NON-ADHERENCE TO LIFESTYLE MODIFICATION RECOMMENDATIONS (DIET AND EXERCISE) AMONGST TYPE 2 DIABETES MELLITUS PATIENTS
ATTENDING EXTENSION II CLINIC IN GABORONE, BOTSWANA

BY

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Declaration

I Dr. Ganiyu Adewale B. hereby declare that the work on which this research is based is concept where acknowledgements indicate otherwise) and that neither the whole work not part of it has been, is being or is to be submitted for another degree at this or any other University.	
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Dedication

I dedicate this work and the entire degree to the almighty God who made it possible within the stipulated time frame. I also dedicate same work to my loving wife, Mrs. Abdul-Ganiyu for her tremendous and invaluable supports, encouragement and efforts throughout the four years race. I sincerely appreciate her sacrifice of time, understanding and endurance for doing my share of the domestic chores while I worked on this research.

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Abstract

Background

Abundant literature supports the beneficial effects of diet and exercise recommendations for improving and maintaining glycaemic levels of people with type 2 diabetes mellitus. Patient adherence to therapeutic lifestyle measures is notoriously difficult to initiate and sustain; however, reason for non-adherence amongst diabetes population is very complex and multifaceted in nature.

Objectives

To determine rates of non-adherence and reasons/barriers for not adhering to diet and exercise recommendations amongst type 2 diabetes mellitus patients attending Extension II clinic in Gaborone, Botswana.

Summary of methods

Design: descriptive cross-sectional study using self administered questionnaire

Setting: Extension II clinic, a public family practice in Gaborone, Botswana.

Study population: Consenting adults diagnosed with type 2 diabetes mellitus, aged 30 years or older, diagnosed 2 or more years and on clinic care.

Sample selection: Convenience sampling method was used to select 35 subjects per month, over a period of three successive months and a total of 105 participants were recruited into the study, made up of 44 men and 61 women.

Results

104 correctly filled questionnaires were included in the data analysis, of which, 59% were female. Estimated rates of non-adherence to diet and exercise were 37.4%; 95% CI, 27.7 – 46.3% and 52%; 95% CI, 42.4 – 61.6% respectively. The main perceived reasons for non-adherence to diet were granting self-permission (36.5%), lack of information (33.3%), eating out (31.7%), financial constraints (28.8%) and poor self control (26.9%); while the main perceived reasons for non-adherence to exercise were lack of information (65.7%), exercise as potentially exacerbating illness (57.6%), lack of exercise partner (24.0%), specific locations away from home (18.0%), and winter weather (15.4%). The overall reasons for not adhering to diet and exercise include lack of moral and emotional supports from the spouse (54.1%), family members (44.8%), and friends (58.7%). 95% and 67.3% of the participants had reported that diet and exercise respectively could improved and maintained their diabetic control.

Conclusion

Non-adherence to diet and exercise recommendations amongst type 2 diabetes patients is far more prevalent and no particular single reason could be attributed to poor adherence to either diet or exercise recommendations, rather a combination of many factors.

Abbreviations List

ACC American College of Cardiology

ADA American Diabetes Association

AHA American Heart Association

BMI Body Mass Index

CAM Complimentary & Alternate Medicine

CDC Center for Disease Control

CI Confidence Interval

CSO Central Statistics Office

Dept Department

DPPRG Diabetes Prevention Programme Research Group

GCC Gaborone City Council

GDM Gestational Diabetes Mellitus

HbA1C Glycosylated Haemoglobin

HST Health Systems Trust

IDF International Diabetes Federation

IFG Impaired Fasting Glucose

IGT Impaired Glucose Tolerance

MOH Ministry of Health

NHS National Health Scheme

NIDDK National Institute of Diabetes & Digestive & Kidney Diseases

NIH National Institute of Health

NNT Number Needed to Treat

OGTT Oral Glucose Tolerance Test

RCTs Randomized Controlled Trials

SD Standard Deviation

SEMDSA Society for Endocrinology, Metabolism & Diabetes of South Africa

UKPDS United Kingdom Prospective Diabetes Study

US United States

USA United States of America

VLCDs Very Low Caloric Diets

WHO World Health Organization

Table of Contents

	Page
Title page	i
Declaration	ii
Dedication	iii
Acknowledgements	iv
Abstract	V
Abbreviations	vi - vii
Chapter 1: Introduction	1-3
1.1 Introduction	1
1.2 Rationale for the study	2
1.3 Setting of the study	2
1.4 Population profile	2
1.5 Health care systems and facilities	2 - 3
1.5.1 Public health care facility	2
1.5.2 Private health care facility	2
1.5.3 Complementary & alternative medicine (CAM)	3
Chapter 2: Literature review	4 - 24
2.1 Search strategy	4
2.2 Introduction	4 - 5
2.3 Global picture of diabetes mellitus	5
2.4 Diabetes in Sub-Saharan Africa	5 - 8
2.5 Diagnosis and aetiological classification of diabetes mellitus	8 - 9
2.6 Over-view of type 1 & 2 diabetes mellitus	9 - 11
2.7 Risk factors associated with type 2 diabetes mellitus	11 - 12

