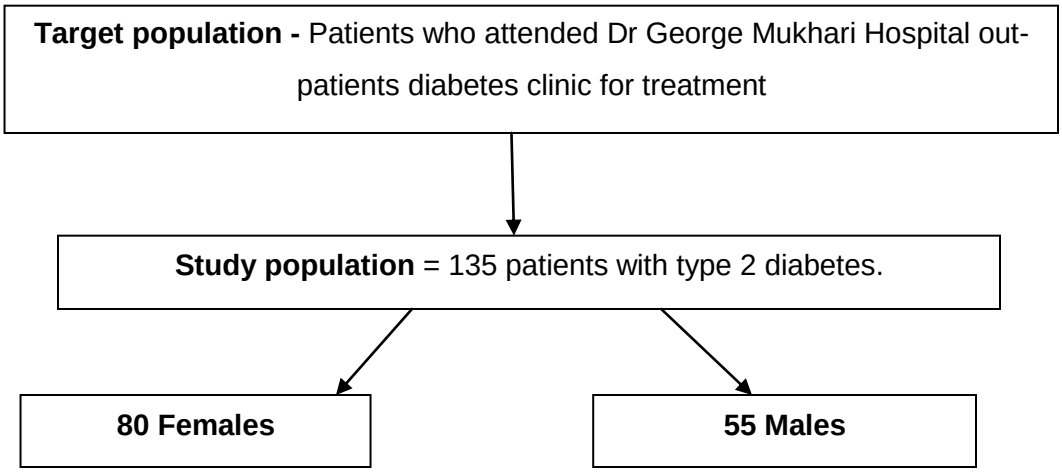

Figure 6.1: Number of Patients Who Participated in the Study

6.3 INSTRUMENTS

6.3.1 Questionnaires

- The Knowledge Questionnaire described in Chapter 3 was used to establish both the demographic data of all patients and their knowledge about the condition and their behaviours with food and exercise.
- The DIMS described in Chapter 3 was used to evaluate the impact of type 2 diabetes on each patient's health related quality of life.

6.3.2 Anthropometric Measurements

- Body Weight: this was measured to the nearest 100g, using an electronic calibrated bathroom scale (SECA 813 model). These measurements were taken with the participants in socks or bare foot and with light clothing only.
- Height: was measured in centimeters to the nearest 1cm using a height telescope. Patients stood against the wall bare feet with their hands at their sides and the telescope pointer at the vertex of the head. These measurements were used to determine each patient's BMI.
- Body mass index (BMI): this was measured as a ratio of body weight in kilograms divided by height in meters squared (kg/m^2).
- Circumferential measurements: were taken over light clothing, in standing, using a tape measure. These measurements were taken to determine the waist-hip ratio at the following sites:

Waist circumference = was measured around the narrowest point of the torso between the ribs and hips at the level of the umbilicus.

Hip circumference = as measured at the level of the greater trochanter (at the point where the buttocks extend to the maximum, when viewed from the side. These measurements were taken twice and averaged.

6.3.3 Blood Pressure and Resting Pulse

Resting blood pressure levels were obtained using an electronic calibrated sphygmomanometer on the right arm. Resting pulse was also recorded.

These measurements were taken in a sitting position. All measurements were taken twice- an average of the two was used.

6.3.4 **Random Blood Chemistry**

These blood samples were taken by a professional nurse to determine glycaemic control of the study population. Random bloods were preferred to fasting blood because the majority of participants (73%) were either on insulin injection only or insulin injection and pills (see table 6.7.3). These participants had to take their insulin early before coming to the hospital and 30 minutes after the injection they needed to have a snack. The levels of the following bloods were analysed:

- HbA_{1c} – measure of diabetic glycaemic control.
- Random blood glucose
- Lipogram – total cholesterol, triglycerides as well as low density and high density lipoproteins.

6.3.5 **The Six Minute Walk Test**

The exercise capacity of each patient was tested by a six minute walk. A 25 meter distance was marked off in a quiet corridor next to the casualty department. Patients were asked to walk along the distance as many times as they could for six minutes at their fastest pace. Chairs were provided if patients needed to rest. Resting pulse and blood pressure were taken prior to the start of the test, immediately after six minutes and after six minutes rest. Patients were monitored for six minutes in recovery. The Borg scale of perceived exertion was used to rate each patients' level of perceived activity, (Bautmans et al, 2004; Enright, 2003). The test was terminated if the patients were exhausted or complained of chest pains and dizziness.

6.4 **DATA ANALYSIS**

Data were analyzed using STATA version 8 statistical programme. Ninety five percent (95%) confidence intervals were calculated for each variable. Means and standard deviations were used to reduce the continuous demographic data and to determine the knowledge scores. Frequencies were used to reduce the categorical data. Fisher's exact test was used to compare any differences between males and females and $p<0.05$ was considered significant. Continuous variables were compared between males and females using the independent t-test.

6.5 RESULTS

Introduction:

This section describes the results of all participants under the following headings:

- Demographic data which includes age, gender, physical and anthropometric measurements.
- Socio- demographic data which includes family support, level of education, settlement, house type and number of people in the household.
- Socio-demographic data which includes employment, total income per month, and availability of electricity, sanitation and mode of transport used to access the hospital.
- Diabetes management and types of available education programmes, including knowledge scores.
- Availability of education programmes
- Emotions about diabetes
- Exercise behaviour
- Food behaviour including food preferences and frequency.
- Blood chemistry, and
- Health related quality of life

6.5.1 Demographic Data

In table 6.5.1, below, the results including age; physical measurements; anthropometric measurements, resting heart rate and resting blood pressure as well as the distance walked for all participants are shown.

Table 6.5.1: The Physical and Anthropometric Measurements (n=135

Variable	FEMALES n= 80			MALES n=55			
	Mean (sd)	**Range**	**95% (CI)**	**Mean (sd)**	**Range**	**95% (CI)**	**p<0.05**
Age (years)	55.3 (±8.5)	35 – 70	53.4 ; 57.1	55.2 (±9.6)	28 -70	52.7 ; 57.7	p=0.17
Body weight (kg)	81.6 (±17.7)	51- 134	77.6 ; 85.5	84.2 (±21.8)	50 - 195	78.3 ; 90.1	p=0.79
Height (cm)	159 (±6.8)	147 – 177	158 ; 161	169 (±6.6)	157 - 184	168 ; 172	p=0.87
BMI (kg/m^2)	32.3 (±6.8)	20 – 53	30.7 ; 33.8	29 (±6.3)	19 – 59	27.4 ; 30.8	p=0.97
Waist circumference (cm)	100.7 (±12.2)	74 – 137	98 ; 103.5	99.7 (±14.4)	72 – 140	95.8 ; 103.5	p=0.23
Hip circumference (cm)	109 (±13.1)	80 – 150	106 ; 112	101.6 (±9.2)	81 – 124	99 ; 104	p=0.46
WHR	0.9 (±0.09)	0.7 – 1.2	0.89 ; 0.94	0.97 (±0.08)	0.8 – 1.2	0.95 ; 0.99	p=0.42
HR at rest (bpm)	88(±12.9)	63 – 135	83.1 ; 87.8	82 (±14.6)	46 - 123	78 ; 86	p=0.89
Systolic BP at rest (mmHg)	144 (±27.0)	103 – 243	138 ; 149	144 (±3.6)	90 - 203	137 : 151	p=0.20
Diastolic BP at rest (mmHg)	83 (±15.0)	57 – 124	81 ; 86	83 (±14.0)	62 - 120	79 ; 87	p=0.44
RPE	12 (±1.6)	10 – 17	12 ; 13	12 (±0.9)	11 - 15	11.4 ;11.9	p=0.34
Distance walked (m)	194 (±48.0)	100 – 250	178 ; 194.6	200 (±49.9)	175 - 275	171 ; 220	p=0.10

Fifty nine percent (80/135) of the sample were females and 41% were males (55/135). The mean age was 55.3 (±8.5) for females and 55.2 (±9.6) for males. Participants were generally overweight with BMI of 32.3 (±6.8) in females and 29 (±6.3) in males. The systolic blood pressure was increased (BP= 144/83) in both males and females. Waist-hip ratio (WHR) was also increased, 0.9 (±0.09) in females (normal = 0.85) but normal 0.97 (±0.08) in males (normal ≤.0.1), see chapter 3. Males walked further (200m) compared to females (194m) but there was no statistical difference, p>0.05.

In table 6.5.2(a), below, the socio-demographic data including family support, level of education, settlement, house type, and number of people in the household are shown.

Table 6.5.2(a): Socio-Demographic Data including Family Support, Level of Education, Settlement, House Type and Number of People in the Household (n=135)

Variable	Females n=80 (%)	Males n=55 (%)	p<0.05
Family member support			
Close family	69 (86.3%)	52 (94.5%)	p=0.35
Friends	5 (6.3%)	2 (3.6%)	
Church and work colleague	6 (7.5%)	1 (1.8%)	
Level of Education			
No education	3 (3.8%)	1 (1.8%)	p=0.27
Primary	18 (22.7%)	11 (20.0%)	
High school	35 (44.3%)	30 (54.6%)	
Passed STD 10 (gr12)	10 (12.7%)	10 (18.2%)	
Post-Matric diploma or degree	13 (16.5%)	3 (5.5%)	
Settlement			
Urban	73 (91.3%)	47 (85.5%)	p=0.40
Rural	7 (8.8%)	8 (14.6%)	
House Type			
Shack	7 (8.8%)	9 (16.4%)	p=0.16
RDP (1 bedroom)	10 (12.5%)	6 (10.9%)	
Municipality (2 bedrooms)	16 (20.0%)	17 (30.9%)	
Big house (3 bedrooms and more)	47 (58.8%)	23 (41.8%)	
Number of people in the household			
1-5 members			
6-10 members	58 (72.5%)	34 (61.9%)	p=0.52
More than 10	22 (27.5%)	18 (33%)	
	0	3 (5.5%)	

A total of 121 (69 females and 52 males) participants received support from their close family members and 14 (11 females and 4 males) received support either from their friends, church or work colleagues. A total of 16 participants (13 females and 3 males) had a post matriculation certificate; 65 participants (35 females and 30 males) had a high school level of education (only up to grade 11); 29 participants (18 females and 11 males) had primary school education and four participants (3 females and 1 male) had no education at all. Eighty nine percent (73 females and 47 males) came from urban environments and 11% (7 females and 8 males) of this sample were living in shacks (informal settlements). There were no differences between males and females in terms of the type of support they received, the level of education, settlement, type of house and number of people in the household, ($p>0.05$).

The data above demonstrated that this group of participants comes from lower socio-economic backgrounds. In South Africa, socio-economic status and poverty is classified according to levels of education which will determine the income of a particular individual. Even though this data shows that most people live in big houses, these houses do not have the municipality infrastructure but are built by the owners themselves and slowly extend from a couple of rooms to more as funds become available.- This is also supported by the number of participants who have water piped in the streets (41/135). Participants who have good sanitation and running water are those who reside in municipal houses which are smaller, but have town planned structures.

In table 6.5.2(b), below, the socio-demographic data including employment, total income, availability of electricity, availability of running water, type of sanitation and the mode of transportation used by patients to go to the hospital are shown.

Table 6.5.2(b): Socio-Demographic Data including Employment, Total Income, Availability of Electricity, Type of Sanitation and Transport (n=135)

Variable	Females n=80 (%)	Males n=55 (%)	p<0.05
Employment			
Full time	28 (35%)	17 (30.9%)	
Part time	1 (1.3%)	1 (1.3%)	
"Piece" jobs (casual job)	5 (6.3%)	4 (7.3%)	
Self employed	0	2 (3.6%)	p=0.73
Unemployed	20 (25%)	14 (25.5%)	
Pensioner	26 (32.5%)	17 (30.9%)	
Total income per month			
Less than R1000	49(61.3%)	30(54.5%)	
Between R1000-R3000	10(12.5%)	12(21.8%)	
Between R3001-R5000	10(12.5%)	8(14.6%)	p=0.44
Above R5000	11(13.8%)	5(9.1%)	
Electricity			
No electricity	0	2 (3.6%)	
Have electricity	80 (100%)	53 (96.4%)	p=0.16
Water			
Piped in the street	2 (2.5%)	2 (3.6%)	p=0.58
Piped in the yard	22 (27.5%)	19 (34.6%)	
Piped indoors	56 (70%)	34 (61.8%)	
Sanitation placement			
In street or neighbor	0	1 (1.8%)	
In yard	23 (28.8%)	21 (38.2%)	p=0.19
Inside house	57 (71.3%)	33 (60%)	
Sanitation type			
Home-made pit latrine	7 (8.8%)	6 (10.9%)	
Non- flush septic tank	3 (3.8%)	4 (7.3%)	p=0.61
Flush	70 (87.5%)	45 (81.8%)	
Transport			
Own car	5 (6.3%)	6 (10.9%)	
Public transport	75 (93.8%)	49 (89.1%)	p=0.35

A total of 34 participants were unemployed, (25%) of both females (20 participants) and males (14 participants) were unemployed. A total of 43 (31.9%) participants (26 female and 17 males) were pensioners. Forty five participants (66%) were full time employed and 22 of these participants (34.3%) had incomes between R1000.00 to R3000.00 per month. Only 16 (22.8%) participants had incomes above R5000.00 per month. Most participants had electricity and indoor running water however there are still a number of people living in urban environments (1.5%) who do not have electricity and indoor water pipes. There are also a number of people living in urban environments (14.8%) still using home-made pit latrines (9.6%) and non- flush septic tanks (5.2%). A total of 124 (91.9%) participants used public transport to visit the

hospital. There were no differences between males and females in terms of the socio-demographic data, (p> 0.05).

In table 6.5.3, below, the management of type 2 diabetes and availability of education programmes at Dr George Mukhari hospital are shown.

Table 6.5.3: Management and Education Programmes (n=135)

Variable	Females: n=80 No (%)	Males: n=55 No (%)	p<0.05
Knowledge scores			
Score of 0-9 (<50%) = inadequate knowledge	14.2 (71%)	13.3(67%)	p=0.64
Score of 10-12 (50-60%) = marginal knowledge	11.6 (19%)	11.5(25%)	
Score of 13-14(>60%) =adequate knowledge (using s-TOFHLA score, Schillinger et al, 2002)	8 (11%)	9(8%)	
Years with Diabetes			
1-5 years	28 (35%)	16(29%)	p=0.19
6-10 years	14 (17.5%)	11(20%)	
More than 10 years	38 (47.5%)	28(51%)	
Type of Treatment			
Injection	3 (3.8%)	3(5.5%)	p=0.19
Injection and Pills	60 (75%)	33(60%)	
Pills only	17 (21.3%)	19(34.6%)	
Rating of own health			p=0.48
Excellent	3(3.8%)	3(5.5%)	
Good	25 (31.3%)	23(41.8%)	
Fair	47 (58.8 %)	25(45.5%)	
Poor	5 (6.3%)	4 (7.3%)	
Rating own health compared to a year ago			p=0.81
Good	19(23.8%)	14(25.5%)	
Fair	40(50%)	25(45.5%)	
Poor	9(11%)	9(16.4)	
Worse	12(15%)	7(12.7)	
Education Programmes			
Nurse	24 (30%)	7(13%)	p=0.58
Doctor	33 (41%)	27(49%)	
Dietitian	23(29%)	21(38%)	

The majority of participants had adequate knowledge (scores of 71% in females and 67% in males) and this is probably because they had been diabetic for more than six years. The majority of participants (60 females and 33 males) were managing type 2 diabetes with injection and pills whilst thirty six (17 females and 19 males) were using pills only and six (3 females and 3 males) were using injection only. Seventy two participants (47 females and 25 males) rated their own health as fair whilst forty eight participants (25 females and 23 males) rated their health as good. Only nine participants (5 females and 4 males) rated their health as poor. Six participants (3 females and 3 males) rated their health as excellent.

When comparing their own health to a year ago, 18 participants (9 females and 9 males) reported that their health was worse than the previous year.

When looking at the type of education available at the clinic, the majority of participants (60) reported that they received their diabetes education from the doctor; 44, received education from the dietician and 31 participants received their education from the nurse.

Below is a summary of responses to questions that were asked about diabetes education:

1. When asked about preferred health care professional:
   - Four males (7.3%) preferred a traditional healer;
   - Fifty five participants (36 females and 19 males), preferred a nurse.
   - One hundred and eleven participants (82%) preferred a doctor
   - Twenty seven participants (20%) preferred a dietician
   - Three participants (2.2%) a psychologist and,
   - Four females (3%) preferred a faith healer.

2. When asked about routine procedures such as BP check, urine and bloods:
   - One hundred and twenty five participants (92.5%) knew that these entire tests are done routinely at the clinic.

3. Duration of each consultation:
   - Twenty seven participants (20%) mentioned that some doctors take only 15 minutes for consultation and during this time, the doctor just looks at the file and writes down the medication without asking about patients' problems or even talking about diabetes.
   - Forty five participants (33%) mentioned that doctors take 20 minutes to consult with patients and during this time, the doctor examines and writes down the medication, he or she does not talk about diabetes or patients' problems.
   - Forty four participants (32.8%) mentioned that doctors take 30 minutes and during this time these doctors examine, write medication and talk about diabetes.
   - Fourteen participants (13.4%) mentioned that doctors take more than 30 minutes and during this time, doctors examine patients, prescribe and talk about diabetes.

4. When asked to give their preferred time for consultation:
   - Thirteen participants (9.7%) preferred 15 minutes.
   - Forty one participants (30.6%) preferred 20 minutes.
   - Fifty nine (44%) preferred 30 minutes and,
   - Twenty one participants (15.7%) preferred more than 30 minutes.

5. When asked about their preferred methods of education:
   - Thirty six percent (36%) preferred individual consultations with a doctor, a nurse and a dietician.
   - Twenty three percent (23%) preferred awareness on television and radios.
   - Thirty one percent (31%) preferred group education because they can learn from each other's' experiences.
   - Only 9.6% (thirteen participants) preferred information booklets.

There were no differences between males and females in terms of management and availability of education programmes, ($p > 0.05$).

In table 6.5.3.1, below, the emotions of all participants about diabetes are shown.

Table 6.5.3.1: Emotions about Diabetes (n=135)

Variable	**Response**	**Females n=80 (%)**	**Males n=55 (%)**	**p<0.05**
Hard to believe I have diabetes	Agree	36(45.6%)	24(44.4%)	p=0.52
	Disagree	44(54.4%)	31(56.6%)	
I feel depressed when I think of its complications.	Agree	46(57.5%)	34(61.8%)	p=0.80
	Disagree	34(42.5%)	21(38.2%)	
I feel I'm not as good as others	Agree	35(43.8%)	25(46.3%)	p=0.97
	Disagree	45(56.3%)	30(53.7%)	
Hard to take good control	Agree	45(56.3%)	26(48.2%)	p=0.40
	Disagree	35(43.7%)	29(51.8%)	
Diabetes does not affect my life.	Agree	31 (38.8%)	23(41.8%)	p=0.81
	Disagree	49(61.2%)	32(58.2%)	
Things are going well now	Agree	33(41.3%)	25(46.3%)	p=0.39
	Disagree	47(58.7%)	30(53.7%)	
Easy to control with support	Agree	66(82.5%)	54(98.1%)	*p=0.005
	Disagree	14(17.5%)	1(1.9%)	

Sixty participants (31 females and 24 males), expressed that they felt depressed when thinking about the complications of the disease, indicating negative emotions about the disease. Sixty one participants (35 females and 26 males), found it difficult to take control of type 2 diabetes. Eighty one participants (49 females and 32 males) felt that type 2 diabetes was affecting their lives. Forty seven females (58.7%) and 30 males (54%), indicated that things were not going well with type 2 diabetes. There were no significant differences with these responses between males and females, ($p>0.05$). Males found it was easy to control diabetes with family support when compared to females. This showed a significant difference between males and females indicating that men need support to manage type 2 diabetes, ($p=0.005$).

6.5.2 **Exercise behaviour**

A total of 106 participants (79%) reported that they walked daily or three times a week. Twenty eight participants (21%) were not engaged in any form of exercise. Nine percent of participants who were not exercising mentioned that they were never told about exercise and did not have a safe environment to perform any type of exercise. There were no significant differences between males and females, ($p=0.46$).

6.5.3 **Food behaviour**

A total of 123 participants (91.8%) reported that they were told about following a diabetes meal plan and 12 participants (8%) reported that they were never told about a plan. Forty participants (30%) reported that they always followed the prescribed diabetes diet. Seventy nine participants (59%) reported that they sometimes followed the recommended diet because diabetic diet is expensive and 16 participants (11%) reported that they never followed recommendations because they do not have money to buy food and they ate any available food. There were no significant differences between males and females with regards to following a prescribed diabetic diet, $p=0.88$.

Participants were also given a list of commonly used food types so that they could indicate their preferences and frequencies of consumption of a particular food type.

The information about each participant's food choices and frequencies at which the food type is eaten is shown in table 6.5.4, below:

The list of food choices shown below was developed from the literature on the recommended and discouraged food types for patients with type 2 diabetes. It is important to note that not all 0recommended food types are listed.

Table 6.5.4(a): Food Preferences and Frequency (n=135)

Variable	FREQUENCY (%)					
	Daily	**3 times a week**	**Once a week**	**Monthly**	**Do not eat**	**p<0.05**
Red meat (Total)	3(2.2%)	21(15.6%)	42(31.1%)	35(25.9)%	34(25.2%)	p=0.45
Females	3(3.8%)	10(12.5%)	27(33.8%)	19(23.8%)	21(26.3%)	
Males	0	11(20%)	15(27.3)	16(29.1%)	13(23.6%)	
Fish (Total)	5(3.7%)	36(26.7%)	36(26.7%)	39(28.9%)	19(14.1%)	p=0.95
Females	3(3.8%)	22(27.5%)	23(28.8%)	22(27.5%)	10(12.5%)	
Males	2(3.6%)	14(25.5%)	13(23.6%)	17(30.9%)	9(16.4%)	
Chicken (Total)	56(41.5%)	57 (42%)	18(13.5%)	3(2%)	1(0.7%)	p=0.40
Females	33(41.3%)	37(46.3%)	8(10%)	2(2.5%)	0	
Males	23(41.8%)	20(36.4%)	10(18.2%)	1(1.8%)	1(1.8%)	
Tripe (Total)	2(1.5%)	1(0.8%)	11(8.2%)	44(32.8%)	76(56.7%)	*p=0.01
Females	0	1(1.3%)	5(6.3%)	20(25.3%)	53(67%)	
Males	2(3.6%)	0	6(10.9%)	24(43.6%)	23(41.8%)	
Pap (Total)	86(64%)	27(20.2%)	17(12.7%)	4(3%)	0	p=0.29
Females	47(58.8%)	20(25%)	11(13.8%)	2(2.5%)	0	
Males	39(72.2)	7(13%)	6(11.1%)	2(3.7%)	0	
Samp (Total)	3(2.2%)	12(8.9%)	46(34.3%)	46(34.3%)	27(20.1)	p=0.16
Females	2(2.5%)	8(10.1%)	33(41.8%)	23(29.1%)	13(16.5%)	
Males	1(1.8%)	4(7.3%)	13(23.6%)	23(41.8%)	14(25.5%)	
Vegetables (Total)	105(78%)	18(13%)	10(7.4%)	2(1.5%)	0	p=0.41
Females	62(77.5%)	11(13.8%)	7(8.8%)	0	0	
Males	43(78.2%)	7(12.7%)	3(5.5%)	2(3.6%)	0	
Fruits (Total)	90(66%)	24(17.8%)	18(13.3%)	3(2.2%)	0	*p=0.01
Females	56(70%)	10(12.5%)	14(17.5%)	0	0	
Males	34(61.8%)	14(25.5%)	4(7.3%)	3(5.5%)	0	
Sweets (Total)	12(8.9%)	3(2.2%)	39(28.9%)	14(10.4%)	67(49.6%)	p=0.58
Females	8(10%)	2(2.5%)	19(23.8%)	8(10%)	43(53.8%)	
Males	6(10.9%)	1(1.8%)	20(36.4%)	6(10.9%)	24(43.6%)	
Cake (Total)	1(0.8%)	0	7(5.2%)	11(8.2%)	116(85.9%)	p=0.53
Females	0	0	3(3.8%)	7(8.8%)	70(87.5%)	
Males	1(1.8%)	0	4(7.3%)	4(7.3%)	46(83.6%)	
Sweet biscuits (Total)	2(1.5%)	1(0.7%)	1(0.7%)	8(5.9%)	123(91%)	p=0.75
Females	1(1.3%)	1(1.3%)	0	4(5%)	74(92.5%)	
Males	1(1.8%)	0	1(1.8%)	4(7.3%)	49(89.1%)	

Variable	FREQUENCY (%)					
	Daily	**3 times a week**	**Once a week**	**Monthly**	**Do not eat**	**p<0.05**
Beer (Total)	2(1.5%)	0	8(5.9%)	3(2.2%)	122(90.4%)	*p=0.00
Females	1(1.3%)	0	0	0	79(98.8%)	
Males	1(1.82)	0	8(14.6%)	3(5.5%)	43(78.2%)	
Wine (Total)	2(1.5%)	0	2(1.5%)	9(6.7%)	122(90.4%)	p=0.66
Females	1(1.3%)	0	1(1.25%)	7(8.8%)	71(88.8%)	
Males	1(1.8%)	0	1(1.25%)	2(3.6%)	51(92.7%)	

Pap: crumb porridge made from maize meal; **Samp**: South African crushed maize used as starch.

A total of 101 participants (75%) ate red meat and mainly weekly. A total of 116 participants (86%) ate fish and this was mostly tinned fish. Most participants said that they could not afford fresh fish because it is expensive even though it is recommended by dieticians. Even though small, it is important to note that there is a percentage of participants (1.5%) who could only afford vegetables and fruits (2.2%), once a month. Sixty eight participants (50%) who ate sweets reported that they only ate them when their blood sugar levels were low. Only thirteen (9.6%) participants drank alcohol, (beer), twelve males and only one female. This was a significant difference between males and females ($p<0.001$). Thirteen participants (9.6%) drank wine, with no significant differences between males and females with regards to drinking wine, ($p>0.05$).