2.8 Complications of diabetes mellitus	12 - 13
2.9 Management of diabetes mellitus	13 - 14
2.10 Lifestyle modification recommendations and glycaemic control	14 - 18
2.11 Non-adherence to diet and exercise recommendations	18 - 20
2.12 Rates of non-adherence to diet and exercise	20 - 21
2.13 Reasons for non-adherence to diet exercise	21 - 23
2.14 Patient's perceptions on diet and exercise	23 - 24
2.15 Summary of Literature reviewed	24
Chapter 3: Methods	25 - 29
3.1 Introduction	25
3.2 Aim, objectives, research question, & epistemological approach	25
3.2.1 Aim	25
3.2.2 Objectives	25
3.2.3 Research question	25
3.2.4 Epistemological approach	25
3.3 Study design	26
3.4 Study population	26
3.4.1 Inclusion criteria	26
3.4.2 Exclusion criteria	26
3.5 Sample size and selection	26
3.6 Recruitment of study participants	27
3.7 Data collection	27
3.8 Data analysis	27
3.9 Reliability and validity	28
3.10 Bias	28- 29

3.10.1 Selection bias	28
3.10.2 Participant bias	28
3.10.3 Language bias	29
3.11 Ethical considerations	29
Chapter 4: Results	30 -39
4.1 Introduction	30
4.2 Sample	30
4.3 Baseline characteristics of the study participants	30 - 31
4.4 Prevalence of non-adherence to diet & exercise recommendations	31 - 34
4.5 Reasons for not adhering to lifestyle modification recommendations	35 - 37
4.5.1 Reasons for not adhering to diet	35
4.5.2 Reasons for not adhering to exercise	35 - 36
4.5.3 Overall barriers to diet and exercise adherence	36 - 37
4.6 Patient's understanding & perceptions about lifestyle modification recommend	lations
	38 - 39
Chapter 5: Discussion	40 - 44
5.1 Introduction	40
5.2 Prevalence rates of non-adherence to diet and exercise recommendations	40 - 41
5.3 Reasons for not adhering to diet and exercise recommendations	41 - 43
5.4 Patient's understanding and perceptions about lifestyle modification recommen	ndations 43
5.5 Strengths and limitations of the study	43
5.6 Implications for policy and practice	44
5.7 Summary	44
Chapter 6: Conclusions and recommendations	45 - 46
6.1 Conclusion	45

6.2 Recommendations	45 - 46
References	47 - 56
Appendices	57 - 88
Appendix one: Approved protocol	57 - 68
Appendix two: Approved questionnaire	69 - 82
Appendix three: Approved consent form	83 - 84
Appendix four: MCREC certificate	85
Appendix five: Botswana's Ministry of Health certificate	86
Appendix six: Letter issued by the local government authority for data collection	87
Appendix seven: Implementation time frame & Research budget estimate	88

List of Tables

Table r	number Title	Page
I	Background characteristics of 104 participants studied	30 - 31
II	Non-adherence to lifestyle measures and barriers for not adhering to diet and exercise	32 - 33
III	Summary of characteristics of the participants adhering to diet & exercise	34
IV	Patient's understanding and perceptions about lifestyle modification recommendations	38

List of Figures

Figu	re number Title	Page
1	Prevalence rates of non-adherence to diet and exercise recommendations	32
2	Bars Chart showing perceived reasons for not adhering to diet recommendations	35
3	Bars Chart showing perceived reasons for not adhering to exercise recommendation	s 36
4	Bars Chart demonstrating moral and emotional supports from spouse, family & friends	nds 37
5	Self-perceptions of diet and exercise recommendations	39

Chapter 1

Introduction and Background

1.1 Introduction

Diabetes Mellitus is defined as a group of heterogeneous disorders with the common elements of chronic hyperglycemia and glucose intolerance due to insulin deficiency, impaired effective of insulin action, or both (Davidson, 2005). It is a chronic debilitating disease that affects large numbers of people of all socio-economic class throughout the world. The individual and public health burden of the disease, already of vast proportions, continues to grow despite interesting advances in the past few years in virtually every field of diabetes research and in patient care including improved treatment, protection against complications, improved lifestyles and even, primary prevention of the disease (WHO, 1985).

Several studies have shown that therapeutic lifestyle modification recommendations (healthy dietary habits and exercise) are the cornerstones of type 2 diabetes prevention and management, because such interventions improve and maintain glycaemic control (Knowler *et al*, 2000, The DPPR Group, 2002, Harris *et al*, 2003, Wadden *et al*, 2004). For example, good dietary management (i.e. overweight patients should aimed for 5 to 10kg weight loss) and gentle aerobic exercise, such as brisk walking that causes sweating for 30 minutes, at least five times per week have been shown to improve and maintain glycaemic control (Dept. of Health, 1998). Adherence to lifestyle modification recommendations can lessen the disease burden and reduce the morbidity and mortality associated with type 2 diabetic complications. However, poor commitment to self management (including adherence to diet and exercise recommendations) of diabetes is more prevalent than previously thought and thus, intensifies the burden of this disease including worse clinical outcomes, frequent hospitalizations, increased health care needs and increased health care cost (Lin *et al*, 2006).