In table 6.5.4(b), below, the blood chemistry results are shown

Table 6.5.4(b): Blood Chemistry (n=135)

Variable (Random blood levels)	**Females n= 80** Mean (sd)	**Range**	**95% (Ci)**	**Males** n=55 Mean (sd)	**Range**	**95% (Ci)**	**p<0.05**
Random Blood Glucose (mmol/l)	12.1 (±4.6)	4.4-24.7	11.1;13.2	12.1 (±6.4)	3.4-32.3	10.4;13.8	p=0.46
HbA1c (%)	9.8 (±2.3)	5.6-17	9.3;10.3	10.3 (±3.1)	5.2-18.8	9.4;11.1	p=0.3
Total Cholesterol (mmol/l)	4.7 (±1.3)	2.3-8.7	4.4;4.8	4.4 (±1.1)	2.3-7.3	4.1;4.8	p=0.10
HDL-C (mmol/l)	1.1 (±0.3)	0.6-2.5	0.98;1.1	1.0 (±0.3)	0.5-1.7	0.9;1.1	p=0.25
LDL-C (mmol/l)	2.8 (±1.0)	0.2-6	2.6;3.0	2.7 (±0.9)	0.5-4.7	2.5;3.0	p=0.11
Triglycerides (mmol/l)	1.6 (±0.9)	0.4-6.1	1.5;1.9	1.7 (±0.1)	0.5-5.2	1.4;1.9	p=0.20

There were increased levels of random blood glucose; total cholesterol; LDL-C and triglycerides, HDL-C levels were low. There were no significant differences between males and females with regards to blood chemistry analysis, ($p>0.05$).

In table 6.5.5, below, the health related quality of life results using the DIMS' scores are shown:

Table 6.5.5: Health Related Quality of Life Data, DIMS Score

Variable	Females n=80 Mean (sd)	Range	95% (Ci)	Males n=55 Mean (sd)	Range	95% (Ci)	p=0.05
Symptoms	72 (±10.8)	47-90	71;74	73 (±10.3)	44-90	70;76	p=0.67
Wellbeing	33 (±5.6)	19-43	33;35	34 (±5.1)	23-42	33;35	p=0.76
Diabetic Morale	40 (±5.1)	28-50	39;41	39 (±5.5)	25-51	37;40	p=0.15
Social role fulfillment	24 (±5.0)	13-30	22;25	23 (±5.1)	9-30	21;24	p=0.17

Participants rated their HRQOL as poor. This is confirmed by the lower rating on symptoms, 73 (95 Cl 70 ; 76) and very low wellbeing, 33 (95% Cl 33 ; 35) low diabetic morale, 39 (95% Cl 39; 41) and low social role fulfillment 23 (95% Cl 22 ; 25).There were no significant differences between males and females with regards to the responses to different domains, (p>0.05).

6.6 DISCUSSION

Introduction

This section discusses the findings presented in section 6.5 above. Using the knowledge questionnaire and DIMS the background characteristics of patients and the management of type 2 diabetes at Dr George Mukhari hospital was obtained. The findings confirmed that the overall participants were obese, came from poor socio economic backgrounds, had poor glycaemic control and poor health related quality of life. The background knowledge was adequate for males and females.

A total of 135 patients with type 2 diabetes participated in this study. There were gender disparities with a gender distribution of 59 % women and 41% men. These findings indicate that type 2 diabetes affects women more than men; this is supported by (van Rooijen et al, 2004; Ramachandan, 2002). The mean duration of the disease was 24 years and 69% of participants were managed with insulin injection and pills.

6.6.1 Age, Anthropometric Measurements Physical Activity and Blood Pressure

- **Age**

  The mean age of all participants was 55 years, ranging from 28 to 70 years. However 85% of participants were distributed between 45 to 70 years. The age distribution is consistent with the literature which reveals that type 2 diabetes is the most common form of diabetes

which increases with age, (van Rooijen et al, 2004; Cagle et al, 2002), and individuals with type 2 diabetes may have any of the disorders such as obesity, insulin resistance and altered metabolic state which are influenced by lifestyle factors, (such as diet and physical inactivity), (Russell et al, 2004; Epple et al, 2003). The insulin resistance results from increased body weight as a result of sedentary lifestyle, (Mahon et al, 2007).

More recent evidence, however, suggests that in addition to these findings, there is increasing evidence of the onset of type 2 diabetes in individuals younger than thirty years even though understanding the pathophysiology for the development of type 2 diabetes in the young is still scarce, (CDC, 2004; Alberti et al, 2004;). It is interesting to note that 20 participants were less than 45 years and within these participants, some were 28 years and some were 30 years old. This is suggesting that there is a growing prevalence of type 2 diabetes in the young at Dr George Mukhari hospital which is consistent with literature, (Pirie 2007).

- **BMI**

  The results of this study showed that only 20% of participants had a normal BMI.
  Thirty one percent of participants were overweight, 26% obese and 22% were severely obese. Females were grade 1 obese compared to males who were overweight according to the WHO classification (table 6.5.1). The WHR was high in females compared to males. Only 15% of participants had a normal blood pressure at rest. Thirty nine percent had a pre-diabetic systolic blood pressure, 22 were stage 1 hypertensive and 25% were stage 2 hypertensive. Forty seven percent of participants had a normal diastolic pressure and 53% had a pre-diabetic diastolic pressure (80-89mmHg).

  Females were obese compared to males, this is because females are more sedentary and tend to engage in less energy involving activities than men. Obesity is a risk factor of type 2 diabetes and it increases the prevalence of type 2 by 3-7 times more in obese than normal weight adults, because it results in disproportionate build up of fat in the body (Klein et al, 2004), they further added that obesity complicates the management of type 2 diabetes by increasing insulin resistance and blood glucose levels, which increases the risk of developing cardiovascular diseases. Evidence from sub-saharan Africa shows that the prevalence of type 2 diabetes is associated to obesity and hypertension in 80% of overweight women and there was no association between men because of lean body mass. Obesity in women is caused by genetic and environmental factors, (Gill et al 2008; Puoane et al 2002).

Evidence from South African research views obesity as a unique challenge which needs to be addressed by multifactoral strategies such as education, behaviour change, political support, adequately resourced programmes and evidence-based planning, (Kruger et al, 2005). Obesity is influenced by a number of factors such as dietary practices, cultural beliefs & perceptions and socio-economic factors. This evidence suggests that, South African women do not perceive themselves as obese even though they actually are because they associate thinness with HIV/AIDS, (Kruger et al, 2005).

- **Physical activity**

  All participants were sedentary even though males walked slightly further (200m) than females (194m). A study conducted in 1999 to estimate the average distance walked by normal subjects during the 6MWT, showed that a distance of 623m with a range of 383m-621m was covered by females and males walked 84m further than females, (Troosters et al, 1999). Recent evidence shown in a study conducted in South African black females with type 2 diabetes, revealed that the baseline results of a six minute walk ranged from 449m to 452m, (van Rooijen et al 2004). These findings suggest that participants in this study led a sedentary lifestyle. There were no significant differences between males and females, ($p>0.05$). Lack of physical activity is associated with increased systolic blood pressure, increased total cholesterol and LDL-C and it is a significant predictor of type 2 diabetes, (Kruger, 2005).

  The literature shows that physical activity is important in the management of type 2 diabetes because it reduces the incidence of obesity that is directly linked to type 2 diabetes, (van der Merwe et al, 2000). Appropriate diet and exercise according to the recommended health standards is reported to improve insulin sensitivity and glycaemic control, (Osei, 2003; Nelson et al, 2002). Studies conducted from 2001-2008, suggest that poor diet practices, physical inactivity and westernization increase the risk of type 2 diabetes, (; Wild et al, 2004; Ossei, 2003; Nelson et al, 2002). Weinstein et al (2004) added that, physical activity and BMI are predictors of the incidence of type 2 diabetes, and they are two of the most neglected aspects of management of type 2 diabetes.

  The environmental drivers of obesity in developing countries have been identified to be related to westernization which result in decreased physical activity and over consumption of cheap food; globalization which results in shifting away from traditional agricultural and other energy intense activities or occupations and changes in types of transportation leading to less use of leisure physical activity, (Hossain et al, 2007; Prentice, 2005).

Findings of this study showed that the majority of participants were from urban environments indicating that they will be influenced by the environmental factors that drive the prevalence of type 2 diabetes in developing countries, such as less engagement in the physical activities practiced in rural environments, (Cheng 2005; Ramachandran et al, 2002). Evidence from South Africa, suggests that urbanisation and globalization, have led to South Africans shifting from traditional foods which are low in fat and rich in fibre towards high fat foods, (Kruger et al, 2005).

- **Blood pressure**

  Findings of this study showed that both males and females were hypertensive with arterial blood pressure of 144/83 mmHg, (ADA, 2011; SEMDSA, 2009; SEMDSA, 2003). These results are consistent with literature which indicates that raised blood pressure is common in people with type 2 diabetes than those without diabetes, (Adler et al, 2000). In their study they found that the incidence of clinical complications was significantly associated with increased systolic blood pressure except for cataract extraction. These findings confirmed that the risk of diabetes complications was strongly associated with increased blood pressure.

  Literature also suggests that the increased epidemic of obesity associated with type 2 diabetes also contributes to increased blood pressure because high prevalence of cholesterol associated with obesity, (Solano et al, 2006; Gregg et al, 2005; Kalk et al, 2000;). Recently, Catalano et al (2009) found that radial artery intima-media thickness and wall cross sectional area were increased in patients with type 2 diabetes which may be enhanced by hyperglycemia.

6.6.2 Socio-Economic Status

All the participants in this study were from poor socio-economic backgrounds, (see table 6.5.2a table 6.5.2b). Fifty eight percent of this study sample had no income or had incomes less than a R1000.00 per month. Most patients were not employed and were either dependent on their children's grants or husband's money for survival. Participants also indicated high frequencies of eating red meat and tripe (75%) per week compared to fruit and vegetables. There were no significant differences between males and females, ($p>0.05$). Some of these participants were residing in informal settlements and RDP houses. According to Kruger, et al (2005), these conditions will have an influence in preparation, consumption and hygiene of food for urban blacks. Alcohol consumption was also reported by some individuals, (9.6%) and males drank alcohol compared to female, ($p<0.05$). A report by CDC' Behavioural Risk Factor Surveillance

System (2011), suggests that more than half of USA adults with chronic diseases had a history of drinking alcohol in the past 30 days.

These findings are similar to previous epidemiological studies which showed that chronic diseases such as type 2 diabetes are major public health burdens around the world, and the prevalence of the disease is strongly influenced by environmental factors such as poverty and, poor socio-economic status as well as health behaviour (ADA, 2011; Bradshaw et al, 2007; Pirie, 2007; Maty et al, 2005;). A 34 year incidence study, between 1965 to 1999 which established the association between education, income and occupation for a community sample from Alameda country, USA, showed that socio-economic disadvantage with low educational levels were significant predictors of type 2 diabetes. This is because patients do not have money to buy the food recommended for diabetes, resulting in eating any available inexpensive sources of food. Ramachandran et al (2002) added that because of the reasons given above, the prevalence of long-term complications is higher in low socio-economic status groups than in high socio-economic status group due to poor control of the disease.

These result in the development of diabetes complications and poor control, (Maty et al, 2005). Reports by Bradshaw et al (2007) indicate that poverty results in the inequitable distribution of disease because of risk factors such as poor nutrition, unsafe water and sanitation which lead to poor health. They also discussed that it is difficult to overcome poverty in developing countries because it is linked to income inequalities where incomes of the rich continue to increase and the poor remains poor.

The report by WHO (2008) on noncommunicable disease (NCD) risk factors and socio-economic inequalities indicated that this group of diseases, with diabetes included, affects both rich and poor countries. The literature shows that the risk factors of NCD occur in populations with higher socio-economic levels first before shifting to lower socio-economic levels. However the burden of disease doubles in populations with lower socio-economic status because their resources (both clinical and prevention) are stretched compared to those with higher socio-economic status.

6.6.3 **Education Programmes**

Sixty three percent of the participants in this study had adequate knowledge, whilst 37.3% demonstrated marginal knowledge, (see table 6.5.3). This shows that almost 40% of the population had marginal knowledge, which supports the fact that education programmes at Dr George Mukhari hospital are not coordinated (they are still conducted on a one on one basis),

(Trento et al, 2002). According to Trento et al (2002), routine diabetes care is still dominated by traditional therapeutic relationships. They further debated that during these interactions doctors, nurses, dieticians and other health professionals interact with patient on a one- on-one basis and this approach may only give information to patients but does not stimulate patients' cooperation. They recommend the use of group discussions because they promote better health behaviours, better knowledge of disease management and finally improve metabolic control and quality of life.

According to Schillinger (2002), health literacy is important in patients with chronic diseases in order for them to understand the instructions given to them on management of the diseases. They further explain that the language used for communication versus the patient's commonly used language is reported to affect adherence and this factor is also reported to be overlooked by clinicians because they tend to overestimate the abilities of patients. They further discuss that some patients cannot interpret common medical terms used at public hospitals such as a stable blood pressure or instructions on medication dosage. These can be interpreted differently by different patients because of limited health literacy. This implies that health professionals must explain instructions on medical dosage at the level of each individual patient's understanding. Gurka et al, 2006 also added that people with different educational backgrounds may respond differently to a lifestyle intervention for weight and diabetes control.

Joshi, (2008), discussed that lifestyle modification through patient education is the mainstay treatment strategy for type 2 diabetes. The diabetes self-management education strategies as recommended by the National Standards for Diabetes Care are important because they empower patients and families with knowledge, treatment skills and social role fulfillment, (Funnnell et al, 2009).

6.6.4 **Emotions about Type 2 Diabetes**

The majority of participants had negative emotions about type 2 diabetes. These findings are similar to the literature which shows that major depression has been found to be a chronic condition in type 2 diabetes. They also added that patients with depression and type 2 diabetes have poorer self management and have more lapses in refilling their medications, (Katon et al, 2005). Other issues like depression, stress, alcoholism, and hypertension also affect adherence, (Vermeire et al, 2005). More males felt that they found it easy to take control of type 2 diabetes with support from home. These findings show that males control diabetes better with support because African men do not cook. It is important for this group of patients to educate their family in order to control the disease better. Because socio-cultural barriers

influence the results of traditional education methods, interactive techniques whereby patients and families are involved result in effective diabetes education, (WHO, 2008). Access to care and a good patient-physician relationship also influence adherence to treatment and this lessens the negative emotions about the disease.

6.6.5 **Random Bloods**

All the participants were hyperglycemic, with blood glucose levels (>11.1mmol/l) and $HbA1_C$ more than 10%. They also presented with high cholesterol levels (>4.5 mmol/l), low HDL-C levels (<1.2 mmol/l), high LDL-C levels (>2.5 mmol/l) and high triglyceride levels (1.5 mmol/l) (see table 6.5.6). Similarly the literature indicates that patients with type 2 diabetes are characterised by increased blood glucose levels and alterations in HbA1c levels because of insulin resistance. Persistent hyperglycemia is responsible for serious damage to large (chronic complications) and small blood vessels (acute complications) together with various organs in type 2 diabetes such as retinopathy, nephropathy and neuropathy These complications lead to cardiovascular morbidity and mortality, (Caro et al, 2002). Findings by Otieno, et al, (2003) indicated that the majority of ambulatory diabetic patients attending out-patients diabetic clinics had poor glycaemic control. They further added that poor glycaemic control is increasing in developing countries, especially in areas where resources are scarce.

According to Kolovou et al (2004), low levels of HDL-C are associated with coronary heart diseases (CHD). They concluded that the delayed clearance of triglycerides post prandially result in low HDL-C. This means that increased levels of triglycerides affect levels of HDL-C. Joshi (2008) added that about 80% of patients with type 2 diabetes are obese and this results in metabolic abnormalities such as dyslipidaemia and hypertension. According to Longo-Mbeza et al (2011), an increase in the prevalence of type 2 diabetes in sub-Saharan Africa is influenced by westernization lifestyle changes which result in reduced physical activity and high caloric intake. This results in obesity which is a risk factor for metabolic syndrome and glucose intolerance.

Clinical trials indicate that an increase in HbA1c, above 7.5% results in poor glycaemic control and diabetes complications; in contrast to this a decrease of HbA1c by 1% can reduce micro vascular complications by 25%-30%. A reduction of blood pressure by 10 mmHg decreases macrovascular and micro vascular complications as well as mortality rates by 35%, (Hossain et al, 2010; Norris et al, 2002; Adler et al, 2000). When the lipid profile is controlled, the risk of coronary heart diseases reduces by 25%-55% and risk of death by 43%, (Saaddine et al, 2002). This means when the quality of type 2 diabetes management improves, patients will

show better control. Therefore treatment goals should address individual patient needs whilst taking into consideration the stage of the disease, (Barnett, 2004).

6.6.6 Health Related Quality of Life

HRQOL was rated as poor; this is confirmed by the higher rating on symptoms and very low wellbeing, diabetic morale and social role fulfillment. Similarly, Testa et al (1998) showed that health related quality of life improves with improvements in glycaemic control in patients with type 2 diabetes. According to Hu and Meek (2005), patients with chronic diseases always rate their health as poor and are less satisfied with their lives when they cannot perform their activities of daily living. As the epidemic of type 2 diabetes continues to increase there is also an increase in micro and macro-vascular complications such as loss of vision, ischaemic heart diseases and kidney diseases because of hyperglycaemia and beta cell dysfunction, resulting in poor HRQOL, (WHO, 2002).

6.7 CONCLUSION

The findings of this study show that patients with type 2 diabetes consulting at Dr George Mukhari hospital are obese and overweight, have poor socioeconomic backgrounds as displayed by the fact that they still have problems with sanitation and indoor running water and most of them are unemployed. The knowledge scores showed that there were available diabetes education programmes, however these programmes were not appropriately conducted as recommended by the National Standards of Diabetes Self-Management Strategies, (this means they were not nurse-based group discussions but one on one education programmes). All participants had poor glycaemic control and poor health related quality of life. The poor HRQOL and poor glycaemic control are amplified by the negative emotions about type 2 diabetes and poor diet practices and sedentary life style. There is a demand for interventions to control type 2 diabetes at Dr George Mukhari hospital.

CHAPTER 7

7. STUDY IV: RANDOMISED CONTROL TRIAL

METHODOLOGY

7.1 INTRODUCTION

This chapter provides detailed information about data sources, study design, study population and various statistical methods used to analyze data in this study.

Objectives 5, 6 and 7 of this thesis were addressed by the randomised control trial. An overview of the studies was described in Chapter 1.

These objectives were:

1. to determine the effects of a family based education and exercise intervention on the control of the levels of the following measures of random blood results:
   - HbA_1c
   - Blood glucose
   - Lipogram

2. to determine the impact of a family based education and exercise intervention on the health related quality of life of patients with type 2 diabetes.

3. to determine the factors that affect the management of diabetes in patients with type 2 diabetes at Dr George Mukari hospital.

The main outcome measures of this intervention included the 6 minute walk test, anthropometric measurements, blood tests and health related quality of life (HRQOL) using DIMS.

These outcome measures were evaluated at three stages:

1. at the beginning of the intervention (baseline test).
2. after six (6) months of intervention (post intervention test).
3. after 12 months during which time there was no intervention (six months post intervention).

7.2 DESIGN

A prospective single blinded randomized control trial with a pre and post- intervention test was undertaken. An exercise programme (home based walking programme), education and family support were undertaken in the intervention group to facilitate behaviour change and lifestyle modification. The intervention group was compared with a second intervention group as well as a control group at the start and end of the six months intervention, as well as at 12 months, that is, six months after the conclusion of the intervention.

7.2.1 Sample

The study sample comprised of patients aged 28 to 70 who were recruited from a group of patients diagnosed with type 2 diabetes and consulting at Dr George Mukhari hospital. A total of 135 type 2 diabetes patients who met the inclusion criteria, participated in study 3, described in chapter 6 were randomly assigned into three groups by an independent research assistant using concealed random allocation. Two groups were intervention groups and one group was the control group. The study sample that participated in the randomized control trial is the same sample that was described in chapter 6.

7.2.2 Inclusion Criteria

The following inclusion criteria were used for the selection of the study participants:

- Patients with type 2 diabetes mellitus who agreed to participate in the study by signing a consent form.
- Patients aged between 28 – 70 years at the beginning of the study.
- Males and Females.
- Controlled blood pressure (BP), this means that patients should be on antihypertensive medication with Systolic BP not more than 150 mmHg and Diastolic BP not more than 90 mmHg at rest, (Pignone, 2010), or a BP not more than 130/80 not using antihypertensive medication, (SEMDSA, 2003; WHO, 2002;).
- No peripheral vascular diseases

7.2.3 Exclusion Criteria

- All patients with uncontrolled BP (BP above 150/90 at rest) or a BP more than 130/80 if not using antihypertensive medication.
- Amputations of the lower limbs
- Diagnosed ischaemic or peripheral neuropathy.
- Patients with any lesions of the lower extremities which may be aggravated with exercise.
- All patients who did not give consent to participate in the study.

7.3 SAMPLE SIZE CALCULATION

A total sample of 105 patients with type 2 diabetes and 35 participants in each group, meaning 70 patients in the two experimental groups and 35 patients in the control group was required. This sample size was necessary to detect a 1% clinical reduction of HbA1c after 12 months. As statistical calculation of 90% power where $\alpha = 0.05$ and $\beta = 0.10$, given a standard deviation of 1.41% was done. In consideration of a ± 20% drop out rate, recruitment was determined by 45 participants in each group, (Brown et al, 2005; van Rooijen et al, 2004).

7.4 ETHICAL CLEARANCE

The Committee for Research for Human Subjects at the University of the Witwatersrand granted ethical clearance, (ethical clearance certificate no M060955) to conduct the study and collect blood from patients with type 2 diabetes, (see Appendix III). In this study patients were given an information sheet and written consent form to obtain their permission to participate in the study which they had to sign. Each patient was allocated a reference number which was applicable to all forms used for data collection and blood specimens. The anonymity of patients was maintained in all stages of the research. All participants were free to decline at any-time during the course of the study without prejudice. A separate application to get permission to conduct the study at Dr George Mukhari hospital out-patient diabetes clinic was made through the CEO of the hospital and consent was granted, (see Appendix III). The sister in charge and the staff members at the diabetic clinic were fully informed about the study.

7.5 OUTCOME MEASURES

7.5.1 The Six Minute Walk Test

The exercise capacity of each patient was tested by a six minute walk test. A 25 meters distance was marked off in a quiet corridor next to the casualty department, where emergency care and doctors were always available. Patients were asked to walk along the distance as many times as they could for six minutes as fast as they could. Chairs were provided if patients needed to rest, and the time plus the distance walked were recorded. Patients were motivated only by saying, “You are doing well carry on” once, as they passed the researcher. Patients were monitored for six minutes during recovery. The results of the six minute walk test served as a baseline for prescription of the home- based walking programme. The following tests were regarded as components of the exercise capacity test and as indicators of safety during exercise:-

- **Resting pulse**

  Resting pulse was recorded in beats per minute (b/min) using an electronic calibrated machine. Pulse was taken before the exercise, immediately after six minutes and after six minutes rest. The pulse was recorded with patients seated.

- **Blood pressure**

  Blood pressure was recorded in mmHg, using an electronic calibrated machine. It was taken prior to the start of the test (at rest), immediately after the six minute walk and after six minutes rest. Blood pressure was recorded with patients seated.

- **The Rate of Perceived Exertion (RPE)**

  The Borg scale of perceived exertion as described by Enright (2003), was used.

  Each patient's level of maximum activity was rated using a 6 to 20 scale, (Bautmans et al, 2004; Enright, 2003). The test was terminated if the patient was exhausted or complained of chest pains and dizziness and the time and distance walked were recorded.

7.5.2 Blood Samples

Random blood samples for laboratory tests were taken by a professional nurse at the diabetic clinic at the beginning (baseline) and at the end of the six months intervention. Postprandial blood was preferred to fasting blood because most patients were on insulin and had to take their insulin early before coming to the hospital and 30 minutes after the injection they needed to have a snack. This was planned due to the fact that patients get to the hospital in the early hours of the morning in order to be in the various queues for the doctor, routine clinic tests and pharmacy.

The levels of the following were analyzed:

- HbA1c – measure of diabetic glycaemic control.
- Random blood glucose .
- Lipogram – total cholesterol, triglycerides as well as low density and high density lipoproteins.

7.5.3 Anthropometric Measurements

The following anthropometric measurements were taken by the researcher, at baseline, after six months of intervention and at 12 months.

- **Body weight**

  Body mass was recorded using an electronic calibrated bathroom scale (SECA 813 model) and all patients were asked to stand bare foot whilst measuring their body weight. Patients wore light clothing only.

- **Height**

  Height was measured in centimeters, using a height chart as a vertical distance from the floor to the head, (vertex of the head). All patients were asked to stand barefoot against the wall with their arms at their sides. Body weight and height measurements were used to calculate body mass index (BMI) as weight in kg/height in meters squared (kg/m^2).

- **Circumferential measurements**

  Circumferential measurements were measured in centimetres. These measurements were taken with the patient standing upright, over light clothing using a tape measure. Measurements were taken at the sites mentioned below in order to determine the waist-hip ratio (WHR):

  1. Waist = at the level of the umbilicus.
  2. Hips = at the level of the greater trochanter.

7.5.4 Level of Knowledge

Baseline knowledge score, socioeconomic status, emotions about diabetes and behaviours with regards to food and exercise was determined using a knowledge questionnaire, described in chapter 5.

7.5.5 Health Related Quality of Life (HRQOL)

HRQOL was assessed using DIMS, a 44 item scale described in chapter 5.

7.6 PROCEDURE

The study sample was randomized into three groups which were:

- Group 1 = home based walking programme, education and family support; and usual management at the clinic.
- Group 2 = home based walking programme and education with no family support; and usual management at the clinic.
- Group 3 = control group, receiving usual management at the clinic only.