However, there is little information and data concerning adherence to lifestyle modification recommendations amongst the studied population in the Republic of Botswana.

This research aimed to examine non-adherence to lifestyle modification recommendations (healthy dietary habits and exercise) amongst type 2 diabetes mellitus patients attending Extension II clinic in Gaborone, Botswana.

1.2 Rationale for the study

This research was motivated as a result of an observation by the researcher that most patients with type 2 diabetes mellitus attending Extension II clinic in Gaborone, Botswana were non-adherent to lifestyle modification recommendations, poorly understood lifestyle measures namely; diet and exercise and therefore presented with poor glycaemic control.

1.3 Setting of the Study

Patients were recruited from Extension II clinic in Gaborone, a family practice primary health care centre. It is centrally located, easily accessible, and operates for 24 hours throughout the week. This centre provides comprehensive health care delivery to the people of Gaborone and its surrounding communities. The practice profile includes promotive, preventative, curative, and rehabilitative health care services.

1.4 Population Profile

Gaborone is the largest district and capital city of the Republic of Botswana. It is located in the southern part of the country with a population of 186,007, of which, 50.7% are female (CSO, 2001).

1.5 Health Care Systems and Facilities

There are three major sources of seeking for health care services in Gaborone, Botswana. These are public, private, and complementary and alternative medicine (CAM).

1.5.1 Public Health Care Facility

There are 23 public primary health care facilities (clinics) and only one public referral hospital (Princess Marina Hospital) in Gaborone, Botswana. Majority of the patients including people with type 2 diabetes usually seek health care services from the clinics due to free health care delivery system in the country.

1.5.2 Private Health Care Facility

There are several private clinics and only one private hospital located within the city. Some patients with type 2 diabetes sometimes seek diabetic care from private health care facilities, especially on weekends, public holidays, emergency situations, and/or as a matter of preference.

Health care services received are usually financed through a third party (via medical aid insurance) and/or out-of- pocket systems {self financing} (Webster, 2005).

1.5.3 Complementary & Alternative Medicine (CAM)

CAM can be defined as different form of indigenous or traditional healing practices in a society, and dependent on geographical variations, socio-cultural and historical background, economical and environmental factors. Gabe, Bury & Elston (2004) described this concept as medical pluralism i.e. the existence in society of differing medical traditions, grounded in different principles or based on different world views. It is commonly referred to as traditional or indigenous medicine, non-orthodox, non-allopathic or non-conventional medicine in the folk sector (Mash, 2005) and can either complement (i.e. as an adjuvant) or substitute (i.e. as a replacement) convectional biomedicine. This concept includes traditional healers, herbalists, spiritualists, religious groups, acupuncture, homeopathy, osteopathy, and e.t.c.

Some of the patients do acknowledge seeking health care services from CAM practitioners leading to combination of both approaches. The rise and increased popularity of complementary and alternative health care services in the Republic of Botswana may be due to any one or combination of the following factors- failure of biomedical model to meet health needs of the people, loss of trust in biomedicine and emerging uncertainty about orthodox medicine, frustration with conventional biomedicine, increasing population growth and individual's preference.

Chapter 2

Literature Review

2.1 Search Strategy

Most of the materials reviewed were accessed from the internet, resource centre from the Department of Family Medicine and Primary Health Care at the University of Limpopo, Journal articles, and Text-books. Frequently used web-pages include Journal of Diabetes Care, Annals of Internal Medicine, Annals of Family Medicine, and British Medical Council Family Practice.

Keywords used: Non-adherence, lifestyle modification recommendations, diet, exercise or physical activity and type 2 diabetes mellitus patients.

2.2 Introduction

Diabetes Mellitus is rapidly emerging as a major public health concern across the globe and increasingly been diagnosed in the developing countries including Botswana. It is a multifaceted disease and thus, poses a tremendous economic burden on individuals, families, health care providers and communities (Dept. of Health, 1998). For example, individuals diagnosed with diabetes have an increased two to four fold risk of stroke and heart disease compared to the general population, and increased incidence of retinopathy, peripheral nerve damage and renal problems (Farmer et al, 2005). Diabetes is one of the most common non-communicable diseases globally and a life-long, costly condition associated with significant morbidity and mortality (Norris et al, 2002). It is the fourth or fifth leading cause of death in most developed countries and there is substantial evidence that it is epidemic in many developing countries, and newly industrialized nations (Farmer et al, 2005 & IDF Diabetes Atlas, 2006) and Botswana is not be an exception. Worldwide, the disease accounts for 3.8 million deaths per year irrespective of age, sex and social status, a number similar in magnitude to the mortality caused by HIV/AIDS (WHO, 2007, HST, 2007). These are preventable deaths, especially in economically viable individuals between aged 35 to 65 years (Roglic et al, 2005, WHO, 2007). Regrettably, evidence shows that, in every 10 minutes, someone would die from complication(s) related to diabetes (Azevedo & Alla, 2008).