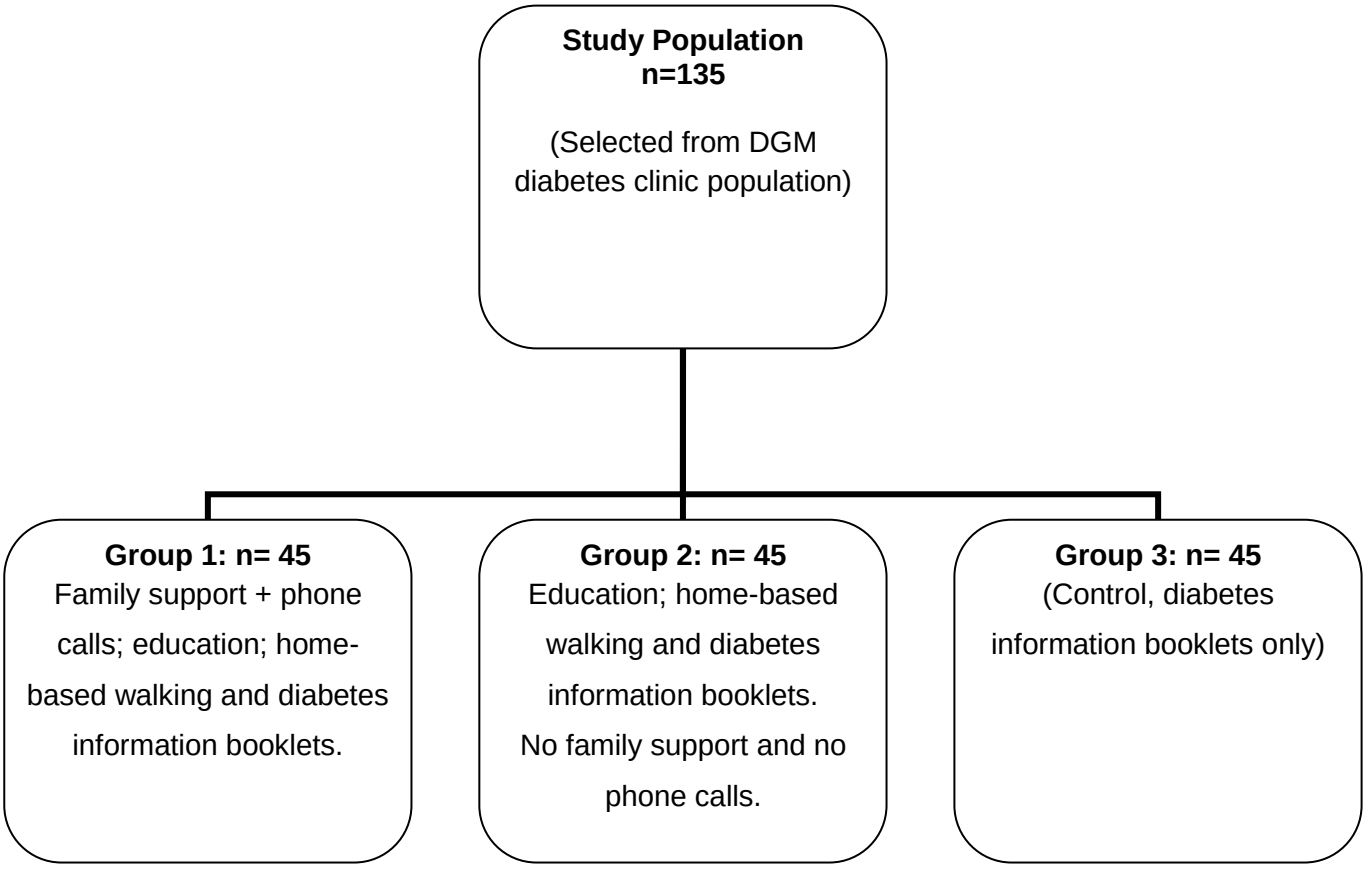

Figure 7.1: Description of the Three Groups after Randomization

The researcher assessed all the patients at baseline, after six months and again after 12 months and was blinded to group allocation. The distance walked, resting pulse, resting blood pressure, body weight, BMI, waist-hip ratio, random blood samples, level of knowledge and health related quality of life were measured at each of the above timelines. The intervention was carried out by two research assistants: a professional nurse who managed the diabetes education and phone calls and a second assistant who was a physiotherapist who supervised the home-based walking programme. Both research assistants were trained by the researcher, prior to commencement of the study.

7.7 INTERVENTION PROGRAMME

The following programmes were given to the experimental groups and were carried out for six months; thereafter there was an observation period for six months.

7.7.1 **Home-Based Walking**

The role of the walking programme was to encourage regular participation in physical activity which would help in glucose metabolism. This intervention was the most preferred because it is cost effective, it can be performed anywhere and most of the participants came from communities with limited resources.

"Time spent walking" was used to progress the exercise programme as this was considered to be an easier way for patients to understand how to progress their programmes:

All patients were instructed to start off walking for a minimum time of at least 20 minutes. They were asked to build up their walking time to 30 minutes and then to a maximum of 45 minutes. Patients were encouraged to walk three times a week, (Taniguchi et al, 2000). An exercise diary was given to all patients to record the days they exercised as well as the actual time taken to carry out the exercise, (see Appendix I). Participants who belonged in group 1 and group 2 were given the same home based walking programme.

7.7.2 **Education**

Both experimental groups group 1 and group 2 received the same education.

An education programme was given once a month with duration of 45 minute per group discussion. All participants were booked on the days of their reviews or repeat medication. The education focused on addressing the goals of type 2 diabetes self-management and the role of exercise in the management of the disease as supported by the International Diabetes Federation (IDF):

- To understand the nature of their disease and the management. Patients were encouraged to understand that type 2 diabetes is a chronic disease therefore it is not cured but controlled. This means that patients needed to adhere to their medication even if they did not feel sick.
- They were taught about the common complications and how to prevent or delay their onset.
- They were encouraged to take responsibility for their own health and know the importance of that. They were given the normal values for good control and were facilitated to understand the benefits of maintaining normal sugar levels.
- The prevention of hypoglycaemia during exercise was described.
- Education on healthy diet was also included.
- They were also helped to understand that they needed to modify their life style by adhering to the prescribed diet, taking their medication at the specified times and that losing weight would help them to control their diabetes better.

7.7.3 **Telephone Calls**: **(for group 1 only)**

A family member was defined as a close family member; a colleague; a friend or a church colleague whom the patient had nominated. The contact details were obtained from each family member and the appointed member was phoned once a month. The role of the family member was to provide support for the patient and encourage the patient to carry out the guidelines on their education programmes.

The following factors were considered when choosing the family member:

- they were both in the same family structure, either as immediate or extended family member.
- same organization, working together or as a church colleague, if not a family member.
- shared the same family emotion, meaning that the appointed person knew about the health problem of the patient, (Chesla et al, 2003). The role of this family member was to support and encourage the patient to carry out the exercise programme and follow the advice given during self – management education.

Telephone call sessions were scheduled to last between 10 to 15 minutes on the first call because the family member was helped to understand the education program given to patients. Follow up sessions were scheduled to take five minutes because they were only checking whether the family member was still giving support and to answer any questions that arose.

Education given to family members:

Family members were expected to come to the clinic for the first education class of each participant in group 1. When no family member came because of financial constraints the following was discussed over the phone:

- Each family member was made aware of the diabetes information booklets that were given at the clinic which had information on how to manage type 2 diabetes and advice on healthy food. They were advised to read these booklets and share the information with participants.

The following step by step checklist was designed on the following areas of diabetes self care so that it was easily managed during the telephone conversation:

- blood sugar testing
- medication management
- diet
- exercise

The following questions were asked from all family members on follow up calls:

- When last did the patient come to the diabetes clinic and when is the next appointment?
- Is the patient still taking his/her medication and doing his/her exercises as prescribed?
- Are there any problems that the patient is experiencing with regards to treatment?

Bias control

To avoid contamination, patients who belong to experimental groups were addressed separately by the research assistant at the beginning of the study and their doctor's appointments were booked together. Those who belong to the control group were grouped together and their appointments were on separate weeks to those of experimental group.

7.8 DATA ANALYSIS

SPSS version, 17.0 and STATA version 8.0 software were used to analyze the data. Means and standard deviations were used to reduce the continuous data; frequencies were used to reduce the categorical data. Continuous variables were compared using an independent student's t-test for between group comparisons and categorical data were compared using both a Chi-square test and Fischer's exact test for small group comparisons. Changes between groups over time were measured using an ANOVA. The primary efficacy variable, i.e. the lowering of $HbA1_C$, random blood glucose, total cholesterol, HDL-C, LDL-C triglycerides, knowledge score, BMI, distance walked in six minutes were analyzed using an analysis of covariance (ANCOVA) with baseline values as covariate.

A logistic regression analysis was done to establish factors influencing the outcomes.

When comparing study groups with respect to "glycaemic control variables at last visit (12 months)", homogeneity of variance could not always be assumed for analysis of variance. The analyses were repeated using the Kruskall-Wallis test, a non-parametric ANOVA, and when significance was indicated the latter result was accepted in view of non-parametric testing being conservative.

The significance of the study was set at the 95% level (p=0.05).

CHAPTER 8

8. RESULTS AND DISCUSSION OF THE RANDOMISED CONTROL TRIAL

8.1 INTRODUCTION

This chapter describes the results of the main study, the randomized control trial. Each outcome measure's results are presented at baseline, six (6) and twelve (12) months post intervention. All findings of the main study are presented in tables and figures.

Data capturing for this study commenced on the 26th February 2009 and ended 30th April 2010. The various stages of the study progress including selection of participants, withdrawals and death are indicated in figure 8.1.

Figure 8.1 below shows the distribution of patients at baseline, six (6) and twelve (12) months post intervention.

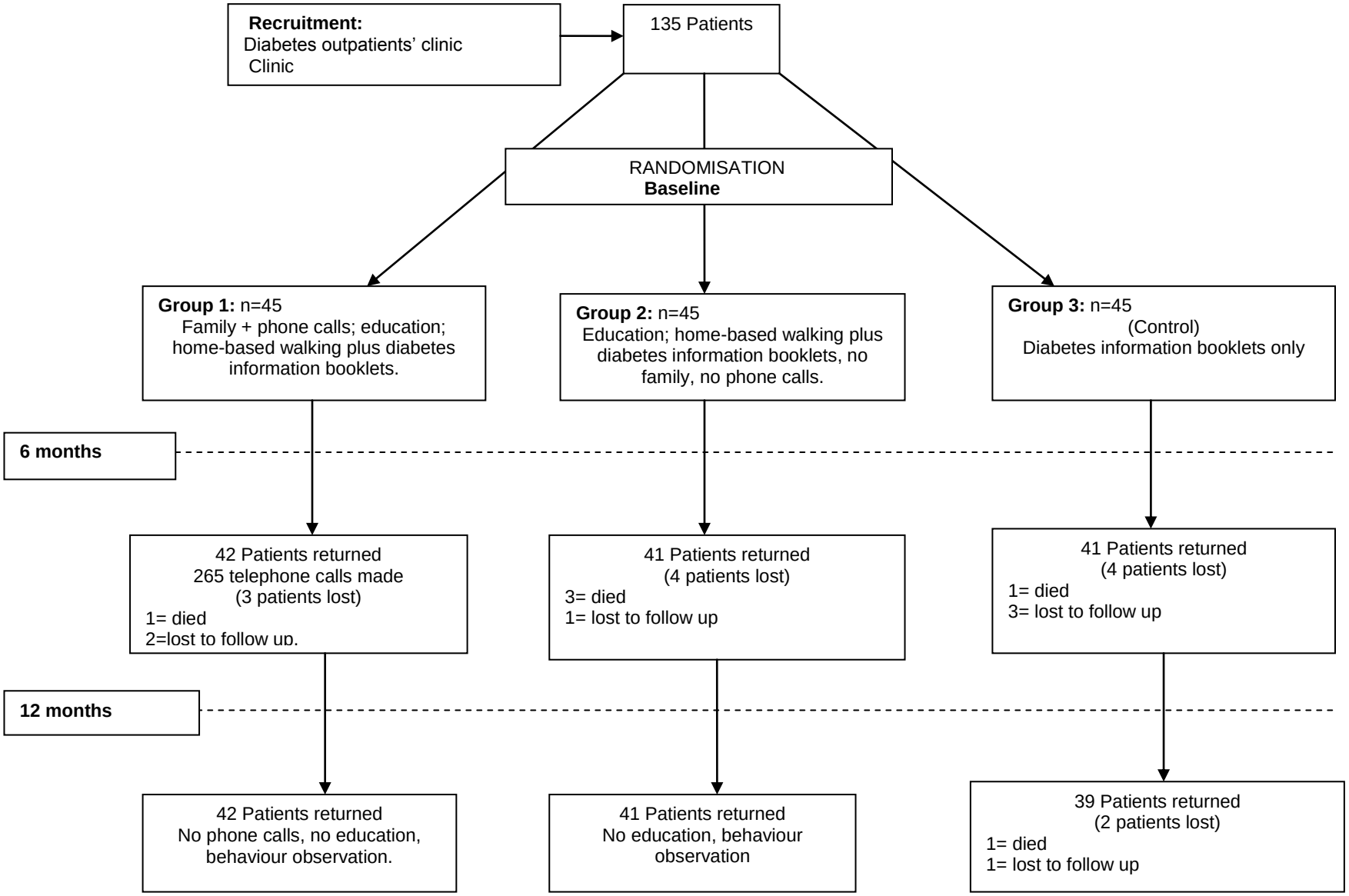

Figure 8.1: Distribution of Patients in Different Groups at Baseline, after the Six Month Intervention, and at 12 Months

The figure above shows the distribution of the sample size at baseline, (a total of 135 patients), after six months of intervention, (a total of 124 patients) and after 12 months, (a total of 122 patients). There was a retention rate of 92% at six months and 90% retention rate at 12 months.

8.1.1 Appointment Attendances

In table 8.1.1 below, the attendance register is shown:

Table 8.1.1: Education Attendance Register (n=90)

Months	Week 1		Week 2		Week 3		Week 4	
	Monday Thursday		Monday Thursday		Monday Thursday		Monday Thursday	
February						6	0	9
March	3	9	1	3	8	2	1	4
April	0	7	9	5	0	2	0	3
May	0	6	3	2	8	1	3	0
June	0	0	0	0	1	4	0	0
July	2	2	0	7	3	5	4	5
August	2	5	3	1	1	4	4	1

Education programmes started on the third week of February and finished at the end of August. The expected number of attendance in each session was 11 or 12 patients. There was never a 100% attendance (11 or 12 patients) regardless of the appointment dates given. There were days where educational sessions were not conducted because there were no attendees (indicated by “0”).

8.2 DEMOGRAPHIC BACKGROUND

Table 8.2.1 below, outlines the demographic backgrounds of all patients and includes type of family support, settlement, house type, employment, number in the household, electricity, availability of water sanitation, total income and mode of transportation used for the hospital appointments.

Table 8.2.1: Socio-Demographic Data (n=135)

Parameter	Group 1 n=45 (%)	Group 2 n=45 (%)	Group 3 n=45 (%)	p-value
Family relative (Support)				
Family member	40 (88.9%)	40 (88.9%)	41 (89.6%)	**p=0.50**
Friends	3(6,7%)	1(2.2%)	3(6.7%)	
Colleague	2(4.4%)	4(8.9%)	1(2.2%)	
Settlement				
Urban	40 (88.9%)	39 (86.7%)	41(91.1%)	**p=0.70**
Rural	5 (11.1%)	6(13.3%)	4 (8.9%)	
House Type				
Shack	8 (17.8%)	3 (6.7%)	5 (11.1%)	**p=0.30**
RDP	5 (11.1%)	5 (11.1%)	6 (13.3%)	
Municipality	9 (20.0%)	16 (35.6%)	8(17.8%)	
Big house	23 (51.1%)	21 (46.7%)	26 (57.8%)	
Employment				
Full time	12 (26.7%)	16 (35.5%)	17 (37.8%)	
Part time, casual jobs and self employed	4 (8.9%)	6 (13.3%)	3 (6.7%)	**p=0.30**
Unemployed	17 (37.8%)	10 (22.2%)	7 (15.6%)	
Pensioner	12 (26.7%)	13 (28.9%)	18 (40.0%)	
Numbers in the House-hold				
1-5 members	27 (59.9%)	33 (72%)	32 (68.8%)	**p=0.20**
6-10 members	17(37.8%)	11 (26.3%)	12 (33.7%)	
> 10 members	1(2.2%)	1(2.2%)	1 (2.2%)	
Electricity				
No	2 (4.4%)	0	0	**p=0.10**
Yes	43 (95.6%	45 (100%)	45 (100%)	
Water				
None	0	1 (2.2%)	3(6.7%)	**p=0.20**
Outdoors	17 (37.8%)	14 (31.1%)	10 (22.2%)	
Indoors	28 (62.2%)	30 (66.7%)	32 (71.1%)	
Sanitation				
No (0)	5 (11.1%)	5 (11.1%)	3 (6.7%)	**p=0.70**
Outdoors	1 (2.2%)	3 (6.7%)	3 (6.7%)	
Indoors	39 (86.7%)	37 (82.2%)	39 (86.7%)	
Total income				
No (0)	29 (64.4%)	26 (57.8%)	24 (53.3%)	**p=0.90**
<R1000	7 (15.6%)	7 (15.6%)	8 (17.8%)	
R1000-R3000	5 (11.1%)	6 (13.3%)	7 (15.6%)	
R3001 and above	4 (8.9%)	6 (13.3%)	6 (13.3%)	
Transport				
Own car	5(11.1%)	2 (4.4%)	4 (8.9%)	**p=0.50**
Public transport	40 (88.9%)	43 (95.6%)	41 (91.1%)	

The groups had similar socio-economic backgrounds at baseline, p>0.05. The majority of patients came from urban areas and very few from rural areas. Patients with higher incomes (from R3000 and above per month) had indoors running water, electricity as well as good sanitation while those with an income of R1000 per month and less or no income at all used

water pipes outside their rooms or in the streets, they also used shared toilets in the yard or pit-latrines. These were equally distributed across the groups. The majority of patients (92%) in all groups used public transport to get to hospital; very few had their own transport (8%). There were no significant differences between groups, (p>0.05).

8.3 PHYSICAL MEASUREMENTS AND KNOWLEDGE SCORE

Table 8.3.1(a) below shows the physical measurements and knowledge scores of the patients:

Table 8.3.1(a): Physical Measurements and Knowledge Score at Baseline (n=135)

Parameter	**Group: 1 n=45** Mean (sd)	**Group 2: n=45** Mean (sd)	**Group 3:n=45** Mean (sd)	**p Value**
Age (years)	55 (±8.9)	54(±8.5)	55(±8.8)	p=0.17
Gender ▪ Female ▪ Male	 27 (±7.1) 18 (±8.5)	 27 (±8.2) 18 (±4.3)	 26 (±5.23) 19 (±5.7)	p=0.65
Body weight (kg)	82.9 (±23.3)	80.7 (±18.2)	84.3 (±16.5)	p=0.79
BMI(kg/m^2)	31 (±7.6)	30.7 (±7.2)	30.9 (±5.5)	p=0.97
WHR	0.9 (±0.1)	0.94(±0.1)	0.94 (±0.8)	p=0.42
Pulse (beats/min)	87 (±15.3)	85(±14.0)	85(±12.2)	p=0.89
Sys BP mm Hg	146 (±31.2)	143 (±23.1)	143 (±26.2)	p=0.20
Dias BP mm Hg	85 (±16.3)	82 (±13.7)	83 (±13.6)	p=0.44
Distance walked (meters)	202 (±41.9)	194 (±55.7)	188(±48.0)	p=0.10
RPE	12 (±1.4)	12.2 (±1.6)	12(±1.4)	p=0.34
Knowledge score	14.0 (±2.81)	14.2 (±2.6)	13.4 (±2.5)	p=0.97

Baseline measurements showed no significant differences amongst the groups in all variables, (p>0. 05).

Table 8.3.1(b) below shows the physical measurements and knowledge scores of the patients after the six months intervention.

Table 8.3.1(b): Physical Measurements and Knowledge Score after the 6 Months Intervention (n=124)

Parameter	6 Months Post Intervention			
	Group 1:n=41 Mean(sd)	**Group 2:n=41** Mean(sd)	**Group 3:n=41** Mean(sd)	**p<0.05**
Body weight (kg)	85.2 (±20.0)	81.4 (±17.3	82.8 (±17.6)	p=0.90
BMI (kg/m^2)	31.9 (±31.9)	31 (±7.3)	30.3 (±5.9)	p=0.67
WHR	1.0 (±0.9)	0.9 (±0.09)	0.9 (±0.1)	p=0.89
Pulse (b/min)	84 (±15.5)	89 (±11.3)	83 (±11.1)	p=0.20
Systolic BP (mmHg)	147 (±24.7)	149 (±24.3)	142 (±19.8)	p=0.17
Diastolic BP (mmHg)	84 (±13.9)	85 (±13.6)	82 (±12.9)	p=0.84
Distance walked (m)	210 (±39.7)	210 (±38.7)	188 (±36.3)	**p=0.04
RPE	11.8 (±1.3)	11.8 (±1.3)	12 (±1.4)	**p=0.00
Knowledge	16 (±2.1)	16 (±16.1)	15 (±2.3)	**p=0.04

****Indicates statistical significance, p<0.05**

Following the six month intervention, there was a significant increase in the distance walked, increased knowledge scores and a decrease in RPE when comparing the experimental groups (group 1 and 2) to group 3, ($p<0.05$). Group 1 gained weight and BMI increased as well as the WHR. There was no change in pulse and blood pressure, ($p>0.05$).

Table 8.3.1(c) below shows the physical measurements and knowledge scores of the patients at 12 months.

Table 8.3.1(c): Physical Measurements and Knowledge Score After 12 months (n=12)

Parameter	12 Months Post Intervention			
	Group 1: n=42 Mean (sd)	**Group 2: n=41** Mean(sd)	**Group 3: n=39** Mean(sd)	**p Value**
Body weight (kg)	84.8 (±17.5)	81.7 (±17.1)	84.4 (±15.6)	p=0.90
BMI (kg/m^2)	31.7 (±6.1)	31.3 (±6.6)	31.4 (±5.3)	p=0.67
WHR	1.0 (±0.1)	0.9 (±0.1)	0.9 (±0.1)	p=0.89
Pulse (b/min)	89 (±12.7)	86 (±10.4)	89 (±8.9)	p=0.10
Systolic BP (mmHg)	147 (±25.7)	147 (±17.5)	142 (±18.7))	p=0.17
Diastolic BP (mmHg)	83 (±10.9)	82 (±10.5)	83 (±12.4)	p=0.84
Distance (m)	202 (±40.3)	196 (±40.1)	187 (±40.4)	**p=0.04
RPE	12.2 (±1.0)	12.1 (±1.2)	12.9 (±1.2)	**p=0.002
Knowledge	16 (±2.3)	15 (±3.3)	15 (±2.7)	**p=0.04

****Indicates statistical significance, p<0.05**

Following 12 months (six months with no intervention), group 1 walked further than group 2 and group 3 (control group), demonstrating better maintenance of the exercise programme, ($p<0.05$). RPE, although higher than six months was still lower compared to group 3. The knowledge score increased in group 1 compared to group 3, ($p<0.05$). There is also a slight reduction in weight in group 1, whilst group 3 (control) gained weight, when comparing baseline and six months results. This was however a non- significant difference between the groups, ($p>0.05$).

8.4 BLOOD CHEMISTRY

Table 8.4.1(a) below illustrates the blood chemistry for all groups at baseline.

Table 8.4.1(a): Blood Chemistry at Baseline (n=135)

Parameter (Random Blood Levels)	**Group 1: n=45 (%)** Mean (sd)	**Group 2: n=45 (%)** Mean (sd)	**Group 3: n=45 (%)** Mean (sd)	**p- Value**
Random blood glucose (mmol/l)	12.6 (±5.4)	11.6 (±4.9)	12.2 (±6.0)	p=0.46
HbA1c (%)	9.9 (±2.4)	9.4 (±2.6)	10.7 (±2.9)	p=0.34
Total Cholesterol (mmol/l)	4.7 (±1.2)	4.4 (±1.2)	4.7 (±1.3)	p=0.1
HDL-C (mmol/l)	1.1 (±0.4)	1.0 (±0.2)	1.0 (±0.2)	p=0.25
LDL-C (mmol/l)	2.7 (±0.9)	2.7 (±1.0)	2.9 (±1.1)	p=0.11
Triglycerides (mmol/l)	1.8 (±1.0)	1.5 (±0.7)	1.8 (±1.1)	p=0.20

Baseline measurements showed increased random blood glucose levels (normal ≤11.1 mmol/l); HbA1c levels (normal <7%); total cholesterol (normal <4.5 mmol/l); triglycerides (normal <1.7 mmol/l) and LDL (normal <2.6mmol/l) in all groups. HDL-C levels were reduced (normal >1.1mmol/l). There were no significant differences between the groups at baseline, ($p>0.05$).

Table 8.4.1(b) below illustrates the blood chemistry after the six month intervention.

Table 8.4.1(b): Blood Chemistry after the 6 Months Intervention (n=124)

Parameter (Random Blood Levels)	**6 Months post intervention**			
	Group1: n=42 Mean (sd)	**Group2: n=41** Mean (sd)	**Group3: n=41** Mean (sd)	**p Value**
Random blood glucose (mmol/l)	11.0 (±5.9)	12.9 (±6.0)	11.7 (±7.5)	p=0.80
HbA1c (%)	10.0 (±3.1)	10.9 (±3.1)	10.2 (±2.8)	*p=0.07
Total Cholesterol (mmol/l)	4.5 (±1.2)	4.1 (±1.0)	4.6 (±1.3)	**p=0.003
HDL-C (mmol/l)	1.0 (±0.4)	1.1 (±0.5)	0.9 9 (±0.3)	p=0.23
LDL-C (mmol/l)	2.6 (±0.9)	2.3 (±0.8)	2.8 (±1.0)	**p=0.0002
Triglycerides (mmol/l)	1.7 (±0.9)	1.6 (±0.98)	1.8 (±1.5)	p=0.80

***Indicates marginal significance** ****Indicates statistical significance**

Following the six months intervention, there was a significant decrease in total cholesterol and LDL-C levels, ($p<0.05$) in experimental groups (group 1 and group 2) compared to group 3. HbA1c showed a slight reduction in group 1 which was marginally significant, ($p=0.07$). There was a clinically relevant reduction of 1.3% in blood glucose levels from 12.6mmol/l to 11mmol/l after six months, in group 1(family support) compared to group 3 (control) but this change was not statistically significant, ($p>0.05$). HDL cholesterol and triglycerides were unaffected by the intervention, ($p>0.05$).

Table 8.4.1(c) below illustrates the blood chemistry at 12 months.

Table 8.4.1(c): Blood Chemistry at 12 Months (n=122)

Parameter (Random Blood Levels)	**12 Months post intervention**			
	Group1: n=42 Mean (sd)	**Group2: n=41** Mean (sd)	**Group3: n=39** Mean (sd)	**p Value**
Random blood glucose (mmol/l)	10.5 (±5.2)	13.5 (±6.2)	12.9 (±6.9)	p=0.76
HbA1c (%)	9.5 (±2.6)	10.4 (±2.9)	10.1 (±2.9)	p=0.68
Total Cholesterol (mmol/l)	4.4 (±1.1)	3.9 (±0.9)	4.2 (±1.2)	**p=0.001
HDL-C (mmol/l)	1.0 (±0.3)	1.0 (±0.6)	0.9 (±0.2)	p=0.11
LDL-C (mmol/l)	2.4 (±0.9)	2.2 (±0.7)	2.6 (±0.9)	**p=0.0001
Triglycerides (mmol/l)	2.5 (±4.1)	1.6 (±0.9)	1.7 (±1.1)	p=0.31

****Indicates statistical significance, p<0.05**

After 12 months, there was a significant decrease in total cholesterol and LDL-C levels, ($p<0.05$), in the experimental groups (group 1 and 2). These results show that group 1 maintained these blood chemistry levels better compared to group 3, even when there was no

intervention. There was a clinically relevant decrease of 2.1% in blood glucose levels from 12.6mmol/l to10.5 mmol/l after 12 months, in group 1. HbA1c decreased by 0.5% clinically (from 10% to 9.5%) in group 1 compared to group 3 but the change was not statistically significantly different, ($p>0.05$). HDL-C and triglycerides did not change, ($p>0.05$).

8.5 **BLOOD CHEMISTRY COMPARING YEARS DIAGNOSED WITH TYPE 2 DIABETES**

Blood chemistry results were also checked through specific categories of diabetic groups comparing years diagnosed with type 2 diabetes. This approach was explored to establish whether patients who had been diagnosed with diabetes more recently were able to control their disease better than those who had the disease for a longer period.

In tables 8.5 (a-c) below are the results at baseline, after the six month intervention and at 12 months of the three groups divided into those who had been diagnosed < 5 years; 5-10 years and more than 10 years ago.

Table 8.5(a): Blood Chemistry for Diabetic Categories Comparing Years of diagnosis at Baseline (n=135)

Parameter (Random blood levels)	**Group 1: n=45** Mean (sd)			**Group 2: n=45** Mean (sd)			**Group 3: n=45** Mean (sd)			**p<0.05**
	0-5 years	**6-10 years**	**>10 years**	**0-5 years**	**6-10 years**	**>10 years**	**0-5 years**	**6-10 years**	**>10 years**	
Random blood glucose (mmol/l)	13.4 (±5.4)	11.1 (±5.97)	12.9 (±4.9)	10.6 (±3.8)	12.6 (±3.7)	12.3 (±5.9)	11.7 (±6.3)	13.9 (±9.8)	12.2 (±4.8)	p=0.46
HbA1c (%)	9.9 (±2.5)	9.6 (±2.1)	10.2 (±2.5)	8.8 (±2.5)	10.4 (±2.2)	9.5 (±2.6)	10.5 (±2.6)	11.8 (±3.2)	10.5 (±2.9)	p=0.27
Total Cholesterol (mmol/l)	4.4 (±1.3)	4.9 (±1.3)	4.8 (±1.1)	4.3 (±1.0)	4.8 (±1.7)	4.4 (±1.2)	4.2 (±1.2)	4.4 (±0.5)	5.0 (±1.5)	p=0.15
HDL-C (mmol/l)	1.2 (±0.4)	1.2 (±0.6)	1.0 (±0.3)	0.9 (±0.3)	0.9 (±0.2)	1.1 (±0.3)	0.9 (±0.1)	0.8 (±0.2)	1.0 (±0.3)	p=0.16
LDL-C (mmol/l)	2.5 (±0.9)	2.7 (±0.9)	2.9 (±0.9)	2.6 (±0.9)	3.1 (±1.2)	2.6 (±0.9)	2.8 (±1.1)	2.4 (±0.9)	3.2 (±1.1)	p=0.12
Triglycerides (mmol/l)	1.5 (±0.8)	2.2 (±1.3)	1.7 (±0.8)	1.6 (±0.8)	1.3 (±0.5)	1.4 (±0.6)	1.6 (±0.9)	2.3 (±1.6)	1.7 (±1.1)	p=0.28

There were no significant differences in blood chemistry for the different diabetic categories in all groups, ($p>0.05$).

Table 8.5(b) below, illustrates blood chemistry for diabetic categories comparing years of diagnosis after the six month intervention.

Table 8.5(b): Blood Chemistry for Diabetic Categories Comparing Years of Diagnosis after the Six Month Intervention (n=124)

Parameter **(Random Blood Levels)**	**Group 1: n=42** Mean (sd)			**Group 2: n=41** Mean (sd)			**Group 3: n=41** Mean (sd)			**p<0.05**
	0-5 years	**6-10 years**	**>10 years**	**0-5 years**	**6-10 years**	**>10 years**	**0-5 years**	**6-10 years**	**>10 years**	
Random blood glucose (mmol/l)	9.9 (±5.2)	12.6 (±6.7)	10.9 (±6.0)	13.8 (±4.9)	12.9 (±7.5)	12.2 (±6.3)	10.1 (±8.4)	11.9 (±8.8)	12.6 (±6.8)	p=0.81
HbA1c (%)	9.5 (±2.6)	10.9 (±3.3)	9.9 (±3.2)	10.4 (±3.4)	11.9 (±3.1)	10.9 (±2.9)	10.5 (±3.5)	10.5 (±2.1)	10.0 (±2.7)	p=0.17
Total Cholesterol (mmol/l)	4.3 (±0.9)	4.8 (±1.6)	4.6 (±1.1)	4.1 (±0.8)	3.7 (±1.3)	4.2 (±1.0)	4.4 (±1.2)	4.4 (±1.1)	4.8 (±1.4)	**p=0.001
HDL-C (mmol/l)	0.9 (±0.3)	1.0 (±0.4)	1.1 (±0.5)	1.1 (±0.6)	1.0 (±0.5)	1.1 (±0.5)	0.9 (±0.3)	0.9 (±0.4)	0.9 (±0.2)	**p=0.014
LDL-C (mmol/l)	2.5 (±0.9)	2.3 (±0.8)	2.9 (±0.9)	2.1 (±0.7)	2.1 (±1.1)	2.4 (±0.8)	2.7 (±0.9)	2.9 (±0.7)	2.8 (±1.2)	**p=0.000
Triglycerides (mmol/l)	1.7 (±1.0)	1.7 (±1.0)	1.7 (±0.8)	1.7 (±0.9)	1.7 (±1.5)	1.6 (±0.8)	1.8 (±0.9)	1.4 (±0.7)	1.9 (±1.9)	p=0.33

Following the six month intervention, there were significant reductions in total cholesterol levels, HDL-C and LDL-C, ($p<0.05$), in patients who had been diagnosed between 0-5 years in group 1 compared to group 3. Blood glucose levels decreased in group 1 (0-5 years) compared to group 3 (control), these changes were not significant statistically, ($p>0.05$). There were no changes in HbA1c and triglycerides levels, ($p>0.05$).

Table 8.5(c) below, illustrates blood chemistry for diabetic categories comparing years of diagnosis at 12 months (n=122).

Table 8.5(c): Blood Chemistry for Diabetic Categories Comparing Years of Diagnosis at 12 Months (n=122)

Parameter (Random Blood Levels)	**Group 1: n=42** Mean (sd)			**Group 2: n=41** Mean (sd)			**Group 3: n=39** Mean (sd)			**p<0.05**
	0-5 years	**6-10 years**	**>10 years**	**0-5 years**	**6-10 years**	**>10 years**	**0-5 years**	**6-10 years**	**>10 years**	
Random blood glucose (mmol/l)	11.1 (±4.5)	10.0 (±4.9)	10.3 (±6.2)	13.5 (±5.7)	11.9 (±5.4)	14.3 (±7.1)	10.9 (±5.7)	11.6 (±5.8)	14.6 (±7.8)	p=0.88
HbA1c (%)	9.4 (±3.4)	10.1 (±2.5)	9.1 (±1.9)	9.6 (±2.9)	11.4 (±2.8)	10.7 (±2.9)	9.5 (±3.0)	11.0 (±1.8)	10.3 (±3.2)	p=0.13
Total Cholesterol (mmol/l)	3.9 (±1.3)	4.6 (±1.1)	4.7 (±0.9)	3.7 (±0.9)	4.1 (±1.1)	3.9 (±0.9)	4.0 (±0.9)	4.3 (±0.4)	4.3 (±1.4)	**p=0.009
HDL-C (mmol/l)	0.9 (±0.2)	1.1 (±0.4)	0.9 (±0.4)	1.1 (±0.9)	0.9 (±0.3)	1.0 (±0.2)	0.8 (±0.2)	0.9 (±0.3)	0.9 (±0.2)	**p=0.04
LDL-C (mmol/l)	2.1 (±0.8)	2.1 (±0.9)	2.8 (±0.7)	1.9 (±0.6)	2.4 (±0.9)	2.3 (±0.7)	2.4 (±0.7)	2.7 (±0.2)	2.6 (±1.2)	**p=0.003
Triglycerides (mmol/l)	1.9 (±1.0)	4.5 (±8.5)	1.9 (±1.3)	1.5 (±0.7)	1.8 (±1.3)	1.7 (±1.0)	1.8 (±1.2)	1.5 (±0.6)	1.6 (±1.2)	p=0.24

Following 12 months, the total cholesterol, HDL-C and LDL-C levels, were reduced from baseline and six months, ($p<0.05$). More changes are observed in diabetic category 0-5 years of group 1 compared to group 3.

8.6 HEALTH RELATED QUALITY OF LIFE

Table 8.6.1(a) below illustrates health related quality of life of the three groups at baseline.

Table 8.6.1(a): Health Related Quality of Life (DIMS) at Baseline (n=135)

Variable	**Groups 1 (n= 45)** Mean (sd)	**Group 2 (n= 45)** Mean (sd)	**Group 3 (n= 45)** Mean (sd)	**p<0.05**
Symptoms	73 (±10.8)	74 (±10.5)	72. (±10.2)	p=0.18
Well-being	34 (±5.5)	34 (±5.4)	33 (±5.4)	p=0.77
Diabetic Morale	39.5 (±5.8)	39.8 (±5.3)	39 (±4.7)	p=0.82
Social role fulfillment	22 (±5.1)	24 (±5.4)	23 (±4.5)	p=0.17

There were no significant differences between groups at baseline, ($p>0.05$). According to the analysis of the DIMS, higher scores in symptoms; well-being; diabetic morale and social role fulfillment indicate a good health related quality of life.

Table 8.6.1 (b) below illustrates the health related quality of life after the six months intervention.

Table 8.6.1(b): Health Related Quality of Life (DIMS) after the 6 Month Intervention (n=124)

Variable	**Group 1 n=42**	**Group 2 n=41**	**Group 3 n=41**	**p<0.05**
Symptoms	80 (±11.0)	79 (±10.5)	80 (±8.7)	p=0.09
Well-being	35 (±6.5)	36 (±5.4)	34 (±5.5)	p=0.34
Diabetic Morale	41 (±7.5)	41 (±6.5)	43 (±5.8)	p=0.30
Social role fulfillment	26.1 (±5.7)	25 (±5.5)	27 (±4.9)	p=0.56

There marginally improvements in symptoms in all groups, ($p=0.09$). Well-being, diabetic morale and social role fulfillment scores were not significant statistically in all groups.

Table 8.6.1 (c) below illustrates the health related quality of life at 12 months.

Table 8.6.1(c): Health Related Quality of Life (DIMS) at 12 Months (n=122)

Variable	Group 1 n=42	Group 2 n=41	Group 3 n=39	p<0.05
Symptoms	80 (±10.5)	80 (±9.5)	77 (±11.9)	p=0.09
Wellbeing	36 (±6.3)	36 (±5.9)	36 (±5.9)	p=0.34
Diabetic Morale	40 (±6.0)	41 (±6.4)	40 (±6.7)	p=0.30
Social role fulfillment	25 ±5.5)	25 (±4.8)	24.8 (±5.3)	p=0.56

The improvements in symptoms were maintained at 12 months, only in experimental groups, (p=0.009). Well-being, diabetic morale and social role fulfillment scores were not significant statistically between the groups, (p>0.05).

8.7 EMOTIONS ABOUT DIABETES

Table 8.7.1(a-c) below illustrates emotions of the three groups about diabetes at baseline, six months post intervention and 12 months post intervention.

Table 8.7.1(a): Emotions about Diabetes at Baseline (n=135)

Variable	Response	Group 1 n=45 (%)	Group 2 n=45 (%)	Group 3 n=45 (%)	p value
Hard to believe I have diabetes	Agree	53.5%	37.8%	44.4%	p=0.52
	Disagree	46.5%	62.2%	55.6%	
I feel depressed when I think of its complications.	Agree	56.4%	55.6%	66.7%	p=0.50
	Disagree	43.6%	44.4%	33.3%	
I feel I'm not as good as others	Agree	46.6%	44.1%	46.1%	p=0.67
	Disagree	53.4%	55.9%	53.9%	
Hard to take good control	Agree	50.1%	49.9%	60.1%	p=0.40
	Disagree	49.9%	50.1%	39.9%	
Diabetes does not affect my life.	Agree	40%	38.8%	42.1%	p=0.41
	Disagree	60%	61.2%	57.9%	
Things are going well now	Agree	43.1%	42.1%	44.4%	p=0.39
	Disagree	56.9%	57.9%	55.6%	
Easy to control with support	Agree	86.3%	88.9%	91.1%	p=0.12
	Disagree	13.6%	11.1%	8.9%	

Sixty percent (60%) of patients in each group confirmed that type 2 diabetes affected their lives. Fifty five percent (55%) across the groups felt they were not as good as others because of their diabetes. These responses confirm negative emotions about type 2 diabetes at baseline. The groups were similar at baseline, (p>0.05).

Table 8.7.1(b) below illustrates emotions about diabetes after the six month intervention (n=124).

Table 8.7.1(b): Emotions about Diabetes after the Six Month Intervention (n=124)

Variable	Response	Group 1 n=42 (%)	Group 2 n=41 (%)	Group 3 n=41 (%)	p Value
Hard to believe I have diabetes	Agree	12.2%	19.5%	23.8%	p=0.61
	Disagree	87.8%	80.5%	76.2%	
I feel depressed when I think of its complications	Agree	19%	26.9%	17.1%	p=0.23
	Disagree	81%	73.1%	82.9%	
I feel I'm not as good as others	Agree	16.6%	17.1%	9.8%	p=0.72
	Disagree	83.7%	82.9%	90.2%	
Hard to take good control	Agree	23.8%	17.1%	26.8%	p=0.17
	Disagree	76.2%	82.9%	73.2%	
Diabetes does not affect my life.	Agree	66.7%	78.1%	66.1%	p=0.90
	Disagree	33.3%	21.9%	33.9%	
Things are going well now	Agree	78.6%	82.9%	82.1%	p=0.64
	Disagree	21.4%	17.1%	17.9%	
Easy to control with support	Agree	100%	97.6%	100%	p=0.58
	Disagree	0	2.4%	0	

Group 1 accepted their condition better after the six month intervention, as supported by 87. 8% responses which confirm that they no longer found it hard to believe that they had diabetes when compared to group 3, where 23.8% still found it difficult to believe that they had diabetes. Similarly, 76.2% responses from group 1 confirmed that this group controlled their diabetes better after the six months intervention compared to group 3.

Table 8.7.1(c) below illustrates emotions about diabetes at months (n=122).

Table 8.7.1(c): Emotions about Diabetes at 12 Months (n=122)

Variable	Response	Group 1 n=42(%)	Group 2 n=40(%)	Group 3 n=39(%)	p Value
Hard to believe I have diabetes	Agree	21.2%	20%	31%	p=0.48
	Disagree	78.8%	80%	69%	
I feel depressed when I think of its complications	Agree	26.9%	25%	23.8%	p=0.89
	Disagree	73.1%	75%	76.2%	
I feel I'm not as good as others	Agree	19.1%	10%	15.1%	p=0.18
	Disagree	80.9%	90%	84.9%	
Hard to take good control	Agree	16.7%	10%	18.5%	p=0.50
	Disagree	83.3%	90%	81.5%	
Diabetes does not affect my life.	Agree	69.5%	72.5%	69.2%	p=0.89
	Disagree	30.5%	27.5%	30.8%	
Things are going well now	Agree	85.7%	80%	89.8%	p=0.32
	Disagree	14.3%	20%	10.2%	
Easy to control with support	Agree	97.6%	97.5%	94.9%	p=0.93
	Disagree	2.4%	2.5%	5.1%	

Group 1 maintained their acceptance of the disease even at 12 months even though the percentages dropped slightly at 12 months compared to at six months. This is justified by 78.8% of responses from group 1, who believe that they have diabetes compared to 69% from group 3. Eighty three percent from group 1 reported that it is not difficult to take good control of their diabetes after 12 months compared to 81.5% from group 3. Ninety seven percent from group 1 confirmed that it is better to control diabetes with support from home compared to 94.9% responses from group 3. There were no significant differences between groups.

8.8 **FOOD PREFERENCES AND FREQUENCIES**

In Table 8.8.1 (a-c), the food preferences and frequencies are shown:

Table 8.8.1(a): Food Preferences at Baseline (n=135)

Variable	Groups	Daily (%)	3x /week (%)	1x /week (%)	Monthly (%)	Do not eat (%)	p<0.05
Red meat	Group 1	0	17.8%	28.9%	22.2%	31.1%	p=0.45
	Group 2	2.2%	13.3%	35.6%	33.3%	15.6%	
	Group 3	4.4%	15.6%	28.9%	22.2%	28.9%	
Fish	Group 1	2.2%	22.2%	24.4%	37.8%	13.3%	p=0.95
	Group 2	4.4%	35.6%	17.8%	20%	22%	
	Group 3	4.4%	22.2%	37.8%	28.9%	6.7%	
Chicken	Group 1	0	0	4%	16%	24%	p=0.40
	Group 2	2.2%	0	2%	11.1%	31%	
	Group 3	2.2%	2.2%	11.1%	37.8%	46.7%	
Tripe	Group 1	0	0	9.1%	36.6%	54.6	*p=0.01
	Group 2	2.2%	0	4.4	24.4	68.9	
	Group 3	2.2%	2.2%	11.1	37.8	46.7	
Pap	Group 1	61.4%	25%	11.4%	2.3%	0	p=0.29
	Group 2	68.9%	13.3%	13.3%	2.2%	0	
	Group 3	62.2%	22.2%	13.3%	2.2%	0	
Samp	Group 1	0	6.8%	34.1%	25%	34.1%	p=0.16
	Group 2	6.7%	6.7%	28.9%	42.2%	15.6%	
	Group 3	0	13.3%	40%	35.6%	11.1%	
Vegetables	Group 1	86.7%	8.9%	4.4%	0	0	p=0.41
	Group 2	73.3%	11.1%	13.3%	2.2%	0	
	Group 3	73.3%	20%	4.4%	2.2%	0	
Fruit	Group 1	86.7%	4.4%	6.7%	2.2%	0	*p=0.01
	Group 2	60%	22.2%	13.3%	4.4%	0	
	Group 3	53.3%	26.7%	20%	0	0	

Variable	Groups	Daily (%)	3x /week (%)	1x /week (%)	Monthly (%)	Do not eat (%)	p<0.05
Sweets	Group 1	17.8%	0	33.3%	8.9%	40%	p=0.58
	Group 2	2.2%	4.4%	31.1%	6.7%	55.6%	
	Group 3	6.7%	2.2%	22.2%	15.6%	53.3%	
Cake	Group 1	2.2%	0	6.7%	11.1%	80%	p=0.53
	Group 2	0	0	2.2%	2.2%	95.6%	
	Group 3	0	0	6.7%	11.1%	82.2%	
Sweet biscuits	Group 1	4.4%	0	0	11.1%	84.4%	p=0.75
	Group 2	0	0	0	2.2%	97.8%	
	Group 3	0	2.2%	2.2%	4.4%	91.1%	
Beer	Group 1	4.4%	0	6.7%	2.2%	86.7%	*p=0.00
	Group 2	0	0	8.9%	4.4%	86.7%	
	Group 3	0	0	2.2%	0	97.8%	
Wine	Group 1	4.4%	0	0	11.1%	84.4%	p=0.66
	Group 2	0	0	2.2%	4.4%	93.3%	
	Group 3	1.5%	0	1.5%	6.7%	90.37	

Pap: Crumb porridge made from maize meal; **Samp:** South African crushed maize used as starch.

Sixty eight percent (68.9%) group 1; 84% group 2 and 71% group 3 ate red meat. Thirteen percent (13%) from both groups 1 and 2 drank alcohol and 16% drank wine. There were no significant differences between the groups at baseline except that males drank more beer than females.

Food preferences and choices were checked after six months and after 12 months. These results are reported descriptively as no statistical test was done because education on diet was given by a professional nurse not a trained nutritionist.
The results showed a degree of behaviour change after six months and this was maintained after 12 months.

Table 8.8.1(b) below, show changes with food preferences after the six month intervention.

Table 8.8.1(b): Food Preferences after the Six Month Intervention (n=124)

Variable	Groups	Daily (%)	3x /week (%)	1x /week (%)	Monthly (%)	Do not take (%)
Red meat	Group 1	0	11.9%	30.95%	30.95%	26.2%
	Group 2	0	7.5%	45%	32.5%	15.0%
	Group 3	4.9%	12.2%	29.3%	29.3%	24.4%
Fish	Group 1	0	16.7%	35.7%	28.6%	19.1%
	Group 2	2.5%	22.5%	45%	12.5%	17.5%
	Group 3	4.9%	12.2%	36.6%	34.2%	12.2%
Chicken	Group 1	47.6%	38.1%	11.9%	0%	2.4%
	Group 2	36.6%	48.8%	12.2%	0	0
	Group 3	36.6%	48.8%	12.5%	0	2.4
Tripe	Group 1	0	0	16.7%	30.95%	52.38
	Group 2	2.5%	0	2.5%	32.5%	62.5%
	Group 3	2.4%	0	9.8%	34.2%	53.7%
Pap	Group 1	54.8%	30.95%	11.9%	2.4%	0
	Group 2	56.1%	24.4%	12.2%	2.4%	4.9%
	Group 3	60%	22.5%	15%	2.5%	0
Samp	Group 1	0	7.1%	30.95%	23.8%	38.1%
	Group 2	7.3%	4.9%	21.95%	41.5%	24.4%
	Group 3	2.4%	7.3%	29.3%	46.3%	14.6%
Vegetables	Group 1	76.2%	14.3%	7.1%	2.4%	0
	Group 2	63.4%	24.4%	4.9%	7.3%	0
	Group 3	68.3%	24.4 %	7.3%	0	0

Variable	Groups	Daily (%)	3x /week (%)	1x /week (%)	Monthly (%)	Do not take (%)
Fruit	Group 1	69.1%	23.8%	7.1%	0	0
	Group 2	63.4%	19.5%	14.6%	0	2.4%
	Group 3	51.2%	29.3%	17.1%	2.4%	0
Sweets	Group 1	2.4%	0	38.1%	19.1%	40.5%
	Group 2	4.9%	2.4%	19.5%	19.5%	53.7%
	Group 3	2.4%	4.9%	17.1%	29.3%	46.3%
Cake	Group 1	0	0	0	9.5%	90.5%
	Group 2	0	0	0	4.9%	95.1%
	Group 3	2.4%	2.4%	2.4%	7.3%	85.4%
Sweet biscuits	Group 1	0	0	2.4%	4.8%	92.9%
	Group 2	0	0	0	7.3%	92.7%
	Group 3	0	0	2.4%	9.8%	87.8%
Beer	Group 1	0	0	2.4%	4.8%	***92.9 %
	Group 2	0	0	2.4%	7.3%	***90.2%
	Group 3	2.4%	0	0	0	97.6%
Wine	Group 1	0	0	2.4%	2.4%	95.2%
	Group 2	0	2.4%	2.4%	9.8%	85.4%
	Group 3	2.4%	0	0	4.9%	92.7%

***** Indicates a positive change in behaviour from baseline**

There were no changes in the behaviour of eating red meat at six months, (table 8.8.1b) in the experimental groups. There were an additional 4.9% of participants in the family support group who were eating red meat compared to baseline. The control group remained eating red meat daily. The behaviour on tripe consumption improved better in group 1 compared to group 3, after the six month intervention as there were fewer participants from group1 were still eating tripe after the six month intervention. Group 1 improved their behaviour with alcohol consumption by 6. 2% (from 86.7% to 92.9%) and there was no change in control group. Group 1 also improved on wine consumption compared to group 3.

In Table 8.8.1 (c) below, the food preferences at 12 months are illustrated.

Table 8.8.1(c): Food Preferences after 12 Months (n=122)

Variable	Groups	Daily %)	3x /week (%)	1x /week (%)	Monthly (%)	Do not eat (%)
Red meat	Group 1	2.4%	7.1%	21.4%	38.1%	30.95%
	Group 2	0	7.7%	38.5%	35.9%	17.95%
	Group 3	2.56%	0	28.2%	48.7%	20.51%
Fish	Group 1	2.4%	30.95%	47.6%	11.9%	***7.1%
	Group 2	7.7%	28.2%	46.2%	10.3%	***7.7%
	Group 3	2.6%	20.5%	51.3%	20.5%	5.1%
Chicken	Group 1	28.6%	38.1%	26.2%	2.4%	4.8%
	Group 2	25.6%	56.4%	15.3%	2.6%	0
	Group 3	25.6%	53.9%	15.4%	0	5.1%
Tripe	Group 1	0	4.8%	19.1%	23.8%	52.4%
	Group 2	0	0	2.6%	38.5%	58.97%
	Group 3	0	2.6%	5.1%	30.8%	61.5%
Pap	Group 1	52.4%	26.2%	16.7%	2.4%	2.4%
	Group 2	53.9%	30.8%	12.8%	2.6%	0
	Group 3	61.5%	20.5%	10.3%	0	7.7%
Samp	Group 1	0	11.9%	16.7%	35.7%	35.7%
	Group 2	0	0	41%	41%	17.95%
	Group 3	5.1%	2.6%	35.9%	33.3%	23.1%
Vegetables	Group 1	69.1%	21.4%	7.1%	2.4%	0
	Group 2	58.97%	35.9%	5.1%	***0	0
	Group 3	69.2%	10.3%	20.5%	***0	0
Fruit	Group 1	52.3%	33.3%	11.9%	0	2.4%
	Group 2	64.1	23.1%	2.6%	7.7%	2.6%
	Group 3	48.7%	30.8%	17.95%	2.6%	0
Sweets	Group 1	4.8%	2.4%	14.3%	16.7%	61.9%
	Group 2	0	5.1%	17.95%	7.8%	69.2%
	Group 3	0	5.1%	12.8%	10.3%	71.8%
Cake	Group 1	0	0	0	14.3%	85.7%
	Group 2	0	0	0	12.8%	87.1%
	Group 3	0	0	2.6%	7.7%	89.7
Sweet biscuits	Group 1	0	0	2.4%	11.9%	85.7%
	Group 2	0	0	0	7.7%	93.3%
	Group 3	0	0	2.6%	7.7%	89.7%
Beer	Group 1	0	0	4.8%	2.4 %	92.9%
	Group 2	0	0	2.6%	7.7%	89.7%
	Group 3	0	0	2.6%	0	97.4%
Wine	Group 1	0	0	0	7.1%	92.9%
	Group 2	0	0	0	12.8%	87.2%
	Group 3	0	0	0	7.7%	92.3%

*****Indicates improvement from baseline**

Behaviour with red meat and alcohol was still maintained by group 1 after 12 months intervention. There was a change in fish consumption in group 1 (30.9%) compared to group 3 (20.1%).

8.9 COMPARISON OF RANDOM BLOOD LEVELS AND DISTANCE WALKED AT 12 MONTHS

Random bloods and the distance walked were compared after 12 months to establish whether there was a change in participants' behaviour that was influenced the intervention.

Table 8.9.1 below outlines the comparison of random blood levels and the distance walked comparing baseline to 12 months.