A recent study has demonstrated a dramatic increased in the number of people with diabetes, especially type 2, during the last decade (Farmer *et al*, 2005), majorly due to sedentary lifestyles, urbanization and globalization. Poor glycaemic control, long term complications of diabetes and its costly hospitalizations are often precipitated by patients' failure to adhere to the total diabetic care, especially therapeutic lifestyle changes (Rowley, 1999). This study focused on non-

adherence to lifestyle modification recommendations (diet and exercise) amongst type 2 diabetes mellitus patients attending Extension II clinic in Gaborone, Botswana.

2.3 Global Picture of Diabetes Mellitus

About 194 million adults worldwide or 5.1% in the age group 20-79 years was estimated to have diabetes in 2003 (IDF Diabetes Atlas, 2006). This number is estimated to increase to some 333 million or 6.3% of the adult populations by 2025 (Zimmet *et al*, 2001). The largest proportional and absolute increase will occur in developing countries, where the prevalence will rise from 4.2% to 5.6% (IDF Diabetes Atlas, 2006) and Republic of Botswana may not be an exception. By 2025, the adult diabetic population is expected to double in India to about 72 million and in China to 46 million. At the same time, diabetes prevalence is expected to increase to 2.8% of the adult population in Africa and 7.2 % in South and Central America (IDF Diabetes Atlas 2006 & Heine *et al*, 2006). The numbers of people with diabetes in the European region and Western Pacific region are 48 million and 43 million respectively, these regions coincidentally have the highest number of people with diabetes (IDF Diabetes Atlas, 2006). However, the prevalence rate of the Western Pacific region at 3.1% is significantly lower than 7.9% and 7.8% in the North American region and European region respectively (IDF Diabetes Atlas, 2006).

The prevalence of known diabetes in the United Kingdom is around 2-3% and many more cases of type 2 diabetes remain undetected (Davidson, 2005). It is a chronic disease that affects about 8% of adults in the United States (The DPPR Group, 2002), and about 11 million adults in the United States in 2002 were diagnosed with this chronic disease (Boyle *et al*, 2001). This figure is expected to reach 29 million adults in the United States by year 2050, an increase of 165% (Boyle *et al*, 2001). More than two million Canadians are estimated to have diabetes; most cases are classified as type 2 diabetes and economic burden of diabetes and its related complications is estimated at between \$4 and \$5 billion United States dollars per year in Canada (Dawson *et al*, 2002). The estimated incidence of type 2 diabetes in Belgium is 231 new cases per 100,000 inhabitants per year (Wens *et al*, 2005). The prevalence of diagnosed diabetes in the New Zealand is 3-4%, which accounts for 115,000 people with the disease and this figure is expected to rise to over 160,000 by 2021 (MOH, 2002). Still in New Zealand, about two-thirds of the estimated increase in the number of people with diabetes is likely to be due to ageing population, longer life expectancy, and population growth in high risk ethnic groups, while the remaining one-third is likely to be due to the increasing prevalence of obesity (MOH, 2002).

2.4 Diabetes in Sub-Saharan Africa

In Sub-Sahara Africa, diabetes is considered as a public health concern epidemiologically and economically. Approximately 7.1 million African were estimated to have diabetes in 2000 and this number is expected to rise to 18.6 million by 2030 (Wild *et al*, 2004); and evidence suggest that the disease will affect mostly working age groups (WHO, 2007). Despite this alarming

trend, awareness regarding the significance of diabetes in Africa is poor, especially amongst public and primary health-care practitioners (WHO, 2004). This chronic disease is far more prevalent among Indian descent of African, especially South Africa and Tanzania (Rheeder, 2006, Gning *et al*, 2007). The rate of diabetes mellitus is high among African Americans (12-15%), closely followed by Caribbeans of African descent (10-13%) and low among African origin populations (1-6%) (Azevedo & Alla, 2008). In the African diabetes, majority of cases are type 2 diabetes (70-90%), followed by type 1 diabetes (5-20%) and atypical presentation accounts for 5-15% (Sobngwi *et al*, 2001, Osei *et al*, 2003). There are limited data on type 1 diabetes among African, but is becoming increasingly more prevalent. However, in type 1 diabetes, available evidence suggest that in African populations the frequency is low and that age of onset occurs later than in the developed world (Motala *et al*, 2003).

In Sub-Saharan Africa, diabetes prevalence appears to be higher in urban, migrant and African-origin populations living abroad when compared to rural populations (Motala *et al*, 2003). It is more common among the wealthy and powerful individuals in Africa (Azevedo & Alla, 2008). For example, in the rural Sub-Saharan Africa, diabetes prevalence was estimated between 0.0 to 2.2%, while in the urban Sub-Saharan Africa, the prevalence ranged between 2.2 to 6.7% (Sobngwi *et al*, 2001). The reasons for differential prevalence may include physical inactivity, unhealthy eating habits (i.e. eating diets rich in saturated fat and refined sugar), increased prevalence of obesity and globalization common with urban populations (Azevedo & Alla, 2008).

The natural pattern of diabetes in African sub-continent depends on interplay of ethnicity/genetic predisposition, socio-economic status, environmental factors, sedentary lifestyle, obesity and residence (Azevedo & Alla, 2008). Preventable and modifiable risk factors associated with the development of African diabetes, especially type 2; include rapid cultural changes, increasing urbanisation and westernisation, over-reliance on imported dietary practices (such as fast and processed food) and behavioural patterns, and physical inactivity. While non-preventable and non-modifiable risk factors are an aging population and genetic influence (Sobngwi, 2007, Azevedo & Alla, 2008).