Table 8.9.1: Comparison of Random Bloods and Distance Walked Comparing Baseline to 12 Months

Parameter	**Group 1** Mean (sd)		**Group 2** Mean (sd)		**Group 3** Mean (sd)		**p<0.05**
Random bloods	**Baseline n=45**	**12 months n=42**	**Baseline n=45**	**12 months n=41**	**Baseline n=45**	**12 months n=39**	
Random blood glucose (mmol/l)	12.6 (±5.4)	10.7 (±5.3)	11.6 (±4.9)	13.5 (±6.2)	12.2 (±6.0)	12.7 (±6.8)	*p=0.09
HbA1c (%)	9.9 (±2.4)	9.5 (±2.7)	9.4 (±2.6)	10.4 (±2.9)	10.7 (±2.9)	10.2 (±2.9)	p=0.24
Total Cholesterol (mmol/l)	4.7 (±1.2)	4.4 (±1.1)	4.4 (±1.2)	3.86 (±0.96)	4.7 (±1.3)	4.3 (±1.3)	**p=0.004
HDL-C (mmol/l)	1.1 (±0.4)	0.98 (±0.3)	1.0 (±0.2)	1.03 (±0.6)	1.0 (±0.2)	0.93 (±0.2)	p=0.25
LDL- C (mmol/l)	2.7 (±0.9)	2.4 (±0.8)	2.7 (±1.0)	2.2 (±0.7)	2.9 (±1.1)	2.6 (±1.03)	**p=0.003
Triglycerides (mmol/l)	1.8 (±1.0)	2.5 (±4.0)	1.5 (±0.7)	1.6 (±0.93)	1.8 (±1.1)	1.7 (±1.1)	p=0.22
Distance (km)	202 (±41.9)	201.8 (±40.4)	194 (±55.7)	195.7 (±40.3)	188 (±48.0)	186.5 (±40.1)	**p=0.003

***Indicates marginal significance** ****Indicates significance at p<0.05.**

Random blood glucose levels decreased by 1.9 mmol/l after 12 months intervention (from 12.6 mmol/l to 10.7 mmol/l at the end of the intervention) in group 1 (family support). There were increased levels in group 2 (11.6 mmol/l to 13.5 mmol/l) and group 3, (p=0.09). $HbA1_C$ levels decreased by 0.4% in group 1, from 9.9% to 9.5% compared to group 2 and the control group but this improvement was not significant statistically, (p>0.05). Total cholesterol, LDL-C and distance walked improved significantly in the intervention group relative to the control group, (p<0.05). However the intervention did not have an effect on the levels of HDL-C and triglycerides, (p>0.05).

8.10 COMPARISON OF RANDOM BLOOD GLUCOSE LEVELS AND HbA1c LEVELS AT 12 MONTHS INTERVENTION

Table 8.10.1 below outlines the comparison of random blood glucose levels and HbA1c levels at 12 months.

Table 8.10.1: Comparison of Random Blood Glucose Levels and HbA1c Levels after 12 Months

Variable	GROUP 1			GROUP 2		
	OR(SE)	95% CI	p-Value	OR(SE)	95% CI	p-Value
HbA1c (%)	0.58 (0.26)	(95%CI: 0.23;1.4)	p=0.23	1.05(0.47)	(95% CI: 0.43;2.5)	p=0.91
Random blood glucose (mmol/l)	0.64 (0.3)	(95%CI: 0.25;1.6)	p=0.34	1.5(0.69)	(95%CI: 0.63; 3.7)	p=0.35

OR= odds ratio SE= standard error CI = confidence interval

The 12 months intervention showed a trend of improvement in glycaemic control even though the results were not significant statistically, ($p>0.05$). The two experimental groups were compared against the control group comparing HbA1c and random blood glucose changes. Findings in group1 (family support) showed a reduced risk of poor glycaemic control (OR= 0.58; p=0.2), whilst group 2 (no family group) showed a higher risk of poor glycaemic control (OR=1.1; p=0.9). Random blood glucose also showed a similar effect:
group 1 showed a reduced risk of poor glycaemic control (OR=0.64; p=0.3) compared to
group 2 which showed a higher risk of poor glycaemic control (OR=1.5; p=0.4).

8.11 DISCUSSION

The primary aim of the randomized control trial was to investigate whether a family based intervention would result in an improvement in blood glucose levels and HbA1c from baseline to 12 months after receiving a six month intervention.

8.11.1 Random Blood Chemistry

The results of this study showed that the group with family support was more likely to get better glycaemic control compared to the no family support and control groups. There were significant reductions in the levels of total cholesterol and LDL-C, ($p<0.05$), following a six (6) month intervention. These improvements were maintained even after six months of behavioural observation. There was a clinically relevant improvement in random blood glucose levels after

the six months intervention and six months after the intervention. There were no significant differences in HbA1c; HDL-C and triglycerides, (p> 0.05). However, there were reductions from the initial values when baseline measurements were compared to six and 12 months. A review by Srinivasan et al (2008), suggests that tight control of blood glucose significantly reduces the risk of complications of type 2 diabetes. There might be contributing factors that explain the results that did not show statistical significant. Some of these factors can be summarized as follows:

8.11.2 **Poor education attendance**

Participants who were in an education group were booked once a month on the day that the patient came for repeat medication or review of treatment. Only 30% of patients came for the education three times, 60% came twice, which were the times they came to see the doctor for review. Only three patients came with a member of their family.

None attendance rates have been observed to be very high in large hospital diabetes clinics resulting in unsustainable poor care, (Ossei et al, 2005; Otieno et al, 2003)). This occurs because patients prefer that their diabetes care be provided locally as this is cost effective for them and also it should be delivered by the health professional that they are familiar with. According to (Chen et al, 2008), diabetes health education is the cornerstone in the management of type 2 diabetes. This means that if patients miss diabetes education, they are missing an important component of their management and this may lead to poor diabetes control. The knowledge score improved in the experimental groups compared to the control after six and 12 months compared to baseline but there were no significant differences, (p>0.05). A qualitative study whereby forty general practitioners (GPs') participated in focus group discussions to explore their feelings on patients' adherence revealed the barriers that arose because GPs' interact with two groups of patients, the motivated (good) and not motivated (bad) patients. GPs' further describe good patients as hard working and following regimes as opposed to bad patients who always think they know everything and they are in control yet they are neglectful, (Wens et al, 2005). Studies indicate that a problem in diabetes care is poor translation of knowledge into lifestyle changes in order to achieve glycaemic control, (Chen et al, 2008; Tseng et al 2005).The results of this study are compatible with other studies and daily clinical practice in that poor attendance is associated with poor glycaemic control.

8.11.3 **Environmental factors**

All participants in this study were from poor socio-economic backgrounds. The groups were similar at baseline. The environmental background of all ranged between participants living in shacks (informal settlements) to those living in big houses. According to Kruger, et al (2005), living in informal settlements will have consequences with regards to preparation, consumption and hygiene of food. Some patients did not have facilities like flush toilets and indoor running water even though they were residing in urban environments. According to WHO 2008; poverty is a major contributing risk factor to type 2 diabetes.

Poor socio economic backgrounds are associated with type 2 diabetes and poor glycaemic control, (Cheng, 2005). A report from the WHO bulletin (2002) indicates that poverty is intertwined with ill-health. Evidence from this bulletin claims that poverty gives rise to ill-health and ill-health keeps poor people poor and this is mainly because of income inequalities which are associated with health care expenses, (Wagstaff[1], 2002). Income inequalities affected attendance rate in this study because only a few patients managed to attend education sessions. In a report of the Word Diabetes Congress held in 2006, it was discussed that many people with diabetes in African countries struggle every day with fundamental issues of survival, whilst those people with diabetes in many developed countries, with free access to an increasing range of modern diabetes supplies, strive for excellence in the control of their blood glucose levels, (Pirie, 2007). This was the case in this study as when patients showed good control they were referred to local clinics. Five patients who were referred to local clinics from this study complained that there no medications at the clinics and their blood glucose levels were increased again.

- Diet

  A 16 year follow-up study, where 84,941 female nurses without type 2 diabetes diagnosis; cancer and cardiovascular diseases were included to provide evidence on the importance of lifestyle and development of type 2 diabetes, showed that a combination of five of the following variables confirmed a low risk group:

  - BMI<25kg/m^2,
  - a diet high in cereal fibre and polyunsaturated fat and low in trans fat and glycaemic load,
  - engaged in moderate to vigorous physical activity for at least 30 minutes a day,
  - no current smoking; and

- a consumption of at least not more than half a drink of an alcoholic beverage per day.

At the end of the follow up period a total of 3300 new cases of type 2 diabetes were reported and obesity was the most important predictor. According to Kruger et al (2005), diets with high fat intake and sugar contribute to increased prevalence of obesity. Other associated risk factors were lack of exercise; poor diet; current smoking and alcohol use, (Hu et al, 2001). In this study the family based intervention that included observation of food choices and frequencies showed that there were behaviour changes towards food after the six month intervention, evidenced by fewer participants still eating red meat and more participants eating vegetables and fruit.

There were significant improvements, ($p<0.05$), in total cholesterol and LDL when visits were compared (baseline, six (6) months and 12 months). The positive results might have been as a result of the intervention. After six months participants indicated eating less red meat, tripe (high fat foods) and more vegetables and fruit. There was also a 6% reduction of alcohol use in the family supported group. A diet with low carbohydrates, high fibre, more vegetables and fruits is recommended for the management of type 2 diabetes, (Butler, 2009; Nishida et al, 2004; Pastors et al, 2002). No strict diet was followed in this study but participants were encouraged to stick to their recommended diet.

- **Physical Activity**

Findings of this study showed significant improvements in the distance walked at the six months intervention and after 12 months of no intervention, ($p<0.05$). The family supported group walked further than the no family support and the control groups. Even though improved, the distance walked by all participants in this study was less than the average estimated distance for an adult.

Physical activity and weight control play an important role in type 2 diabetes prevention and management, because they reduce the risk of cardiovascular disease and overall mortality, (Christian et al, 2008). They further discussed that weight loss of as little as 2.25 kg to 4.5 kg, is sufficient to improve metabolic control. This means that patients will experience reduced diabetes related risk factors without achieving ideal body weight.

The results of physical activity in this study might have been influenced by the short duration of the study, which was only six months of intervention compared to 12 a months intervention which included counseling on healthy diet practices by a physician and an individualized feedback report to motivate patients to increase physical activity whilst decreasing caloric intake and to identify any potential barriers to achieving their set goals, (Christian et al, 2008). The results showed that education by physicians on behavioural goals leads to increased physical activity and weight loss. The findings of a meta analysis which looked at metabolic effects of interventions to increase exercise in type 2 diabetes found that intervention that concentrated on multiple health outcomes and not on exercise behaviours alone, showed smaller effects on HbA1c and BMI, (Conn et al, 2007). This is because a number of competing demands may shift the behaviour to concentrate on one outcome whilst diminishing a change in health behaviour. This study focused on multiple health outcomes of which the primary outcome was the reduction of HbA1c by 1% at the end of the intervention. BMI, distance walked, health related quality of life and knowledge were secondary outcomes. A report by Funnell et al (2009), suggests that physically active individuals are less likely to develop type 2 diabetes, but sedentary individuals are likely to develop diabetes and its complications resulting in mortality and morbidity.

- **Body weight**

Overweight is a risk factor for type 2 diabetes and glucose intolerance, (Steyn et al 2009). Increased physical activity with appropriate diet has been observed to reduce weight and delay type 2 diabetes complications (Brown et al, 2002). In this study, the experimental groups gained weight after the six months intervention. Observations after 12 months showed that the experimental groups lost weight and a weight gain was observed in the control group, however, there were no significant differences between groups, ($p>0.05$). Findings from the Third National Health and Nutrition Examination Survey (NHANES III) showed that the majority of patients with type 2 diabetes ate a diet high in saturated fat and fewer fruit and vegetables. They also reported insufficient levels of activity, with the exception of individuals more than 65 years old who adhered to the recommendations. Individuals who did not exercise regularly were overweight or obese, Nelson et al (2002). These findings are in contrast with the results of this study with regards to physical activity, even though there were no changes in BMI, efforts towards recommended food choices were shown. Distance walked was statistically significant; however participants need to be encouraged to continue with regular physical activity for better glycaemic control. Weight loss improves blood glucose control by lowering the liver's glucose production and

increasing insulin sensitivity. Weight loss and a decrease in body fat percentage, in the absence of dietary changes have been observed in patients with type 2 diabetes following an exercises programme (Yamanouchi et al, 1995). Mourier et al (1997) also found that physical activity reduces abdominal fat (evaluated by magnetic resonance imaging) and visceral adipose tissue with no effect on body weight. A study by Kirk et al (2003) also found that improvements in physical activity improved glycaemic control after a six month intervention but there was no change in BMI measurements and diastolic blood pressure.

8.11.4 Health Related Quality of Life

Health related quality of life changed after six months especially symptoms of the disease, when comparing with baseline but these changes were not significant statistically. These results were maintained at 12 months but there were no significant differences between the groups. Similarly the literature claims that patients with type 2 diabetes have a substantially decreased quality of life in association with symptomatic complications, (Wexler et al, 2005). The results of a study conducted by Redekop et al (2002), showed that patients without complications had a slightly lower HRQOL than people of the same age in the general population. They also found that, patients who were obese, had complications of type 2 diabetes and were using insulin, had lower HRQOL independent of age and sex.

8.11.5 Factors Affecting the Management of Diabetes at Dr George Mukhari Hospital

The findings of this study showed that access to the hospital because of financial problems was a major barrier to patients. Access to care and a good patient-physician relationship are also perceived to play a significant role in adherence to treatment. Other issues like depression and lack of motivation also play a role (Vermeire et al, 2008). In this study participants showed signs of depression and lack of motivation as they referred to the diagnosis with type 2 diabetes as a “death sentence”. They even went further to say “it affects you mentally”; this came from young males, below 30 years of age when they think of impotence as a complication of type 2 diabetes.

Patients also indicated that accepting the condition is a problem because they do not know who to tell about the diagnosis. They are also afraid that when they lose weight because of the recommendations of diabetes management, it will be interpreted by the community as having HIV/AIDS. Communication between the physician/doctor in the hospital and patient is important to facilitate patient motivation and adherence. In this study patients reported that some doctors who spent little time during consultations were the doctors who did not talk to

them about diabetes whereas others spent more than 20 minutes to half an hour talking about diabetes. Other barriers that were also evident in this group were:

- Lack of resources: because there is a shortage of personnel, education programmes were not conducted as required in the guidelines as recommended by the National Standards of Diabetes Care. There is a need for trained physicians to run the diabetes clinic at Dr George Mukhari hospital for patients to have the necessary information for disease control. Training physicians in diabetes improves the process of care in patients with diabetes, (Alberti et al 2007a; Alberti et al, 2004). In this study, patients reported variations on the time spent when consulting with the doctor, ranging from 15 minutes to more than 30 minutes. This shows that doctors who run the clinics differ and there is no standard recommendation for the education protocol of a patient with type 2 diabetes, which might indicate that there is no training given to doctors who run the clinic.
- A lack energy to exercise was reported by most female patients who said that the disease make them feel tired especially at the end of the day.
- Lack of financial support:
  - This resulted in high rates of poor attendance by most participants.
  - Most patients reported that they adhered to the recommended diabetic diet sometimes and some patients did not follow the recommended diet at all because they did not have money to buy food.
  - Some patients did not manage to come to the hospital for follow up; the researcher had to go fetch them from their homes.

8.12 **CONCLUSION**

A family based intervention resulted in significant improvements in knowledge scores, the distance walked, total cholesterol and LDL-C, when comparing the family supported group to the no family support and control groups. The intervention however did not change HDL-C and triglyceride levels. There was a trend of improvement in random blood glucose and HbA1c levels after 12 months follow up in the family supported group compared to the no family and the control groups. There was a clinically relevant improvement in random blood glucose and HbA1c levels. The results showed that a patient who belonged to the family support group had less chance of poor glycaemic control compared to the no family and control groups, when checking HbA1c and random blood glucose levels after 12 months. Health related quality of life did not change statistically even though levels of different domains especially diabetes symptoms improved at 12 months compared to baseline.

CHAPTER 9

9. DISCUSSION OF THE WHOLE THESIS

9.1 INTRODUCTION

Whilst there is substantial information worldwide about the benefits of diabetes self-management education strategies (DSME) both in developed and developing countries, (Rubin et al, 2006; Jack, et al, 2004; Brown et al, 2002; Norris et al, 2001), very little research has been done with regards to family based interventions in South Africa. The role of family support in patients with type 2 diabetes has been recommended in the National Standards of DSME which are reviewed every five years, Funnel et al, (2009) and in the Standards of Medical Care in Diabetes which are reviewed yearly, (ADA, 2011). Like in many other chronic diseases, diabetes self-management plays an important role in limiting disease-related morbidity and mortality, (2002; Nathan, 2006; Otieno et al, 2003; National Standards of Medical Care, 2011). Cost effective interventions to improve diabetes care are needed, (Sacco et al, 2008; Neuhann et al, 2002).

This study examined the role of family support in multiple health outcomes after a six month intervention and six month follow-up. The primary outcomes were improvements in glycaemic control (where HbA1c and random blood glucose levels were analysed) and health related quality of life. The secondary outcomes were focused on addressing quality of diabetes care, which included the demographic backgrounds, the available care for management of patients with type 2 diabetes at Dr George Mukhari hospital; knowledge about the disease process and lifestyle modification. The results of this study showed that a patient from a family supported group had less chance of poor control (OR= 0.58, p=0.2) compared to control, whilst a patient that belonged to a no family support group had OR=1.1, (p=0.9) for HbA1c. Random blood glucose also showed a similar effect, group 1 had OR=0.64, (p=0.3) and group 2 had OR=1.5, (p=0.4). The intervention was hospital based and aimed at improving the glycaemic control and health related quality of life in patients from poor socio-economic backgrounds.

In order to establish the need for the intervention, a framework was designed through which the current situation at Dr George Mukhari hospital was examined against the recommended guidelines for diabetes care both international and the South African guidelines as recommended by the National Department of Health in the National Programme for Control

and Management of type 2 diabetes at primary level (1998) and A National Policy on Quality in Healthcare for South Africa (2007) documents.

Thus, the discussion of this thesis will be covered in two phases:

- Phase 1 = the patients' demographic characteristics
- Phase 2 = the effects of the intervention

9.2 PHASE 1: PATIENTS DEMOGRAPHIC CHARACTERISTICS

A qualitative research approach (described in chapter 4) was used to in this study to establish the knowledge of patients with type 2 diabetes and the perceptions of both patients and health-care professionals about the management of type 2 diabetes. The health-care professionals' perceptions were explored in order to understand the challenges that they experience with the management of patients with type 2 diabetes. This approach was explored using validated methods from social science research, (2005; Bailey et al, 2007; Becker and Bryman; Strauss and Corbin, 1990; Stewart and Shamdasani, 1990). Five factors that needed to be considered in the management of patients with type 2 diabetes were highlighted by both patients and healthcare professionals.

These were:-

- Knowledge/ health communication: health professionals recommended that patients with type 2 diabetes be educated so that they understand that type 2 diabetes is a lifelong disease that needs understanding and control. Therefore it is important to reinforce knowledge of these patients through health communication.
- Education and behaviour change: both patients and professionals felt that behaviour change should be encouraged by encouraging participation in physical activities and adherence to a recommended diet through education programmes.
- Support at three levels: both patients and professionals highlighted that support in the form of emotional, material and informational is necessary for the management of type 2 diabetes.
- Patient centered approach: A programme that involves healthcare professionals, family and patients was recommended by health professionals. This was the overall recommendation because individual patient's environmental backgrounds are unique. Brown et al (2002) supported these findings by highlighting that an integration of careful medical supervision and patient education on changes in lifestyle behaviours results in improved diabetes control. They further argued that investigations on prevention strategies of type 2 diabetes are necessary because type 2 diabetes is influenced by lifestyle factors and behaviour.

In order to test these factors on a large population of patients with type 2 diabetes consulting at Dr George Mukhari, potential indicators to knowledge relating to type 2 diabetes management and availability of care were identified through the literature, (Comino et al, 2008) and a quantitative tool was developed to identify questions that seek information about management of type 2 diabetes at Dr George Mukhari hospital, (WHO, 2008; Cresswell et al, 2007; Francis et al, 2004).

The developed knowledge questionnaire revealed that patients consulting at Dr George Mukhari hospital were obese, physically inactive; had poor glycaemic control and poor health related quality of life. The knowledge scores indicated that there were 38% of participants who had inadequate knowledge. This showed that the quality of diabetes care is poor at Dr George Mukhari hospital with education programmes that are not conducted according to the recommended guidelines from DSME strategies, (Funnel et al, 2009). According to Bruce et al (2003), adequate knowledge is a key component of diabetes care and its potential benefits include a sense of empowerment and improve quality of life. They further debate that it is difficult to demonstrate that education alone improves metabolic control but evidence strongly supports that improvements in outcomes cannot occur without adequate instruction about diabetes.

Durations of doctors' consultation sessions were not consistent as some patients indicated that the doctors rotate on a monthly or two monthly basis and they do not have enough time with patients because of high workloads. These results are supported by the findings of Oteino et al (2003) which indicated that ambulatory patients with type 2 diabetes consulting at a hospital clinic in developing countries had poor glycaemic control. They further explained that the contributing factor was scarcity of resources. Further, Katz et al (2009), in their South African outreach programme study in Soweto, highlighted that, primary healthcare teams are overworked, poorly supported, poorly educated and frustrated. Their results also showed that primary health-care nurses had poor knowledge concerning the management of chronic diseases using the chronic care model. Whilst these findings are specific to primary health care chronic disease management, they have potential transferability to the education programmes that are run in hospital clinic settings. Evidence suggests that there are patients with chronic diseases who are engaged and actively participating in their health care have better health outcomes, (Heisler et al, 2005; Norris et al, 2002;). Heisler et al (2005), added that chronic illness care self-efficacy is positively associated with good health outcomes and collaboration with health-care providers to formulate shared clinical decision making are associated with

better self-care behaviours and disease outcomes. These results suggested that there was a gap in the management of patients with type 2 diabetes consulting at Dr George Mukhari hospital. There is a need for interventions that will give education according to the prescribed guidelines as recommended by National Standards for Diabetes Self-Management Education and guidelines as recommended by the South African Department of Health. A family based intervention with telephone calls was designed and implemented for this population, leading to phase 2 of this study.

9.3 PHASE 2: THE EFFECTS OF THE INTERVENTION

The intervention that was given to participants is detailed in chapter 7. This was a hospital based programme.

The results of the six months intervention showed that patients from the family supported group who received phone calls one a months for six months, had less chance of poor glycaemic control (OR = 0.58; p = 0.23) compared to the control group when using HbA1c as a primary outcome variable, whilst a similar effect was also confirmed for random blood glucose, (OR = 0.64; p = 0.34). Group 2 showed more chance of poor glycaemic control, (OR = 1.5; p = 0.91). However this programme did not change health related quality of life, BMI and triglycerides. The significant effects of the programme at six months were sustained at twelve months (six months of no intervention). This shows that the intervention had an impact on behaviour change.

The intervention showed a 0.4% reduction in HbA1c (from 10% to 9.5%) and a 2.1% decrease of random blood glucose levels (from 12.6 mmol/l to 10.5 mmol/l) after 12 months. This was a positive effect of the programme because none of the participants changed their medication during the period of the study. This finding is supported by the findings in the meta analysis by Norris et al (2002), where the UK Prospective Diabetes study highlighted that each 1% reduction in HbA1c, over 10 years is associated with risk reductions of 21%, of death (due to diabetes) , 14% reduction of myocardial infarction and 37% reduction of overall microvascular complications. Similarly, Saaddine et al (2002) added that clinical trials suggest that decreasing HbA1c levels by 1% reduce microvascular complications by 25% to 30%.A 10mmHg reduction in blood pressure decreases macrovascular and microvascular complications as well as mortality rates by 35%. They added that good lipid control can reduce the risk of coronary heart disease by 25% to 55% and the risk for death by 43%.

Previous reports have indicated that the prevalence of type 2 diabetes is increasing in developing countries and countries of the world with poor socioeconomic levels, (WHO, 2008; Oteino et al, 2003; Brown et al, 2002b). Poor socioeconomic levels have a negative impact on quality of diabetes care, (Kruger et al, 2005; Bradshaw et al, 2004; Oteino et al, 2003). The results of this study suggest that, improving the quality of diabetes care at Dr George Mukhari hospital and other healthcare centers in developing countries might improve the health of patients with type 2 diabetes nationwide.

There are three randomized control trials conducted in different countries with poor socioeconomic levels, that demonstrated that improving the quality of care through a cultural competent DSME strategy for six to 12 months improves glycaemic control, self behaviours and physical activity, (Sacco et al, 2008; Brown et al, 2002a; Keyserling et al, 2002). In these studies the use of “cultural competence” is similar, only meaning the education was carried out in the language that patients understood best. In this study cultural competence was ascertained by appointing bilingual research assistance, (Brown et al, 2002).These studies will be briefly described below:-

Brown et al (2002b) conducted their study in Starr County, the poorest county in Texas characterized by the highest unemployment rate and lowest incomes. Family members or friends of patients with type 2 diabetes were included in a 12 months intervention. The results showed a statistical significant increase in HbA1c and fasting blood glucose levels at six months and 12 months; an increase in diabetes knowledge scores even though at six months the experimental knowledge scores were 1.4% below the control group.

Keyserling et al (2002) conducted their study on African American women, in North Carolina. The primary outcome measure was physical activity over a period of 12 months. There were two intervention groups, the clinic and community based intervention and the clinic only intervention plus the control group, receiving education pamphlets. The community-based intervention consisted of three group sessions and 12 monthly phone calls. The results showed improvements in diabetes knowledge, and physical activity; increased participation rates for individuals who received counseling and telephone follow-up were also observed. There was very little effect on glycaemic control, although measures of diabetes–specific health status improved except for social well-being. There was no impact on blood lipids and individuals gained weight.

Sacco et al (2008) in their study conducted at the University of South Florida, USA showed improvements in diet, increased frequency of exercise and feet inspection, reduced diabetes medical symptoms and lowered the symptoms of depression in a coaching group compared to a control group. The six month intervention did not have an impact on HbA1c levels and BMI.

In this study the socio-demographic profiles of patients in this study and the intervention given to patients were similar to those reported in international studies, with the exception of the duration of the intervention, frequencies of phone calls and length of education contact time. Most studies reported interventions of 12 months or more and two hourly contact time with compressed weekly or biweekly education discussions in order to achieve statistically significant self-care behaviours. In this study, the intervention was carried out for six months and during this time there was a single attendance of the education programme, once a month telephone calls and exercise was home-based. The duration of the education sessions in this study was only 45 minutes; as this was the only time available between 7 and 8 in the morning before the routine clinic work began. This was the only suitable time because patients were available while waiting for their routine tests, which start at 8 o'clock and thereafter they had to queue for doctors' consultations, which start at 9 o'clock.