In Africa, it is crucial to understand that the severity of the disease is usually influenced by many factors. For example, the average number of visits for patient care in the diabetic population is low and usually occurs only when complications is imminent (Otieno *et al*, 2003, Gning *et al*, 2007). Similarly, a reviewed of literature suggest that some patients with diabetes do source for care from the complementary and alternative practitioners such as traditional healers that rarely refer patients to orthodox practitioners, except when complications has occurred (Azevedo & Alla, 2008). Another important factor impacting on diabetic course in Africa is poor access to health care i.e. differential access to health care due to various reasons such as transportation difficulties, lack of trained health care providers, limited resources, inadequate health facilities and e.t.c. For example, in Mozambique, Mali, and Zambia, only 15% of individuals with diabetes have access to care; 35% of the diabetic populations have difficult accessing care; and

50% have not been diagnosed (Azevedo & Alla, 2008). This finding suggests that, in Sub-Sahara Africa, there is an urgent need to intensify efforts to ensure follow-up of patients, whenever treatment has commenced in order to reduce and/or prevent the high morbidity and mortality rates from this chronic disease (Azevedo & Alla, 2008).

The potential severity of increasing prevalence rate of diabetes in African continent may be translated into severe economic burden, high morbidity and mortality rates that will surpass the ravages of HIV and AIDS in the near future (Azevedo & Alla, 2008). However, the most common causes of death in the African diabetic population are infection and acute metabolic complications in comparison to Western world where renal and cardiovascular complications are known to be the prevalent causes (Azevedo & Alla, 2008). In Africa, HIV/AIDS, malaria and tuberculosis are the commonest infectious diseases causing death among individual diagnosed with diabetes.

In Sub-Sahara Africa, most people diagnosed with diabetes extremely find it difficult to achieve and maintain the desired gylcaemic level of control (HbA1c < 7%). Chronic shortages of drugs (including insulin) and their high cost are the major factors for the poor gylcaemic control (Otieno *et al*, 2003, Skyler, 2004). This means that the economic capabilities of the health care system in most Africa countries may not be sufficient enough to withstand the burden of this chronic disease, considering the fact that the continent's resources is already overwhelmed by HIV/AIDS, malaria and tuberculosis. Hence, a need to put in place effective and sustainable strategies to promote diabetes awareness and public health policies that empowers individuals to diabetes self-management in order to improve the quality of life, reduce morbidity and premature mortality caused by the disease (Kaushik, 2004, Unwin & Marlin, 2005). The resulting strategic planning should involve policy makers, communities and individuals.

The prevalence of diabetes varies from country to country in Sub-Sahara Africa. In Kenya, the official statistics shows a prevalence of 3.5%, but the authority believes the rate may be up to 10% of the population (Azevedo & Alla, 2008). In Tanzania, estimated number of people with diabetes was 201,000 in 2000 and this number is expected to increase to 605,000 by 2030, while in Uganda, the estimated number was 98,000 in 2000 and it is expected to rise to 328,000 by 2030 (IDF, 2001). In West Africa, estimated numbers of people with diabetes in Nigeria, Ghana and Cote d'Ivoire were about 1.7 million, 302,000 and 264,000 in 2000 respectively and these figures are expected to increase to 4.8 million, 857,000 and 636,000 in 2030 respectively (IDF, 2001). In North Africa, estimated number of people living with diabetes in Algeria was 426,000 in 2000 and this number is expected to rise to about 1.2 million in 2030 (IDF, 2001). In the Republic of South Africa, diabetes prevalence was estimated to range between 4.8-8.0% (Sobngwi et al, 2001). Recent estimate shows that approximately 3 million South African have diabetes and an estimated 3 million individuals living with the disease remain undiagnosed (IDF, 2007). In Botswana and Zimbabwe, estimated numbers of individuals with diabetes were 25,000 and 108,000 in 2000 respectively and these numbers are estimated to rise to 45,000 and 256,000 in 2030 respectively (IDF, 2001).

In summary, Sub-Saharan Africa is witnessing major rapid epidemiological and economical transition of world history with the growing burden of diabetes, especially type 2, that is already overwhelming health care system. However, this increasing health care burden is impacting on the meager resources in the continent. Therefore, primary prevention based on strict adherence to lifestyle modification recommendations must be the cornerstone of healthy policies to fight diabetes in Africa. And for primary prevention to be successful, obstacles such as low awareness, diabetes not been prioritised on national health-care agendas, inadequate funding and resources for national diabetes programmes, and shortage of drugs (including insulin), manpower and health facilities in rural areas must be adequately addressed.