The effects this study which included family support, education and a home based exercise programme were largely based on the Health Belief Model as indicated in Chapter 4. When the results of the qualitative study (patients' focus group) were tabulated using the HBM, patients indicated that they needed education in order to understand their disease and be able to manage it. They also indicated that they could change their behaviours with support. Their main threats were the complications of type 2 diabetes and how to face the community, because losing weight was perceived as having HIV/AIDS by the community and this stigmatized them. Social stigma, as highlighted in studies dealing with HIV/AIDS, serves as a barrier to treatment adherence and because of this, clinic care should include counseling, (Rintamaki et al, 2006). Support was described by participants as emotional support because they found it difficult to accept their diagnosis. There was also a cultural factor linked to emotional support because men indicated that *"African men do not cook".* This means there is a need for educating the person who prepares food. Barnett (2004) highlighted that there are a variety of issues that can impair diabetes self-management. Emotional wellbeing and depression can influence the patients' attitudes to therapy and ultimately treatment outcomes. Kruger et al (2005) highlighted that culture shapes eating habits and how different individuals perceive their body image. This was also supported by Levitt, (2008). High fat intake in foods

consumed by urban participants is associated with the increasing prevalence of obesity in South Africa. Kruger et al (2005) further reported that the daily fat intake is 23g higher in urban participants than rural counterparts. Moderate overweight women in South Africa are perceived as attractive by the community and thinness is associated with illness. Participants also mentioned that they did not have money to buy diabetes recommended food. Poverty has an influence on environmental factors and this include situations whereby poor food choices are influenced or individuals are prevented from engaging in physical activities. In South Africa food choices are influenced by taste, family preferences and price, (Puoane et al, 2008). They highlighted that poor eating habits are influenced by easy access to cheap unhealthy food found in townships and street vendors and there was a shortage of healthy, low-fat food with few fruits and vegetables. Street vendors sell Russian sausage, deep fried fish, tripe, French fries and fatty meat, (Puoane et al, 2008; Steyn, 2006; Kruger et al, 2005). Findings by Skinner et al (2001) showed that there is a correlation between socio-economic status and diet. In their study, participants from poor socio-economic status had poorer diets and poor glycaemic control. These problems indicate that economic factors such as poverty remain an important barrier in care delivery, (Gill et al, 2009). This problem does not affect patients only; health system utilisation is also affected because the low doctor/nurse: patient ratio results in short consultation times and limited or no time for patients' education, (Kalk et al, 2000). There is also a problem of minimal communication with public to address preventative strategies and lack of infrastructure, (Katz et al, 2009).

Despite the general barriers to the success of diabetes interventions that are aimed at improving metabolic control, this study showed that consistent reminders by phone calls about treatment strategies with support from a family member can improve the metabolic control even for six months interventions. In contrast to this, previous clinical trials showed that education programmes that are carried out at the hospital clinic are not effective because of poor attendance rates, (French et al, 2008). This is because patients do not have money to go the hospital and therefore prefer local clinics. Similarly, there were high levels of poor attendance in this study probably for the same reasons.

Although there were no significant changes in health related quality of life, the family based intervention reduced diabetes medical symptoms when baseline values were used as covariates, after six and at 12 months. Health related quality of life in this study was influenced by the fact that BMI, HDL-C and triglyceride levels did not change significantly after the intervention. A study conducted by Redekop (2002), indicated that patients who were obese

and had diabetes complications were associated with lower HRQOL. Similarly, Skinner et al (2002), found that major diabetes complications were associated with worse quality of life.

Findings by Kaplan et al (1999), indicated that interventions with durations shorter than 18 months did not show changes in quality of life but 18 months interventions improved quality of life and glycaemic control. They debated that health related quality of life is also influenced by psychological factors, poor diet practices, obesity and physical inactivity. The findings of this study demonstrated significant improvements in physical activity after the six months intervention and there were better scores in diabetes symptoms when comparing the baseline and at 12 months results.

In addition, the findings of a meta-analysis which studied the metabolic effects of interventions that increased exercise in type 2 diabetes found that interventions that concentrated on multiple health outcomes and not on exercise behaviours alone, showed smaller effects on HbA1c and BMI, (Conn et al, 2007). This is because a number of competing demands may shift the behaviour to concentrate on one outcome whilst diminishing a change in health behaviour.

This study revealed that the main challenges in managing patients with type 2 diabetes in order that they might achieve good metabolic control are mainly influenced by high rates of poor attendance due to financial constraints which lead to poor health communication. However, there is evidence from the literature which shows that doctors/physicians are not widely involved in day to day practice as recommended by the DSME guidelines, (Katz et al, 2009; Alberti, 2003; Brown et al, 2002). They highlighted that the barriers to implementation of the recommended guidelines are caused by the lack of education, lack of time and confidence in clinical skills and complexity.

Obesity and poor diet practices are found to be the major challenge to diabetes management in patients consulting at Dr George Mukhari hospital. In South Africa, obesity is influenced by urbanization and globalization, (Kruger et al, 2005). They further debate that there are cultural and societal influences attached to the efforts that can be made by patients to lose weight. First of all, South African women do not perceive themselves as overweight/obese even though they are, because it is “normal” in African culture. Steyn (2006) added that South Africa has a mix of developed and developing areas, characterized by a majority of low-income households. Urbanization and globalization result in the newly-arrived urban dwellers having to

change their lifestyle to adapt to the changes in their surroundings. This leads to physical inactivity because transport is readily available, traditional foods are replaced by fast foods and this results in obesity and other chronic diseases such as hypertension. There is less consumption of vegetables and fruit compared to rural dwellers. Sharma et al (2010) highlighted that dietary inadequacies and heavy reliance on non-nutrient- dense shop food and physical inactivity contributed to the growing evidence of obesity. They further highlighted that the shop-bought foods are consumed by individuals from lower socio-economic groups compared to those from higher socio-economic groups. The frequency of consumption of shop-bought foods is five to seven times more than traditional foods such as low-fat and high in fibre, fruit and vegetables, (Steyn, 2006).

Implications of the Study

Self-management education strategies for diabetes play a major role in type 2 diabetes by improving knowledge and skills to control the disease. This study demonstrated that there was very poor attendance at the education sessions when these programmes are conducted in a hospital setting because of the distance and money involved in accessing the hospital. Despite some outcomes that were not achieved, this study showed a trend of good glycaemic control in patients with type 2 diabetes when given family support and the potential to delay complications. The study also highlighted the current standard of care at Dr George Mukhari hospital which does not help to improve the glycaemic control of the patients who attend the hospital. The National Standards for Diabetes Self-management Education encourages that education programmes should focus on patients' needs and there has to be ongoing training of the personnel responsible for conducting the education programmes.

Impact on Policy makers

There is a need to improve health promotion strategies by increasing awareness of diabetes. Hospitals and local clinics need to be staffed with trained diabetes educators so that the education given at hospital clinics should be continued. According to Chin et al, (2001), diabetes care is complex because it involves both self-care by the patient and the administration of the key processes of care by the provider, therefore quality improvement of diabetes care in health centres requires an approach that will encourage patient education, improved training in behaviour change and enhanced delivery systems. Further they added that there is a need for systematic reforms that will lower the cost of care to patients and improve access to patients.

In order to achieve this, doctors/physicians working with type 2 diabetes should be given training on how to counsel their patients to adhere to lifestyle changes because chronic patients tend to believe in their doctors. The findings of a systemic review by Rustand et al (2011), suggested that there is an intertwined link between diabetes and depression, these conditions need to be treated together not in isolation for best outcomes hence counseling is important for self-care behaviours. This finding was evident in cross-sectional studies, (Golden et al, 2004; Delamater et al, 2001). They strongly suggested a patient-centered approach as an effective intervention to improve quality of care and patient outcomes in patients with diabetes.

This study and the supporting literature suggest that health care professionals, especially doctors/physicians need to give attention and quality time to their patients in order to create adherence awareness. It is the responsibility of the health sector to prevent risk factors through population-based approaches to promote healthy lifestyles whilst on the other hand facilitating cost-effective management of the risk factors, (Bradshaw et al, 2007).

Implications for Family, Friends, Colleagues and Community

Self-care behaviours can be positively reinforced when all involved work together with healthcare professionals to support patients, as the disease affects everyone, (National Standards of Diabetes Medical Care, 2011; National Health policy, 2007;). Chronic diseases need to be addressed in the wider community.

9.4 CHALLENGES FACED IN THIS STUDY

- Poor attendance of education group discussions programme.

- Financial constraints, which illustrates the difficulty of working with patients from poor socio-economic areas. This affected attendance of the education discussion programme as well as attendance at data collection. The researcher had to go to patients' homes and fetch them in order to collect their data at the hospital.

- Tracking patients: It was difficult to get hold of some family members on their phones because they had changed their phone numbers or lost their cell phones.

- Referral to local clinics:

Five participants reported that they were referred to their local clinics because they were controlling their disease well. They stated that they did not get all the medication that was prescribed or sometimes only one drug was available at the local clinic. This is supported by World Diabetes, (2006), which demonstrated how people from developed countries strive for excellence in the control of their blood glucose levels while many people with the condition in African countries struggle every day with fundamental issues of survival, (Pirie, 2006). Further, Ossei et al (2005), argue that discharge of patients to a primary care service with poor support and lack of access to specialist advice results in poor care, whereas discharge to structured clinics with ongoing specialist support, education and communication improves outcomes.

- The study did not check adherence of patients to their medication because participants had been taking their medication for some time. Ideally clinical barriers to medication adherence could have been assessed as they may determine a change in self-management behaviour, (Grant et al, 2003).

CHAPTER 10

10. CONCLUSIONS AND RECOMMENDATIONS

10.1 CONCLUSION

This chapter describes an overall conclusion for all studies conducted in this thesis.

The aims of this study were to:

- determine the effects of a family based education and exercise intervention in maintaining normal glycaemic control in patients with type 2 diabetes.
- determine the effects of a family based education and exercise intervention on health-related quality of life in patients with type 2 diabetes.

- The findings of the qualitative study that was preliminary to the development of a diabetes knowledge questionnaire that was specific to this population demonstrated that the management of type 2 diabetes as viewed by patients and professionals in this study may be enhanced by reinforcing patients' knowledge. This should be in the form of health communication and encourage behavior change in terms of lifestyle modification (monitor food portions and regular exercise), taking into consideration patients' backgrounds. The management team (health-care professionals) emphasized utilization of a patient-centered approach. There was an overlap on themes developed by the patients and health care teams and they strongly indicated that there were distinct barriers in the implementation of type 2 diabetes management at Dr George Mukhari hospital and that quality of care could improve when these barriers were addressed. These barriers included lack of knowledge about the management of the disease and patients felt strongly that there should be awareness programmes in order for their families and community to know more about the disease especially as men do not cook in an African culture. Support was also felt to be necessary as patients indicated that they perceived the disease as a death sentence. They also indicated that they were ready to change their health behaviour but there HIV/AIDS stigma that is linked to weight loss was problematic. These barriers indicated that patients would like an intervention that has a knowledge facilitation component. To address these concerns, a diabetes knowledge questionnaire was developed for this population. When a population developed questionnaire was administered to a group of patients with type 2 diabetes consulting at Dr George Mukhari hospital, the following results were found.

- This study showed that patients with type 2 diabetes consulting at Dr George Mukhari hospital were from poor socioeconomic backgrounds.

- The available education programmes were not conducted according to the recommended guidelines by the National Standards of Diabetes Self-Management Strategies as these programmes were still conducted on a one-on-one basis.

- Patients were obese, led sedentary lifestyle and had poor glycaemic control; this indicated poor quality of diabetes care at Dr George Mukhari hospital.

Following these findings a six month family based intervention was developed for this group of patients and the findings demonstrated the following:

- The six months intervention and six months follow-up demonstrated a clinically relevant improvement of random bloods at six months and 12 months and a trend of improvement in HbA1c, when comparing the family support to the no family support and the control groups.

- The study showed significant improvements only in diabetes knowledge scores; distance walked; total cholesterol and LDL, in the experimental groups compared to the control group, but there were better improvements in the family supported group. This means that support is essential for the management of type 2 diabetes. In recognition of these results, (Butler 2009; SEMDSA 2009; Funnel et al, 2009) recommended that education programmes should concentrate on group participation focusing on a patient centered approach, where the healthcare professionals, the family and the patient work together to enhance self-care behaviours. This has recently been supported by (ADA, 2011).

- There were no changes in BMI, HDL-C, triglycerides and health related quality of life. This means that patients need counseling on weight loss issues, thus improving their lipid profiles. Compliance with diet and physical activity is difficult in patients with type 2 diabetes, it is therefore necessary that patients should be reassured that losing as little as 2.25 kg to 4.5 kg is sufficient to achieve a good metabolic control, (Christian et al, 2008).

- This study has highlighted that even with durations of six months, the education programmes that are conducted for 45 minutes by a professional nurse, can improve the levels of physical activity; total cholesterol; LDL-C and diabetes knowledge in patients with

type 2 diabetes. These effects were sustained even at 12 months, indicating that the intervention had an impact on the self-care behaviours of patients with type 2 diabetes consulting at Dr George Mukhari hospital. This suggests that patients who belonged to the family support group had less chance of poor glycaemic control compared to the no family support and the control groups.

10.2 RECOMMENDATIONS

Future studies could be done which would address the following gaps that were identified in this study: So further studies could:

- involve a nutritionist and a psychologist for better counseling on diet.
- investigate the effects of ongoing education at the hospital and at community primary care settings, schools and church halls, venues that are easier to access than the hospital.
- investigate the effects of computerized telephone messaging through sms.
- investigate the effects of in-depth counseling on diet practices and physical activity by suitably qualified health professionals at clinics.
- investigate activity and participation difficulties using the International Classification of Function (ICF).

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APPENDIX I:

- **INVITATION LETTERS FOR FOCUS GROUP DISCUSSION PARTICIPATION**
- **GUIDE OF QUESTIONS FOR THE FOCUS GROUP DISCUSSIONS**
- **EXERCISE PROGRAMME**

Department of Physiotherapy
University of Limpopo-Medunsa Campus
11 July 2008

Dear Participant

Ms Nombeko Mshunqane is conducting a research that is looking at the knowledge of patients with type 2 diabetes about management of the disease and perceptions of healthcare providers on the treatment they give to these patients.
This research is aimed at developing a questionnaire that would be administered in a larger group of patients with type 2 diabetes to test their knowledge about the disease management. A key component of this process is obtaining important input from you because of your expertise in chronic disease and type 2 diabetes management and how you view the effects of the treatment given to patients with type 2 diabetes. The study will include the group of patients consulting at Dr George Mukhari Hospital outpatient diabetes clinic.

I would like to invite you to attend a professional's focus group discussion that takes place on the 18th August 2008 at 9H00 sharp, ending at 10H30. The focus group will include a maximum of 12 patients with type 2 diabetes and a light morning snack and tea will be served. You may please confirm your availability at the following email address:
tsatsie@medunsa.ac.za. Or use my office number 012 521 5803.

The goals of each focus group are to:

- firstly to establish what patients with type 2 diabetes think about the various opinions that they are given by the management team about the medical management of their disease.
- secondly, to establish how health care professionals (management team) feel about the services given to patients with type 2 diabetes.

Before we start the discussion you will be given an information sheet and a consent form to sign confirming your voluntarily agreement to participate.

I appreciate your consideration of my request, and look forward to hearing from you soon.

Department of Physiotherapy
University of Limpopo-Medunsa Campus
11 July 2008

Dear Participant

Ms Nombeko Mshunqane is conducting a research that is looking at the knowledge of patients with type 2 diabetes about management of the disease and how healthcare providers observe the treatment they give to these patients.
This research is aimed at developing a questionnaire that would be administered in a larger group of patients with type 2 diabetes to test their knowledge about the disease management. A key component of this process is obtaining important input from the group consulting at Dr George Mukhari Hospital outpatient diabetes clinic; this will be achieved when you express your experience and expertise.

I would like to invite you to attend a patient focus group discussion that take place on the 14th August 2008 at 9 am sharp, ending at 10H30. The focus group will include a maximum of 12 patients with type 2 diabetes and a light morning snack and tea will be served. You may please confirm your availability with the sister in charge of the clinic who is going to take your name and contact details for follow up.

The goals of each focus group are to:

- firstly to establish what patients with type 2 diabetes think about the various opinions that they are given by the management team about the medical management of their disease.
- secondly, to establish how health care professionals (management team) feel about the services given to patients with type 2 diabetes.

Before we start the discussion you will be given an information sheet and a consent form to sign confirming your voluntarily agreement to participate.

I appreciate your consideration of my request, and look forward to hearing from you soon.

Guide of Questions for the two focus groups and interviews

A. Questions for the Patients' focus group discussion

1. What do you understand about type 2 diabetes? (**probing**, what made you to consult?)
2. What are the causes of type 2 diabetes?
3. What are the signs of type 2 diabetes?
4. Is type 2 diabetes curable? (**probing**, what do you need to live with the disease?)
5. How did you feel the first day you were told you had type 2 diabetes, (**probing** why?, expand.)
6. What is the management of type 2 diabetes? (**follow up**, do you need to change your lifestyle to manage type 2 diabetes?
7. What do you suggest health care professionals need to do in order to manage type 2 diabetes?

B. Questions for the Professionals' focus group discussion

These questions were used as interview guide for all professionals who were not available to be part of this focus group.

1. Do you think the level of knowledge in patients with type 2 diabetes can affect the management of the disease, if yes how?
2. What do you think are the contributing factors to the increase in the prevalence and complications of the disease despite the treatment that these patients get on a daily basis?
3. Do you think doctors and other health professionals play an important role in the management of the disease? (probing, do you exercises/physical activity play an important role?)
4. Are there any suggestions that you can give that can help improve the implementation of the treatment for patients with type 2 diabetes?

EXERCISE PROGRAMME

Research No: **Date Started:**

It is important for you to note that the results of this study will be beneficial for you in improving your diabetic control. This can only be obtained with an ongoing commitment from you to try and modify your lifestyle so that your sugar levels are controlled, hence preventing complications like cardiac problems, which can result due to lack of physical activity. It is therefore vital that exercise forms part of your management.

Below is your exercise programme to be followed at home everyday for 30 minutes each day for a period of six (6) months. You must tick square on days that you have exercised.

WEEK 1

Walking time:…….

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

WEEK 2

Walking time:…….

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

WEEK 3

Walking time:…….

Monday		Wednesday	Thursday	Friday	Saturday	Sunday

WEEK 4

Walking time:…….

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

APPENDIX II

- **ANTHROPOMETRIC MEASUREMENTS**

ANTHROPOMETRIC MEASUREMENTS

Research No: **Date started:**

Height : …….. cm
Body Weight :…….. kg
Waist : …… cm
Hips : …… cm

Blood analysis

Cholesterol : …… HDL : …… LDL : …….
Cho/HDL ratio: …… Triglycerides: …….. Glucose: ……..
HbA_{1c}: ……

APPENDIX III

- **INFORMATION SHEET AND CONSENT FORM**
- **ETHICS CLEARANCE CERTIFICATE**
- **HOSPITAL PERMISSION**

INFORMATION SHEET AND CONSENT FORM

Miss N Mshunqane is undertaking research into benefits of a family based intervention to manage type 2 diabetes. The main aim of the study is to find out whether participants with family support will have better diabetes control compared to those without family support as well as whether the intervention will have an effect on health related quality of life. If you agree to participate, an exercise program to improve your fitness as well education program to empower you with skills and knowledge to manage type 2 diabetes, will be provided.

- **Education**- will cover skills on self-monitoring of blood glucose, lifestyle changes (healthy food practices and home walking).
- **Tests**- will include asking questions about your personal details and how diabetes has affected your life. Random blood samples of ±5 ml will be collected for laboratory test by a professional nurse. This will involve mild discomfort or pain. Body weight and height will be measured to determine your BMI. Distance walked during a six minute walk test will be recorded to test your physical fitness. Exercise program will continue over the period of six months. All tests will be taken with strict consideration of your privacy and all information will be kept confidential.

Participation in this study is entirely voluntary. You can withdraw at any time if you wish and that will not affect the treatment which you receive at the diabetic clinic.

In signing the consent form, I affirm that I have read this form and that I understand the description of the test and their components. I also affirm that all my questions regarding this have been answered to my satisfaction.

Should any unusual symptoms occur during the exercise programme, I will stop exercising and inform the instructor of my symptoms.

---------- ----------
SIGNATURE OF PATIENT **DATE**

---------- ----------
SIGNATURE OF RESEARCHER/ASSISTANT **DATE**

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mshunqane

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M060955**
PROJECT	A Family Based Intervention to Manage Type 2 Diabetes in Patients from Poor Socio-Economic Background
INVESTIGATORS	Ms N Mshunqane
DEPARTMENT	Department of physiotherapy
DATE CONSIDERED	06.09.29
DECISION OF THE COMMITTEE*	APPROVED UNCONDITIONALLY

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

DATE 06.10.23 **CHAIRPERSON** .....
(Professors PE Cleaton-Jones, A Dhai, M Vorster, C Feldman, A Woodiwiss)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof A Stewart

DECLARATION OF INVESTIGATOR(S)

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

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Nombeko ext 743847

GAUTENG PROVINCIAL GOVERNMENT

DEPARTMENT OF HEALTH

DATE: 15 - 09 - 2006.

NAME OF RESEARCH WORKER: N. MSHUNQANE
LECTURER, PHYSIOTHERAPY DEPT. UNIVERSITY OF LIMPOPO - Medunsa Campus

TITLE OF RESEARCH PROJECT: A FAMILY BASED INTERVENTION TO MANAGE TYPE 2 DIABETES IN PATIENTS FROM POOR SOCIOECONOMIC BACKGROUND

OBJECTIVES OF STUDY (briefly or include a protocol):

- To determine availability of education programmes at Dr. G.M. Hosp.
- To determine the level of knowledge of patients with type 2 diabetes
- To identify cultural influences on lifestyle modification.
- To determine the impact of type 2 diabetes on an individual's HRQOL.

METHODOLOGY (briefly or include a protocol): Three groups will be used for this intervention;- Group 1 - control group Group 2 - receiving home based walking + educati no family support considered Group 3 - Home based walking, educati + Family support. This will be carried out for a period of 6 months.

CONFIDENTIALITY OF PATIENTS MAINTAINED: YES, only research numbers will identify patients.

COSTS TO THE HOSPITAL: Hospital will not be responsible for costs of this research. Funding has been applied for.

APPROVAL OF HEAD OF DEPARTMENT: Medwaha (HOD - Diabetic clinic)

APPROVAL OF CRHS OF WITS UNIVERSITY: Prof A STEWART Ass Professor Physio Dept Wits

SUPERINTENDENT PERMISSION:
Signature: [signature] date: 7/10/2006
Subject to any restrictions:

APPENDIX IV

- **DEFINITION OF TERMS**

DEFINITION OF TERMS

Culture : is human behaviour as a whole, it unifies beliefs of any group of people of similar religion, values, attitudes, rituals, family structure and language or mode of social organization.

Diabetic Mellitus Pathologic and metabolic state caused by inadequate insulin action.

Insulin : Anabolic hormone, promoting uptake of glucose by cells and the formation of intracellular glycogen from glucose.

Non-Insulin Dependent Diabetes Mellitus (NIDDM) : Disease characterised by defects in both insulin secretion and insulin action. Overweight and Obesity are the main features in all the individuals.

Obesity : Nutritional disorder characterised by overweight (BMI.>30kg/m^2).

Overweight : BMI >27kg/m2

Healthcare giver : Any medical personnel involved in diabetes education.

Diabetes education : This is an interactive ongoing program involving the person with diabetes and the educator. It focuses on setting goals for self care promotion and addressing those goals.

Family based intervention : is the involvement of a family member or a friend of a patient with type 2 diabetes in the management of type 2 diabetes. This will be to achieve successful health related outcomes.

Lower socioeconomic background : inability to afford basic house hold needs e.g using homemade pit latrine for sanitation due to low income.

Participant : A person with diabetes and/or a family member or any other.

Target population : Individuals with type 2 diabetes consulting at Dr George Mukhari hospital who meet inclusion criteria.

Community : The social, cultural, political environment and its target population

Diabetes Self-management education strategies (DSME) : Education strategies that are use to empower patients and encourage self care.

BLOODS

HbA_{1c} : Glycosylated haemoglobin – Measure of diabetic glycaemic control over the last 3-4 months.

Blood glucose : Amount of sugar level in the blood.

Lipogram : Includes total cholesterol, triglycerides, low density lipoprotein and high density lipoprotein.

LDL : Low density lipoprotein (“bad cholesterol”)

HDL : High density lipoprotein (“good cholesterol”)

INSTRUMENTATION DEFINITIONS

Tape measure : Butterfly brand - used to measure the circumference of part or the whole body area. Calibrated in centimeters.

Bathroom scale : Calibrated bathroom scale.

APPENDIX V

- **KNOWLEDGE QUESTIONNAIRE**

- **KNOWLEDGE QUESTIONNAIRE (BEFORE PILOTING)**

Section A: Demographic data

Research No :……

Gender :……

ID :……

Age :……

Hospital no :……

Physical Address:……

……

……

Tel (H) :…….. (W) ……..

(Cell) :……

Level of Education (specify) :……

Employment (specify):……

Year Diagnosed:……

Settlement : Urban

: Rural

Smoker/non smoker **(tick one)**

Name of a family member/ Friend (who gives you support):

…….....

Address :……

……

Tel (H) :…….. (W) ……..

(Cell) :……

Section B: Socio-economic Status (housing quantity index)

Wall (predominant material of external walls)

2 = Masonry (brick, cement block)

1 = Metallic sheet (zinc), boards, wood

0 = Cardboard, plastic bags

Floor (predominant material floors)

1 = Cement, tiles, brick, wood

0 = Dirt, cardboard, plastic bags

Roof (predominant material of roof)

2 = Tiles, cement, brick

1 = Metallic sheet, wood, asbestos

0 = Cardboard, plastic bags

Type of Housing

3 = Big house (specify number of rooms)……..

2 = Municipality

1 = RDP house

0 = Shack

Number of people living in the house hold

3 = Bread winner…….

2 = Adults…..……..

1 = Children…….

0 = dependants…….

Electricity

1 = Yes

0 = No

Water supply

2 = Piped indoors

1 = Piped to yard

0 = Piped in street

Sanitation

2 = Inside house

1 = In yard

0 = In street, neighbour

Type of sanitation

2 = Flush

1 = Non-flush septic tank

0 = Home-made pit latrine

Total income per month

3 = Above R5000

2 = Between R3001 – R5000

1 = Between R1000 – R3000

0 = Less than R1000 (specify):…….

Mode of Transport to Hospital

2 = Own car (specify km)

1 = Public transport (specify the number of taxi used):……

0 = Motor bike ……..

Section C: Knowledge

1. Answer the following questions about your diabetes.

1.1 How long have you known you have diabetes? Years □ or Months □

1.2 Are you taking insulin injection and pills or pills only to control your diabetes?

Injection & pills □ Pills only □

1.3 How would you rate your overall health?

Excellent □ Good □ Fair □ Poor □

2. Compared to one year ago, how would you rate your overall health?

Good □ Fair □ Same □ Worse □

3. Do you keep your blood sugar in good control? Yes □ No □

4. Do you get worried when your blood sugar levels are low? Yes □ No □

5. If yes what do you do in this situation? Yes □ No □

6. Do you get worried when your blood sugar levels are high? Yes □ No □

7. If yes what do you do in this situation? Yes □ No □

8. Should someone who is overweight loose weight to cure diabetes? Yes □ No □

9. Do you keep your weight under control: Yes □ No □

10. If diabetes is not treated, will the person die early? Yes □ No □

11. Should someone with diabetes check their blood sugar levels regularly? Yes □ No □

12. Will drinking herbal tea help cure diabetes? Yes □ No □

13. Which of the following are complications of diabetes?
Eye blindness □ Foot Ulcers /unhealing wounds □ Renal failure □
Heart diseases □ Peripheral neuropathy □

14. Is it true that diabetes cannot be cured but only controlled? Yes □ No □

15. Have you ever received diabetes education (such as attending group classes or having a meeting with a:
doctor □ nurse □ dietitian □ any other health care provider □

16. Whom of the following healthcare providers do you prefer?
traditional healer □ nurse □ doctor □ dietitian □ psychologist □ physiotherapist □

17. Out of the following methods of education, which one would you prefer?
individual at clinics □ mass media (T.V/radio) □ group □ information(booklets) □

18. On each of the following statements indicate your emotions about issues related to diabetes.

	Strongly Agree 1	**Agree 2**	**Disagree 3**	**Strongly disagree 4**
1. I find it hard to believe that I really have diabetes.				
2. I feel unhappy and depressed when I think about the complications of my diabetes.				
3. I feel I'm not as good as others because of my diabetes.				
4. I find it hard to take good control of my diabetes.				
5. Diabetes doesn't affect my life at all.				
6. Things are going very well for me right now.				
7. I find it easy to take control of my diabetes with support from home, friends and church.				

19. Indicate to what extent do the following statements stop you from exercising regularly?

	Strongly Agree 1	**Agree 2**	**Disagree 3**	**Strongly disagree 4**
1. Exercise takes too much effort.				
2. Exercise takes too much time				
3. My health problems prevent me from exercising.				
4. Exercise makes my diabetes more difficult to control.				
5. I don't have a safe and convenient place to exercise.				
6. I was never told about exercises				
7. I don't believe exercise is helpful for me.				

20. Have you been seen by a dietitian since you were diagnosed? Yes □ No □

21. Has any health care provider advised on what to eat? Yes □ No □

22. Do you have an eating plan that you follow? Yes □ No □

23. If yes how often do you follow the recommendations?

Never □ Sometimes □ Always □

24. If no, what is preventing you from following recommendations?

No money □ the food is not nice □

25. Does following an eating plan help reduce the blood sugar? Yes □ No □

26. The following questions are about the frequency of your food preferences.

	More than 3 times a day	3 times a day	Once a day	Once a week	Don't take it at all
a) Red meat					
b) Fish					
c) Chicken					
d) Tripple					
e) Eggs					
f) White bread					
g) Cooking oil					
h) Margarine					
i) Fruits					
j) vegetables					
k) Pap, Stamp, Rice (tick one)					

KNOWLEDGE QUESTIONNAIRE FOR TYPE 2 DIABETES (AFTER PILOTING)

Section A: Demographic data

Research No :……

Gender :……

ID :……

Age :……

Hospital no :……

Physical Address:…….

……

……

Tel (H) :…….. (W) ……..

(Cell) :……

Level of Education (specify) :……

Employment (specify):……

Year Diagnosed:…….

Settlement : Urban

: Rural

Smoker/non smoker **(tick one)**

Name of a family member/ Friend (who gives you support):

…….....

Address :……

……

Tel (H) :…….. (W) ……..

(Cell) :……

Section B: Socio-economic Status (housing quantity index)

Wall (predominant material of external walls)

2 = Masonry (brick, cement block)

1 = Metallic sheet (zinc), boards, wood

0 = Cardboard, plastic bags

Floor (predominant material floors)

1 = Cement, tiles, brick, wood

0 = Dirt, cardboard, plastic bags

Roof (predominant material of roof)

2 = Tiles, cement, brick

1 = Metallic sheet, wood, asbestos

0 = Cardboard, plastic bags

Type of Housing

3 = Big house (specify number of rooms)……..

2 = Municipality

1 = RDP house

0 = Shack

Number of people living in the house hold

3 = Bread winner…….

2 = Adults…..……..

1 = Children…….

0 = dependants…….

Electricity

1 = Yes

0 = No

Water supply

2 = Piped indoors

1 = Piped to yard

0 = Piped in street

Sanitation

2 = Inside house

1 = In yard

0 = In street, neighbour

Type of sanitation

2 = Flush

1 = Non-flush septic tank

0 = Home-made pit latrine

Total income per month

3 = Above R5000

2 = Between R3001 – R5000

1 = Between R1000 – R3000

0 = Less than R1000 (specify):…….

Mode of Transport to Hospital

2 = Own car (specify km)

1 = Public transport (specify the number of taxi used):……

0 = Motor bike ……..

Section C: Knowledge

1.1 Are you taking insulin injection and pills or pills only to control your diabetes?

Injection □ Injection & pills □ Pills only □ Diet & Exercises □

1.2 How would you rate your overall health?

Excellent □ Good □ Fair □ Poor □

2. Compared to one year ago, how would you rate your overall health?

Good □ Fair □ Same □ Worse □

3. Do you need to control your blood sugar levels in order to manage diabetes? Yes □ No □

4. The normal blood sugar levels ranges are:

Below 4 □ Between 4& 6 □ Above 8 □

5. Do you keep your blood sugar in good control? Yes □ No □

6. Do you get worried when your blood sugar levels are very low? Yes □ No □

7. If yes what do you do in this situation?

Take a snack □ take a sweet/sugar □

8. Do you get worried when your blood sugar levels are high? Yes □ No □

9. If yes what do you do in this situation?

Take medication □ Drink lots of water □

10. Should someone who is overweight lose weight to cure diabetes? Yes □ No □

11. Do you keep your weight under control? Yes □ No □
12. If diabetes is not treated, will the person die early? Yes □ No □
13. Should someone with diabetes check their blood sugar levels regularly? Yes □ No □
14. Will drinking herbal tea help cure diabetes? Yes □ No □
15. Which of the following are complications of diabetes?
    blindness □ amputations □ unhealing wounds □ renal failure □ heart diseases □ stroke □
16. Is it true that diabetes cannot be cured but only controlled? Yes □ No □
17. During which of these sicknesses do you stop taking your insulin?
    repeated vomiting □ drowsiness □ breathing fast □

Diabetes Education

18. Have you ever received diabetes education (such as attending group classes or having a meeting with):
    doctor □ nurse □ dietitian □ any other health care provider □
19. Whom of the following healthcare providers do you prefer to consult?
    traditional healer □ nurse □ doctor □ dietitian □ psychologist □ faith healer □
20. Which of the following tests are taken routinely every time you go to the hospital?
    urine test □ BP check □ bloods □
21. How long do you spend consulting with the doctor?
    15min□ 20 min □ 30min □ more than 30min □
22. Which of the following do doctors do at the clinic?
    examines you and writes down medicine □ looks at the file and writes down medicine □
    talk about your disease □
23. How long do you think you should spend consulting with the doctor?
    15min □ 20 min □ 30min □ more than 30min □
24. Of the following methods of education, which one would you prefer? individual at
    clinics □ mass media (T.V/radio) □ group □ information(booklets) □

Emotions about diabetes

25. On each of the following statements, indicate your emotions about issues related to diabetes.

	Strongly Agree 1	**Agree 2**	**Disagree 3**	**Strongly disagree 4**
1. I find it hard to believe that I really have diabetes.				
2. I feel unhappy and depressed when I think about the complications of my diabetes.				
3. I feel I'm not as good as others because of my diabetes.				
4. I find it hard to take good control of my diabetes.				
5. Diabetes does not affect my life at all.				
6. Things are going very well for me right now.				
7. I find it easy to take control of my diabetes with support from home, friends and church.				

Behavior towards exercises

26. Do you participate in any form of exercise? Yes □ No □

27. If yes, what exercises are you currently doing:

Walking □ Jogging □ Cycling □ Gardening □ Other……..

28. How often do you exercise: Daily□ 3Times/week□ Once/week □

29. If your answer in (26 above) is no, indicate to what extent do the following statements stop you from exercising regularly?

	Strongly Agree 1	**Agree 2**	**Disagree 3**	**Strongly disagree 4**
1. Exercise takes too much effort.				
2. Exercise takes too much time				
3. My health problems prevent me from exercising.				
4. Exercise makes my diabetes more difficult to control.				
5. I don't have a safe and convenient place to exercise.				
6. I was never told about exercises				
7. I don't believe exercise is helpful for me.				

Behavior towards Food

30. Has a health care provider told you to follow a meal plan? Yes □ No □

31. If yes how often do you follow the recommendations?

Never □ Sometimes □ Always □

32. If no, what is preventing you from following recommendations?

No money □ the food is not nice □

33. The following questions are about the frequency of your food choices.

	Daily	**3 times a week**	**Once a week**	**Monthly**	**Don't take it at all**
Red meat					
Fish					
Chicken					
Tripe (malamohodu)					
Pap					
Samp					
Vegetables					
Fruits					
Sweets					
Cake					
Sweet biscuits					
Beer					
Wine					

APPENDIX VI

- **DIABETES IMPACT MEASUREMENT SCALE (DIMS)**

DIABETES IMPACT MEASUREMENT SCALE (DIMS)

Please circle the number of answers that fits your best.

IR 1. How often were you bothered by excessive thirst and urination during the last month?

	(Circle one)
Never	1
Rarely	2
Sometimes	3
Often	4
Usually	5
Always	6

II 2. During the past month, have been anxious or worried?

	(Circle one)
Yes, extremely so, to the point of being sick	1
Yes, very much so	2
Yes, quite a bit	3
Yes, some, enough to bother me	4
Yes, a little bit	5
No, not at all	6

III 3. During the past month, have you felt optimistic about your diabetes?

	(Circle one)
No, I have felt it has ruined my life	1
I have felt generally quite discouraged	2
I've had lots of ups and downs about it	3
I've been optimistic for the most part, occasionally discouraged	4
Very optimistic, rarely discouraged	5
Extremely optimistic, never discouraged	6

IR 4. How good has your muscular strength and endurance been during the past month?

	(Circle one)
Better than ever before	1
As good as ever	2
Almost as good as ever	3
Fair, not as good as usual	4
Rather poor, little muscular strength and endurance	5
Very poor, almost no muscular strength and endurance	6

I 5. Over the past month, have you been bothered by blurring of vision?

	(Circle one)
Always	1
Usually	2
Often	3
Sometimes	4
Rarely	5
Never	6

I 6. Over the past month, how much exercise could you do without developing low blood sugar?

	(Circle one)
Very little, virtually none	1
A little	2
A fair amount	3
Quite a bit	4
A great deal	5
Maximum exercise	6

I	7.	During the past month, have you felt that you were good at doing the most important things you do (for example, your work, school, homemaking, parenting, handling personal affairs)?	
			(Circle one)
		I have felt very skilled and competent	1
		I have felt competent and skilled for the most part	2
		In some things I feel competent, in others not competent	3
		I have not felt very skilled or competent in most things	4
		I have felt incompetent in just about everything	5
IIR	8.	Over the past month, how much have you felt personally in charge of managing your diabetes?	
			(Circle one)
		I've felt I played no part in managing my diabetes	1
		I've felt I played a small, unimportant part in managing my diabetes	2
		I've felt I play a small but important part in managing my diabetes	3
		I've felt I played a major part in managing my diabetes	4
		I've felt completely in charge of managing my diabetes	5
IR	9.	Over the past month, how much energy have you had?	
			(Circle one)
		Lots of energy; enough to do everything I've wanted to do	1
		Quite a lot of energy; there have been a few things I haven't felt able to do	2
		A fair amount of energy; I've felt able to do most of what I wanted to do	3
		Somewhat low in energy; there have been many things I haven't felt able to do	4
		Quite low in energy; I've been able to do very little of what I've wanted to do	5
		Extremely low in energy; I've felt unable to do virtually anything	6

IR 10. During the past month how well have you slept?

	(Circle one)
Very well, with no problems	1
Well, only minor problems	2
Pretty well, some problems	3
Not very well	4
Poorly	5
Very poorly	6

III 11. During the past month, how worried have you been about having an insulin reaction or a dangerously low blood sugar?

	(Circle one)
Extremely worried, practically obsessed	1
Very much worried	2
Quite worried	3
Somewhat worried	4
A little worried	5
Not worried at all	6

IV 12. Have you met the obligations and responsibilities you feel towards your family during the past month?

	(Circle one)
Never	1
Rarely	2
Sometimes	3
Often	4
Usually	5
Always	6

I 13. During the past month, have you been bothered by constipation?

	(Circle one)
All of the time	1
Most of the time	2
A good bit of the time	3
Some of the time	4
A little of the time	5
None of the time	6

II 14. Have you felt depressed during the past month?

	(Circle one)
Yes, to the point that I did not care about anything for days at a time	1
Yes, very depressed almost every day	2
Yes, quite depressed several times	3
Yes, a little depressed now and then	4
No, never felt depressed at all	5

IIR 15. During the past month, was it an inconvenience or bother to you to take your diabetes medicine (pills or insulin)?

Mark here if you don't take medicine for diabetes. _____

	(Circle one)
It was no problem	1
It was a minor nuisance	2
It was a small problem	3
It was a major problem	4
It made my life miserable	5

16. During the past month, have you eaten too much?

	(Circle one)
Never	1
Rarely	2
Sometimes	3
Often	4
Usually	5
Always	6

I 17. During the past month, were you bothered by burning, tingling, pain, or numbness in your feet or hands?

	(Circle one)
Yes - the discomfort was unbearable	1
Yes - the discomfort was severe, almost unbearable	2
Yes - the discomfort was very bothersome	3
Yes - the discomfort was moderately bothersome	4
Yes - I noticed this kind of discomfort, but it was mild	5
No - I had no such discomfort	6

II 18. During the past month, how worried or fearful have you been about your future?

	(Circle one)
Extremely worried	1
Quite worried	2
Fairly worried	3
A little worried	4
Not worried at all	5

IIIR 19. Have you eaten what you wanted to during the past month?

	(Circle one)
Always	1
Usually	2
Often	3
Sometimes	4
Rarely	5
Never	6

IIIR 20. During the past month, have you felt it was worth the effort to take care of your diabetes?

	(Circle one)
Absolutely, without a doubt	1
For the most part it has seemed worth the effort	2
I've been unsure whether it was worth the effort	3
I've been doubtful that it was worth the effort	4
I have felt it was not worth the effort	5

IR 21. During the past month, how often were you able to function sexually as well as you wanted to?

	(Circle one)
Always	1
Usually	2
Often	3
Sometimes	4
Rarely	5
Never	6

22. Over the past month did you develop low blood sugar with exercise?

	(Circle one)
Never	1
Rarely	2
Sometimes	3
Often	4
Usually	5
Always	6

IVR 23. Have you functioned well, not limited by your health, in your usual occupation (homemaking, school, work, etc.)?

	(Circle one)
Very true - I've felt no limitations	1
Quite true - I've felt only trivial limitations	2
For the most part - I've functioned pretty well with some limitations	3
Not really - I have been significantly limited, not functioning very well	4
I have been severely limited, barely functioning	5
I have been completely unable to perform my usual occupation	6

I 24. How often did you vomit after eating during the past month?

	(Circle one)
Always	1
Usually	2
Often	3
Sometimes	4
Rarely	5
Never	6

IIIR 25. During the past month, my whole schedule of activities was restricted by my diabetes.

	(Circle one)
Not at all; I did what I wanted, when I wanted	1
A little; I had to make adjustments now and then, but not often	2
Somewhat; there were numerous times that I couldn't do what I wanted to do because of my diabetes	3
Quite a bit; my schedule was quite restricted by my diabetes	4
A great deal; most of the time I couldn't do what I wanted to do because of my diabetes	5
Completely; I didn't do anything but take care of my diabetes	6

I 26. Over the past month, have you been bothered by feeling faint or dizzy on sitting up or standing up?

	(Circle one)
Always	1
Usually	2
Often	3
Sometimes	4
Rarely	5
Never	6

IIR 27. How much of the time, during the past month, has your daily life been full of things that were interesting to you?

	(Circle one)
All of the time	1
Most of the time	2
A good bit of the time	3
Some of the time	4
A little of the time	5
None of the time	6

IIIR 28. Overall, during the past month, how do you think your diabetes has been doing?

	(Circle one)
It couldn't have been better; it has caused me no difficulty	1
It has caused me only minor difficulties	2
It has caused me some difficulties, but not major ones	3
It has caused me some major difficulties	4
It has caused me many major difficulties	5
It has been doing very badly, pretty much ruining my life	6

I 29. Has your appetite been good during the last month?

	(Circle one)
Never	1
Rarely	2
Sometimes	3
Often	4
Usually	5
Always	6

IVR 30. During the past month, have you participated in and enjoyed family life?

	(Circle one)
Always	1
Usually	2
Often	3
Sometimes	4
Rarely	5
Never	6

IVR 31. During the past month, how often have you been able to function well in your usual occupation (homemaking, school, work, etc.)?

	(Circle one)
Always	1
Usually	2
Often	3
Sometimes	4
Rarely	5
Never	6

IIR 32. How high has your interest in sex been over the past month?

	(Circle one)
Very high	1
Moderately high	2
Fairly high	3
Fairly low	4
Quite low	5
No interest	6

IR 33. How often did you have abdominal discomfort after eating during the past month?

	(Circle one)
Never	1
Rarely	2
Sometimes	3
Often	4
Usually	5
Always	6

III 34. How often have you been uncertain about how much to eat and/or how much insulin to take?

	(Circle one)
Always	1
Usually	2
Often	3
Sometimes	4
Rarely	5
Never	6

IVR 35. Have you enjoyed social and recreational activities during the past month?

	(Circle one)
Very much so, without limitations	1
Mostly, with few limitations	2
For the most part, but with some limitations	3
I've been rather limited in what I could enjoy	4
I've been able to enjoy very few such activities	5
I've been unable to enjoy any such activities	6

IIR 36. During the past month, have you felt useful?

	(Circle one)
Yes, quite useful	1
For the most part	2
I haven't felt useful	3
I have felt useless	4

I 37. During the past month, how much of the time were you lacking enough energy?

	(Circle one)
All the time	1
Just about all the time	2
Most of the time	3
Sometimes, but not most of the time	4
Not often	5
Never	6

I 38. How often did you have diarrhea during the past month?

	(Circle one)
Always	1
Usually	2
Often	3
Sometimes	4
Rarely	5
Never	6

39. During the past month, have you been able to follow medical recommendations concerning your diabetes?

	(Circle one)
Never	1
Rarely	2
Sometimes	3
Often	4
Usually	5
Always	6

III 40. During the past month, was your diabetes monitoring an inconvenience or bother to you?

	(Circle one)
It made my life miserable	1
It was a major problem	2
It was a small problem	3
It was a minor nuisance	4
It was no problem	5

IIR 41. During the past month, how much of the time did you feel that things were going well for you?

	(Circle one)
All of the time	1
Most of the time	2
A good bit of the time	3
Some of the time	4
A little of the time	5
None of the time	6

42. Have you eaten when you wanted to during the past month?

	(Circle one)
Yes - without any thought of my diabetes	1
I usually ate whenever I felt like it	2
Sometimes I ate just when I felt like it, but usually it was dictated by my diabetes	3
I always ate according to a fixed schedule, whether I wanted to or not	4

IR 43. During the past month how often did you feel nauseated after eating?

	(Circle one)
Never	1
Rarely	2
Sometimes	3
Often	4
Usually	5
Always	6

IIIR 44. Over the past month, how well do you feel you have understood your diabetes?

	(Circle one)
I have felt I understood it completely, without any doubt	1
I have had only minor questions or doubts about my diabetes	2
I have had significant doubts and uncertainties about my diabetes	3
I have had many doubts and uncertainties about my diabetes	4
I have been completely uncertain; I haven't understood my diabetes at all	5

APPENDIX VII

- **NATIONAL STANDARDS FOR DIABETES SELF-MANAGEMENT EDUCATION (DSME)**

NATIONAL STANDARDS FOR DIABETES SELF-MANAGEMENT EDUCATION (DSME)

The National standards for DSME are designed to define quality diabetes self-management education and to assist diabetes educators in a variety of settings to provide evidence based education. These standards were approved in March 2007 and are reviewed every five (5) years because of on-going diabetes research feed backs and dynamic nature of health care, Funnel et al, 2009.
There are 10 standards for DSME which are classified into three (3) categories:

- Structure- standards 1-4
- Process- standards 5 -8
- Outcome- standards 9-10

Structure

Standard 1: The DSME entity will have documentation of its organisational structure, mission statement, and goals and will recognise and support quality DSME as an integral component of diabetes care.
Documentation of the organisational structure, mission statement, and goals will lead to efficient and effective provision of DSME.

Standard 2: The DSME shall appoint an advisory group to promote quality. This group shall include representatives from the health professions, people with diabetes, the community and other stakeholders.
Broad participation of organisations and community stakeholders will result in a patient-centered approach and joint decision making.

Standard 3: The DSME entity will determine the diabetes educational needs of target population(s) and identify resources necessary to meet these needs.
It is important to determine the needs of the target population in order to focus resources and maximize health benefits.

Standard 4: A coordinator will be designated to oversee the planning, implementation and evaluation of diabetes self-management education. The coordinator will have academic or experiential preparation in chronic disease care and education in program management.
The coordinator ensures accountability and continuity of the educational process.

Process

Standard 5: DSME will be provided by one or more instructors. The instructors will have recent educational and experiential preparation in education and diabetes management or will be a certified diabetes educator. The instructor(s) will obtain regular continuing education in the field of diabetes management and education. At least one of the instructors will be a registered nurse, dietician, or pharmacist. A mechanism must be in place to ensure that participants' needs are in met if those needs are outside the instructors' scope of practice and expertise.

This means that DSME is most effective when delivered by multidisciplinary team.

Standard 6: A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes, will serve as the framework for the DSME entity. Assessed needs of the individual with pre-diabetes and diabetes will determine which of the content areas listed below are to be provided:

- Describing the diabetes disease process and treatment options.
- Incorporating nutritional management into lifestyle.
- Incorporating physical activity into lifestyle.
- Using medication(s) safely and for maximum therapeutic effectiveness.
- Monitoring blood glucose and other parameters and using the results for self-management decision making.
- Preventing, detecting, and treating acute complications.
- Preventing, detecting, and treating chronic complications.
- Developing personal strategies to address psychosocial issues and concerns.
- Developing personal strategies to promote health and behaviour change.

Standard 7: An individual assessment and education plan will be developed collaboratively by the participant and instructor(s) to direct the selection of appropriate educational interventions and self-management support strategies. This assessment and education plan and the intervention and outcomes will be documented in the education record.

This means that it is vital to assess individual patients to obtain information about their health beliefs, cultural influences, diabetes knowledge, self-management skills and behaviour, whether they are ready to learn, family support, physical limitations and financial status.

Standard 8: a personalised follow-up plan for on-going self- management support will be developed collaboratively by the participant and instructor(s). The patient's outcomes and goals and the plan for on-going self-management will be communicated to the referring provider.

This means that patients need an on-going diabetes self-management support to sustain self-care behaviours.

Outcomes

Standard 9: The DSME entity will measure attainment of patient-defined goals and patient outcomes at regular intervals using appropriate measurement techniques to evaluate the effectiveness of the educational intervention.

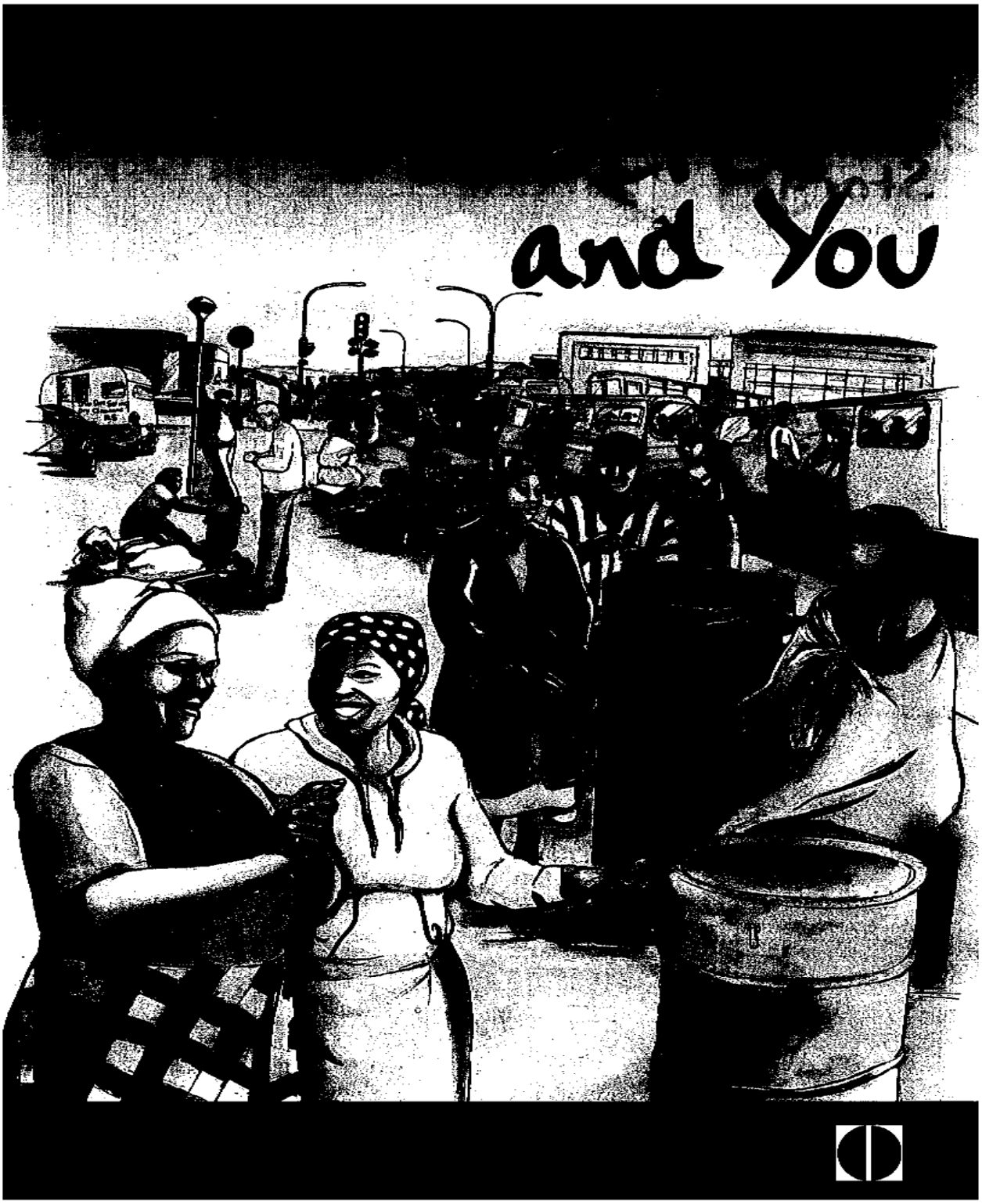
This means that in addition to program-defined goals and objectives, the DSME entity should assess each patient's personal self-management goals and his/her progress towards those personal goals.