2.5 Diagnosis and Aetiological Classification of Diabetes Mellitus

Diabetes Mellitus is a clinical syndrome characterized by hyperglycemia due to absolute or relative deficiency of insulin (Davidson, 2005). The disease is defined by fasting plasma glucose of 7.0mmol/l or above, or random plasma glucose of 11.1mmol/l or above, or an abnormal oral glucose tolerance test of 11.1mmol/l or above (Davidson, 2005). This chronic disease can be classified aetiologically into type 1 diabetes, type 2 diabetes (familiar type), gestational diabetes, and other specific types (Davidson, 2005 & McWhinney, 1997). Type 1 diabetes is usually immune-mediated or idiopathic in origin (Davidson, 2005); but in type 2 diabetes, insulin resistance is the main defect which is usually followed by β cell exhaustion, and often associated with obesity (McWhinney, 1997). In gestational diabetes (GDM), occurrence of the disease is first noted during pregnancy, which remits after the pregnancy, but is associated with a risk of type 2 in later life (McWhinney, 1997). Repeated pregnancy may increase the likelihood of developing diabetes, especially type 2, particularly in obese women; 80% of women with gestational diabetes would ultimately develop clinical diabetes requiring life-long treatment (Davidson, 2005 & McWhinney, 1997).

Davidson (2005) defined other specific types of diabetes as those secondary to other causes such as genetic defects of β cell function, genetic defects of insulin action, pancreatic disease (e.g. pancreatitis, neoplastic disease, pancreatectomy, cystic fibrosis, and e.t.c.), excess endogenous production of hormonal antagonists to insulin (e.g. growth hormone, glucagon glucocorticoids, catecholamines, and thyroid hormones), drug-induced (e.g. corticosteroid, thiazide diuretics, and phenytoin), viral infections (e.g. congenital rubella, mumps, Coxackie virus B), and associated genetic syndromes (e.g. Down's syndrome, Klinelfelter's syndrome, Turner syndrome and e.t.c.).

Finally, impaired fasting glucose or impaired glucose tolerance (IGT) is a clinical condition with impaired glucose metabolism without clinical diabetes. Impaired fasting glucose (IFG) is said to develop when the fasting plasma glucose is between 6.1 and 6.9mmol/l (Davidson, 2005), while impaired glucose tolerance (IGT) is defined as abnormal intermediate readings of random plasma glucose and 2 hours after glucose load between 7.0-11.0mmol/l and 7.8-11.0mmol/l respectively (Davidson, 2005). Both conditions indicate the need for further evaluation with oral glucose

tolerance test (OGTT) in order to make a definitive diagnosis. Most people with IGT would progress to frank diabetes with time (Davidson, 2005). That is, a quarter of individuals with IGT would develop symptomatic diabetes after five years, and two-third after ten years (McWhinney, 1997). Both IFG and IGT have an increased risk of developing vascular disease; and it may be necessary to keep such individuals under scheduled and strict follow-up appointments in a family practice.

2.6 Over-view of Type 1 & 2 Diabetes Mellitus

The prevalence of type 1 and 2 Diabetes Mellitus varies considerably, around the world, and is related to differences in underlying behavioural, genetic, environmental and social risk factors, such as unhealthy dietary habits, increasing level of obesity and less physical activity (IDF Diabetes Atlas, 2006). The disease is frequently not diagnosed until complications appear, and appropriately one-third of all people with diabetes may remain undiagnosed (Wens *et al*, 2005) especially in developing countries, where resources are limited. As a result, the magnitude of the emerging epidemic of diabetes may be underestimated (Warren, 2004). A pronounced rise in the proportion of people with diabetes occurs in migrant populations to industrialized countries, for examples, Asian and Afro-Caribbean immigrants to the United Kingdom (Davidson, 2005). In the United States, the disease is more frequent among American Indians, Asians, Hispanics, African Americans and Pacific Islanders due to diversity in lifestyle patterns (The DPPR Group, 2002). In Europe and North America, the ratio of types 2:1 is about 7:3 (Davidson, 2005). However, in northern Europe, the prevalence of type 1 in children has doubled in the last 20 years, especially in children less than 5 years of age (Davidson, 2005).

Diabetes is one of the most common chronic childhood diseases in the United States; more than 13,000 youths are diagnosed with diabetes every year and type 2, accounts for 8 – 45% of new childhood diabetes due to sedentary lifestyles (Peterson *et al*, 2007). In the United States, the prevalence of childhood type 2 diabetes has increased by 33% in the past 15 years, mirroring the increasing rates of overweight in this population and insulin resistant (Ogden *et al*, 2007). These two factors i.e. overweight and insulin resistant can substantially increase the risk of unstable atherosclerosis leading to coronary heart disease and stroke (Molnar, 2004). However, optimal management of overweight in at risk individual will significantly delay progression of the disease. This can be achieved by promoting healthy eating habits and increasing physical activity (Peterson *et al*, 2007).

Diabetes is world-wide in distribution and the incidence of type 1 and 2 diabetes is rising to epidemic proportions in both developed and developing countries. This global pandemic mainly involves type 2, and is associated with several contributory factors such as increased longevity, sedentary lifestyles, unhealthy dietary habits, obesity and increasing urbanization, and globalization. Type 2 diabetes is characterized by insulin resistance and relative insulin deficiency, either of which may be present at the time of diagnosis. It constitutes about 85% to

95% of all diabetes in developed countries and may account for even a higher percentage in developing countries (IDF Diabetes Atlas, 2006). But early detection (based on at risk routine screening) coupled with comprehensive and effective management (including lifestyle changes) may be associated with a normal lifespan, delay in the development of complications and improved quality of life in people with diagnosed type 2 diabetes (Lin *et al*, 2006).