Standard 10: The DSME entity will measure the effectiveness of the education process and determine opportunities for improvement using a written continuous quality improvement plan that describes and documents a systematic review of entities 'process and outcome data.

This means that diabetes education must be responsive to advances in knowledge, treatment strategies, educational strategies, psychosocial interventions and the changing health care.

APPENDIX VIII

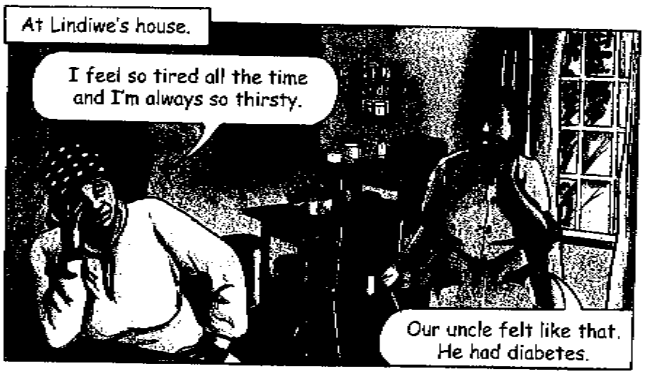
- **BOOKLET 1: DIABETES AND YOU**
- **BOOKLET 2: UNDERSTANDING DIABETES**

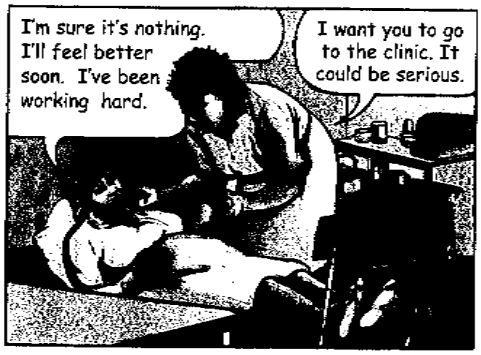


Education booklet 1

Lindiwe's Story

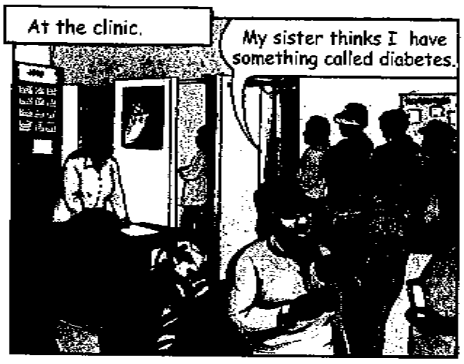
This story shows how Lindiwe found out she had diabetes and how she learnt to manage her condition.

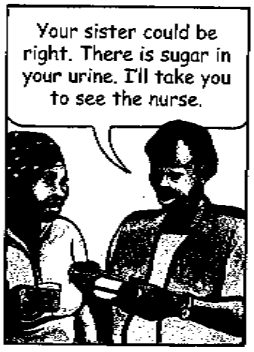
















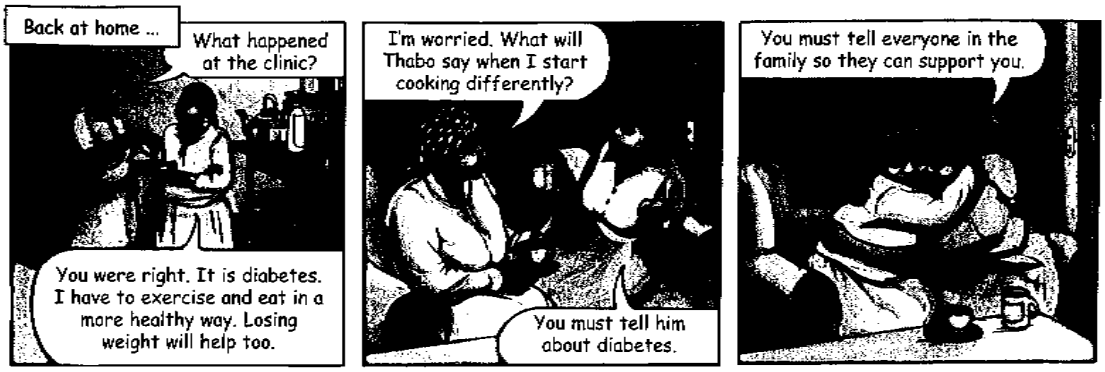







Your blood sugar is high. You have diabetes.
Oh no! Do I have to stop work?
No. Diabetes is a serious condition, but if you manage it carefully you can still lead an active life.
I will explain what you can do to keep your blood sugar at a normal level. We will check it again when you come back next week.
One way to lower your blood sugar is to exercise.
But I'm too tired to exercise.
One of my patients began with just a little exercise. He walked quickly up and down the stairs twice a day. Soon he began to feel better and started to exercise more and more.
Losing some weight will help your diabetes.
You will need to eat healthy food ...
vegetables, fruit, chicken, fish, mealie meal, rice .. in small, regular meals.
Do you eat three meals a day?
Not during the week ... No, I don't have breakfast.
You should try to eat three meals a day - breakfast, lunch and dinner.
But I leave very early in the morning. I don't have time to cook breakfast.
I understand that it is difficult for you. You could make some porridge the night before.
2


You may have lost some feeling in your feet because of diabetes. You need to look after your feet carefully.
One of my patients stood on a nail and did not notice the nail until his foot was infected.
I can't see my feet. I will have to ask my granddaughter to help me check them.
What can you see on the wall?
It's quite blurred. I can't see much.
Will I have to wear glasses?
Not necessarily. Your eyesight may get clearer in a few days once your blood sugar has gone down.
But you'll need to have your eyes tested every year by an eye doctor.
You will need to test your blood sugar regularly to help you control your diabetes.
How do I do that?
Don't worry, I'll show you how. Just a small prick is enough to get a little blood.
This colour shows that your blood sugar is 13 - it is high.
My uncle needed to have injections. Will I need to have them too?
I can see that worries you. No, you won't need injections at this stage.
First try exercising and eating healthily. When you come back to the clinic we will test your blood sugar again. We may need to give you some tablets.



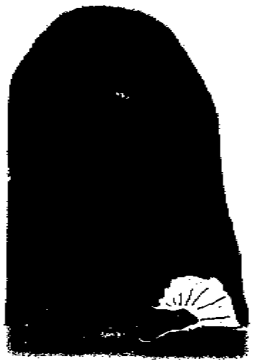
Lindiwe joined a Diabetes South Africa support group at her local clinic. They helped her too.



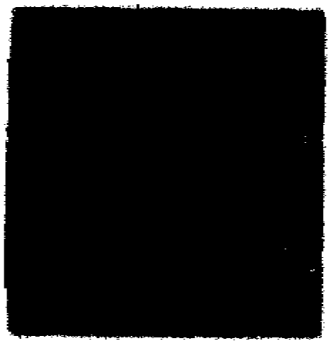
Here are some of the health problems that can be caused by diabetes. If you have any of these problems go to your clinic or doctor and ask to be tested for diabetes.



- Feeling very, very thirsty



- Sores and boils that do not heal



- Always feeling tired
- Not seeing well
- Losing weight even though you eat well
- Itchiness of private parts
- Impotence



- Going to the toilet often

Some people with diabetes have no signs or symptoms.

If diabetes is not treated it can lead to more serious problems like:

- blindness
- kidney failure
- heart attacks and strokes
- amputation of legs and feet

If you know what to do and get the right treatment these problems can be avoided!

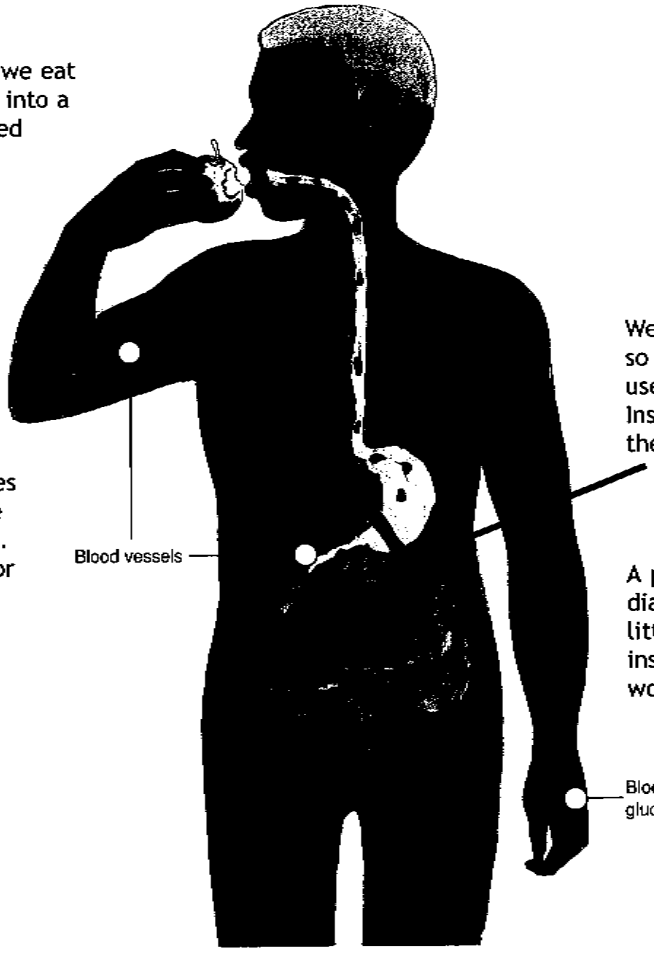


We need energy to live. Our bodies get energy from the food we eat. People who have diabetes cannot use food correctly to give them energy.

Some of the food we eat gets broken down into a type of sugar called **glucose**.

Glucose gives the body energy to work, think and play.

Glucose is taken from our intestines to all parts of the body in our blood. Glucose is used for energy inside our body cells.



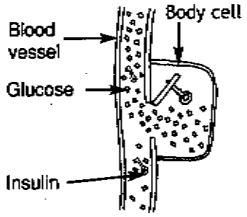
We need **insulin** so our bodies can use the glucose. Insulin is made in the pancreas.

A person with diabetes has too little insulin or the insulin does not work properly.

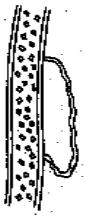
Blood vessels carry glucose and insulin

How insulin works

Insulin is like a key that opens the door to allow glucose from the blood into the body cells.



If there is not enough insulin the glucose stays in the blood. This means that the body cells get no energy.



If you have diabetes you have to make sure that there is not too much or too little glucose in your blood. To do this you need to exercise regularly and eat in a healthy way. You may also need to take tablets or have insulin injections.



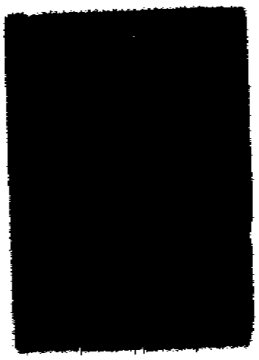
◆ Exercise regularly



◆ Eat small, regular healthy meals



◆ Take tablets or insulin injections if your doctor recommends them



◆ Exercising and eating healthily will help you to lose weight



◆ Having regular blood tests will help to show if you are managing your diabetes correctly



◆ Don't smoke if you have diabetes



If you think you may have diabetes you can go to a traditional healer but you must also:

- **go to a clinic or hospital to be tested for diabetes *and***
- **take any tablets or insulin that the doctor gives you *and***
- **go back to the clinic or hospital for regular check-ups.**

Regular exercise is good for everyone. It is especially important for people with diabetes.

Try to exercise at least three times a week for 30 minutes each time.

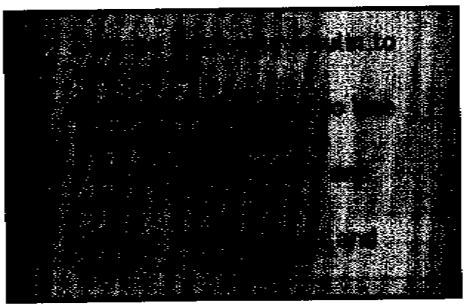
Any kind of exercise helps. You do not need a gym or special equipment to exercise. Here are some ideas.

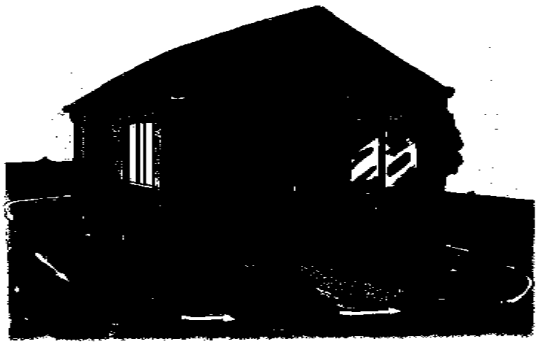


◆ Use music to help you do housework a little faster!



◆ Join the TV exercise class!





◆ Walk around your house every day



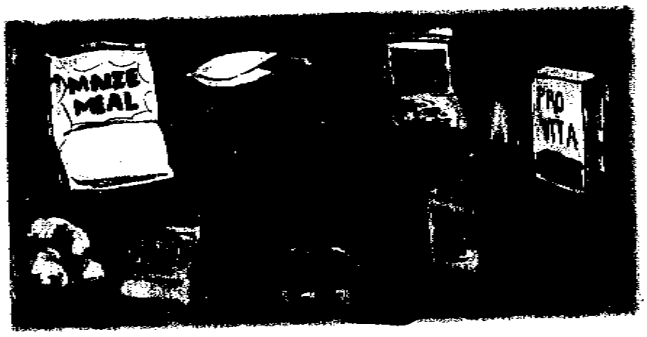
◆ Get out of the taxi early and walk the last few blocks home.

Eating puts glucose into your blood. If you have diabetes you must be careful about <u>what</u> you eat, <u>how much</u> you eat and <u>when</u> you eat.

What to eat

To stay healthy we need to eat the **right** amount of different types of food. There are no good or bad foods, but we need to mix the foods we eat carefully.

- Make starchy foods the basis of most meals.



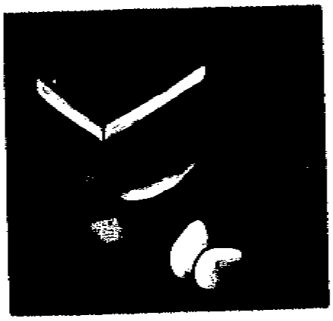
- Eat plenty of vegetables and fruit every day.



- Eat dried beans and peas, lentils, peanut butter, tinned beans and soya products regularly.



- Chicken, fish, meat, eggs or milk can be eaten every day.



What to drink

[illegible] of clean, safe water.

[illegible] alcohol, drink no [illegible] standard drinks [illegible]

[illegible] drinks [illegible]

[illegible] instead of [illegible] you use [illegible] do so in [illegible]

How much to eat and when to eat

Make meals more or less the same size. If you are overweight, eat smaller meals. Very large meals can put too much glucose into your blood at one time.



Space your meals evenly throughout the day. Eat at the same time each day, if possible.



◆ Eat breakfast

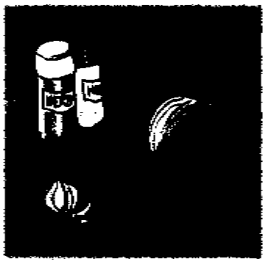


◆ Eat lunch

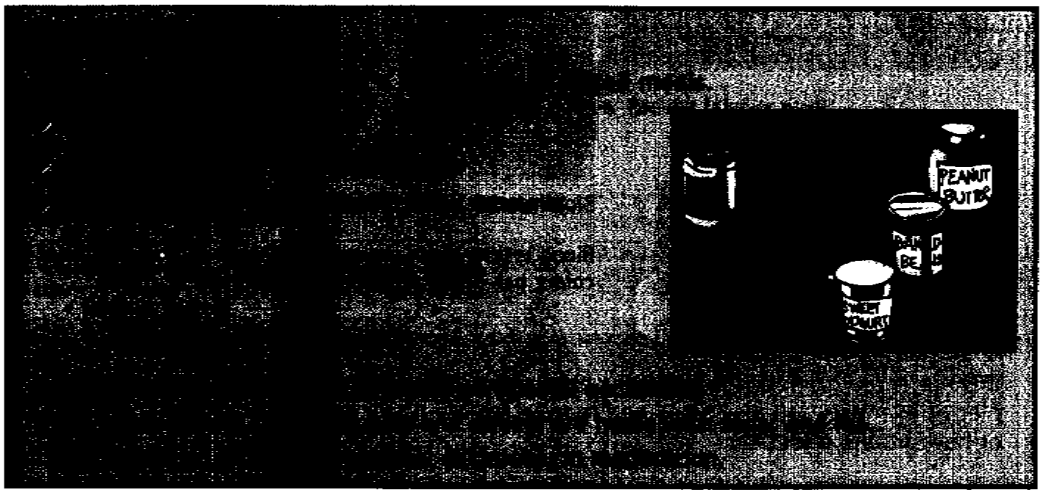


◆ Eat supper

Use salt sparingly. Rather use herbs, garlic and chilli to flavour your food.







Eating healthily, exercising regularly and losing weight may be all you need to manage your diabetes. But most people also have to take tablets or have insulin injections.

If you have to take medication remember:

- Take tablets or insulin injections exactly as your doctor or clinic nurse tells you.
- Take tablets at the same time every day, with meals.
- Do not stop taking the tablets unless your doctor tells you to.
- Always make sure you have enough tablets to last until your next clinic visit.
- If you have high blood pressure take your tablets everyday. Do not stop.

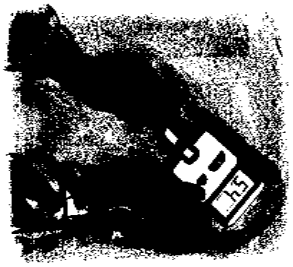




Measuring the glucose in your blood

When you visit the clinic the nurses will do a blood test to see how much glucose is in your blood. You can learn how to test your own blood for glucose. Make sure your health worker shows you how to do this and ask questions if anything is not clear. Ask a family member or a friend to help you do the tests if you need help.

Write your test results in a book. Take the book with you when you visit the clinic.





Blood testing meter

Blood testing strips are put in a meter or compared to a colour bar. Strips are often provided free at clinics.

If there is too much or too little glucose in your blood you may need to change your diet or exercise. You may also need to take tablets if you are not already taking them or have insulin injections.

Learn to recognise your body's warning signs of having too much or too little glucose in your blood.

All these are warnings that you have **too much glucose** in your blood:



- going to the toilet often



- feeling very tired and weak



- feeling very thirsty



- not seeing well

If you have diabetes and you have these signs check that you are eating healthily, exercising and taking your medicines as you should. If you are doing all these things correctly, go to the clinic for advice.

If you take **diabetes tablets** or **insulin** you need to watch out for these signs. They are warnings that you have **too little glucose** in your blood. People call this hypoglycaemia (hypo).



- sweating



- feeling confused



- feeling faint or weak
- feeling shaky, nervous or irritable
- pounding of the heart
- feeling drunk

As soon as you feel any of these signs eat a sweet or have a sweet drink, then eat a sandwich.



If you take diabetes tablets or insulin always:

- carry sugary sweets like Super C with you;
- wear a MedicAlert bracelet, with 'diabetic, give sugar if confused' written on it.

If you have diabetes your body can easily get infections. Small injuries can develop into serious problems if they are not noticed at an early stage.

Looking after your feet

Diabetes can reduce the flow of blood to your feet and make them cold. It can also cause loss of feeling in your feet.



- Check your feet carefully every day (go to the clinic if you have sores that won't heal)



- Wash feet every day in warm (not hot) water



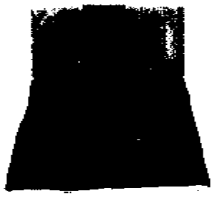
- Dry feet well especially between toes



- Put cream on feet (not between toes) to keep them soft



- Cut toe nails straight across



- Wear comfortable, well-fitting shoes or sandals (not plastic)



- Check shoes every day for nails and stones



- Keep feet warm and dry in winter



- Don't walk barefoot



- Be careful of heaters and hot water bottles (you may burn your feet on these and not feel it)

Looking after your eyes

High blood sugar may affect your eyesight. If you notice any changes in your eyesight go to see a doctor at the clinic. Have your eyes tested once a year, even if your vision has not changed.



Looking after your mouth

Brush your teeth at least twice a day. Visit your dentist regularly and tell him you have diabetes.



Good nutrition is important because it improves your blood glucose control. Everyone in the family should follow this healthy plan. How much you eat and when you eat are as important as what you eat. Try to eat regular meals that are high in complex carbohydrates and fibre but low in fat.

If you are overweight, your blood glucose control will improve if you lose some weight.

Take the correct medication.



People with type 1 diabetes need to take insulin injections every day to stay alive. People with type 2 may need to take tablets or later even insulin injections to improve their glucose control.

Test your blood glucose.

It is important to test your blood glucose regularly so that you can make sure that your diabetes management – activity, eating plan and possibly medication – is working well.

Try to learn as much as you can about diabetes and how to manage it.

UNDERSTANDING

DIABETES



Diabetes South Africa

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ENGLISH

Education booklet 2

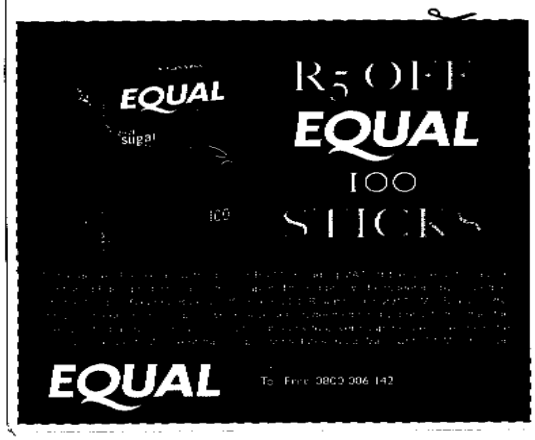
WHAT IS DIABETES?

When you have diabetes, your body is either unable to make enough insulin or it is unable to correctly use the insulin it does make. As a result, blood glucose cannot move into your cells to be changed into energy.

The glucose builds up in your bloodstream. This is called hyperglycaemia. This blood glucose (sugar) is not just sugar from eating table sugar, jam or other sweet foods. It comes from the breakdown of all foods which contain carbohydrates.

When blood glucose levels are high it spills over into your urine.

The amount of blood glucose in your blood is measured in millimols per litre. The normal range is considered to be 4-6 mmol/l.



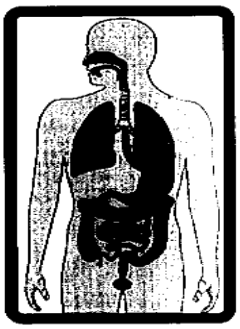
Dangers of uncontrolled diabetes

High blood glucose over a long period of time can lead to serious health problems such as heart attacks and strokes, blindness, kidney failure, amputations and impotence. It is important that you have your blood glucose tested often if you have diabetes.

UNDERSTANDING NORMAL DIGESTION

To understand diabetes you need to know what your body does with the food you eat and how it uses it.:

- **1.** When you eat, your body breaks your food down to release nutrients. One group of these nutrients is carbohydrates.
- Carbohydrates are found in starchy foods such as bread, porridge, cereals, pasta and rice, and also in vegetables, fruit, milk, yoghurt, and sugar.



- **2.** Carbohydrates provide your body with energy. Your body breaks carbohydrates down into sugar molecules. These are absorbed into your blood as blood glucose. Your body carries the glucose to every cell in your body.

3. Every time you eat food rich in carbohydrates, your body makes a hormone called INSULIN. This insulin is sent through your blood stream to your body cells. It opens the cell walls, just like a key opens a lock so that the blood glucose can move into the cells. This glucose is the fuel that the cells need as energy to stay alive and active, as a car needs petrol to drive. Without insulin the glucose can't move into the cells of your body.

Insulin is the key



When people are told that they have diabetes they are often shocked. Sometimes they try to deal with this shock by ignoring what they have heard. They hope that they will get better or that the diabetes will just go away. Sometimes they try special remedies. But diabetes won't just go away, although it can be treated and controlled.



Diabetes does not mean the end of a normal lifestyle. Knowing how to manage it day by day will keep you healthy.

Why do some people get diabetes?

Diabetes is a common condition which affects about two million people in South Africa of all ages, all races, both men and women from all walks of life.

Who is at risk?

Scientists are not sure what causes diabetes. They do know that people:

Who are overweight,
Who do little exercise and
Who have a family history of diabetes are most at risk.

OTHER PROBLEMS LINKED WITH DIABETES

Too much glucose in your blood (usually more than 10 mmol/l) is called hyperglycaemia. Your body may react in a number of ways to warn you that your blood glucose is too high.

You may find that you:

- ***Go to the toilet more often.*** This happens because your kidneys draw more water from your body to dilute and remove the glucose.
- ***Are very thirsty.*** Because you pass a lot of urine you will become dehydrated and thirsty.



- ***Lose weight without dieting.*** Body cells get the energy they need from blood glucose. Because your cells won't open up and take this blood glucose in, your cells can't get energy and they starve. Your body tries to use other body stores for energy and so you lose weight.
- ***Are very tired.*** Your body can't use the energy it needs from your food.
- ***Are very hungry.*** This is because your body cells are starving.
- ***Have blurred vision.*** The extra blood sugar in your eyes causes them to become swollen and unable to focus properly.
- ***Itch and discharge*** in the genital area and have sores that heal slowly. Your blood becomes thicker and unable to fight infections well.

But sometimes you may have no warning that your blood glucose is high!

TREATMENT OF DIABETES

There are two main types of diabetes:

Type 1 usually starts in young people and occurs when the body stops producing insulin.

Type 2 usually develops in older people and occurs when the insulin produced by the body is insufficient or not able to work properly. Increasing numbers of younger people are being affected by type 2 adult-onset DM.

A person with diabetes can live a normal healthy life. This is possible if diabetes is properly managed. To have good control, try to follow these guidelines.

Be active.

Being active everyday will help to improve your blood glucose control. Your body uses insulin better when you exercise. Exercise also helps with weight. Any activity or exercise is better than none.



Follow a healthy, high-fibre, low-fat eating plan.