The incidence of type 2 diabetes is rapidly increasing worldwide and perhaps, reaching epidemic proportions due to increasing occurrence of obesity and sedentary lifestyle. Increased incidence of the disease, especially among youth, portends a serious increase in early mortality, health care costs, and lost of productivity (Burnet *et al*, 2005). Modifiable risk factors associated with the onset of type 2 diabetes include obesity (especially central adiposity), alcohol intake, cigarette smoking, physical inactivity, increasing intake of fatty meals i.e. saturated fat, low intake of dietary fiber and whole-grain foods (Bazzano *et al*, 2005). The disease is no longer confined to a particular age group; middle aged and elderly people, but now commencing at an earlier age in many populations across the globe (Uusitupa, 2002). In some ethnic groups such as Hispanic and Afro-Americans, is now being observed in children and adolescents as a result of the recent trends in unhealthy lifestyles and dietary habits.

The disease constitutes a major health burden in both developed and developing countries, and with rapid growing of obesity, it is becoming one of the largest challenges to health care systems (Uusitupa, 2002). It is now a common and serious global public health concern; which for most nations, has evolved in association with rapid socio-cultural changes, ageing populations, less physical activity, unhealthy eating habits, increasing urbanization and westernisation detrimental to human health (IDF Diabetes Atlas, 2006). Type 2 diabetes is recognized as a strong risk factor for cardiovascular disease and for associated complications that result in substantial morbidity and mortality (Gertein & Melter, 1999).

Type 2 diabetes commonly occurs in individuals who are obese or overweight with body mass index equal or greater than 25 kg/m^2 and insulin resistant, but these two factors alone are not sufficed to cause diabetes unless accompanied by impaired beta cell function. It is usually preceded by a long period of impaired glucose tolerance (IGT) or milder disturbance in glucose metabolism and persistent excess energy consumption (Uusitupa, 2002). The natural cause of obesity or overweight has been associated with increased consumption of beverages with high sugar content, excessive eating of unhealthy diets and reduced physical activity (Ludwig *et al*, 2001). The occurrence of type 2 diabetes depends on multiple factor, with interaction of genetic and environmental factors playing a significant role. The environmental factors include unhealthy lifestyle such as over eating and less physical activity, malnutrition in utero, ageing and gestational diabetes. It should be noted that lifestyle and environmental factors does influence the onset and progression of type 2 diabetes, and that the underlying β -cell abnormality is genetically programmed (Warren, 2004). As a result, a significant proportion of individuals

with type 2 diabetes will eventually require insulin to control their blood glucose levels in order to achieve and maintain ideal glycaemic control (Warren, 2004). However, slower rate of disease progression and good quality of life for people with type 2 diabetes may be achieved using a combination of lifestyle modification recommendations and oral hypoglycemic drugs.

2.7 Risk Factors Associated With Type 2 Diabetes Mellitus

Inappropriate weight gain leading to obesity is one of the major risk factors for type 2 diabetes and risks of the disease increase steadily with increasing body mass index – BMI (IDF Diabetes Atlas, 2006). However, in Western countries, around 90% of type 2 diabetes mellitus cases are attributable to overweight (IDF Diabetes Atlas, 2006). Evidence suggest that obesity (especially central obesity), physical inactivity, high fat diet, diet rich in saturated fatty acids, low intake of dietary fibers, low glycaemic carbohydrates, and whole grain cereals increases the risk of type 2 diabetes (Uusitupa, 2002, Bazzano *et al*, 2005). Similarly, individuals with a diet at the highest level of the glycaemic index or glycaemic load are more likely to develop type 2 diabetes mellitus than those at the lowest levels (Bazzano *et al*, 2005). These factors are potentially reversible with strict adherence to lifestyle modification recommendations.

However, modest weight reduction through dietary improvement and gentle aerobic exercise can substantially reduce the development of type 2 diabetes, if not prevent it completely; among at risk populations i.e. those with impaired glucose tolerance and impaired fasting glucose, and that weight loss (for overweight people) can substantially reverse type 2 diabetic state (IDF Diabetes Atlas, 2006). This intervention also prevents and/or delays the development of associated complications amongst individuals with diagnosed type 2 diabetes. The DPPR Group (2002) has convincingly demonstrated that modest weight loss and increased physical activity (for example, brisk walking 3 hours per week) would significantly reduce the proportion of individuals with impaired glucose tolerance developing type 2 diabetes.

Obesity probably acts as a diabetogenic factor by increasing resistance of the action of insulin and individual is genetically predisposed to develop type 2 diabetes mellitus. The natural history for people at risk of developing type 2 diabetes is weight gain and deterioration in glucose tolerance (Swinburn *et al*, 2001), hence healthy dietary habits and increase physical activity does play a tremendous role in the prevention and management of type 2 diabetes. Engaging in regular physical activity is known to improve glucose, blood pressure, and lipid abnormalities that serve as the principal risk factors for the associated microvascular and macrovascular complications of diabetes (US Dept. of Health & Human Services, 1996 & Boule *et al*, 2001). Encouraging more physical activity among patients with type 2 diabetes is a known standard of practice and should be part of routine patient education programs in all primary care settings across the globe, but requires an understanding of individual exercise preference(s) and potential barriers.

2.8 Complications of Diabetes Mellitus

Persistent elevations of blood glucose may lead to long term complications that include macrovascular damage (e.g. ischemic heart disease, stroke, and amputation), and microvascular damage. Microvascular damage may lead to diabetic nephropathy, diabetic retinopathy, diabetic neuropathy and sexual dysfunction. However, short-term complications include hypoglycemia, hyperglycemia, super-added infection and diabetic ketoacidosis. The rate of developing heart disease and stroke among diabetic patients is 2 to 4 times higher that of general population (nondiabetic groups), possibly due to the unstable atherosclerosis (National Diabetes Information, 1999). Cardiovascular disease is the leading cause of death among patients with diabetes, and both diseases share similar risk factors namely; unhealthy dietary habits, sedentary lifestyle and smoking (Welschen et al, 2007). Although, a few diabetic patients die from acute metabolic complications (ketoacidosis and hypoglycemia), the major problem is the excess mortality and serious morbidity suffered as a result of the long-term complications of diabetes, the factors associated with these are duration of diabetes, early age at onset of diabetes, high glycosylated hemoglobin (HbA1c), raised blood pressure, proteinuria, microalbuminuria, obesity and hyperlipidaemia. However, the risk of complications (macrovascular and microvascular) may be more frequent and greater with type 2 diabetes mellitus than type 1 diabetes mellitus (Nazimek-Siewniak et al, 2002).

The findings by U.K. Prospective Diabetes Study (UKPDS) Group (1998) suggest that each 1% reduction in HbA1c over 10 years is associated with reductions in risk of 21% for any end point related to diabetes, 21% for deaths related to diabetes, 14% for myocardial infarctions, and 37% for microvascular complications. However, people diagnosed with diabetes are at increased risk of significant reduction in life expectancy and quality of life (Bazzano et al, 2005). The overall cost of diabetes to the individual, family, community and health care system is over-whelming and enormous. For example, the current cost of diabetes in the United Kingdom is estimated at 30% reduction in life expectancy, most common cause of blindness in age group 20-65 years, 600 patients per annum reach end-stage renal failure, lower limb amputation rate increased 25fold, use of hospital beds increased six-fold and accounts for 4-5% of total Natural Health Service budget (UKPDS Group 1998, Davidson, 2005). This chronic disease was found to be the sixth leading cause of death in the United States, accounting for 71,372 deaths in 2001 (Anderson & Smith, 2003), but fourth leading cause of death globally (HST, 2007). Still in the United States, Caro et al. (2002) estimated the average cost of diabetic complications over 30 years at \$47,240 per patient. It is the most common cause of blindness among working-age adults, the most common cause of non-traumatic amputations and end-stage renal disease in the United States (CDC & Prevention, 2004).

2.9 Management of Diabetes Mellitus

The overall aim of diabetes management is to achieve as near normal metabolic control as is practicable through a broad based intervention with lifestyle modifications as the building block. However, the goals of diabetes management are: relief of symptoms, achievement of prescribed normal physical activity and healthy diets, achievement and/or maintenance of normal body weight (between 18 – 25 kg/m²), little or no glycosuria, fasting plasma glucose of 80 – 110 mg/dl (Dudley, 1980, Davidson, 2005), as well as the achievement of normal HgA1c levels < 7% (Norris *et al.*, 2002, Peterson, 2002, Davidson, 2005, Heine *et al.*, 2006, SEMDSA, 2009). The nearer the body weight approaches the ideal level and the closer the blood glucose level is maintained near normal, the better the total metabolic profile and the lower the incidence of complications from diabetic. Proper management of diabetic condition would allow the patient to live a completely normal life, to remain symptoms free with good health, to achieve a near normal metabolic state and perhaps, to escape most of the long-term complications of diabetes. Successful management of diabetes requires proper evaluation and understanding of the patient's lifestyles (including perceived barriers), perceptions, beliefs, and family and social networks (Bradley & Gamsu, 1994).

People with diagnosed type 2 diabetes must be managed through intensive medical therapy with a tailored, stepwise approach of lifestyle modification recommendations including diet and exercise programs, oral hypoglycemic agent and insulin. The physician should not delay to change from one treatment modality to the next level, if a strategy does not achieve the desired glycaemic control within an acceptable time frame, usually within 3-6 months of commencing a modality (Warren, 2004). The family physician should be aware that approximately 50% of new cases of diabetes can be controlled adequately by lifestyle changes (diet and exercise); 20-30% will need oral hypoglycemic drugs (as an additional measure); and 20-30% will require insulin (Davidson, 2005). Similarly, about 80% of cases are preventable by adopting a healthy diet and increasing physical activity (IDF, 2007). However, management of type 2 diabetes should begin with an individualized regimen of diet, exercise, and medical counseling targeted to reduce body weight by 5-10%. The primary goal of this approach is to achieve and maintain ideal glycaemic control, while secondary benefits include weight loss and reduction in risk factors for common co-morbidities of type 2 diabetes such as hypertension and cardiovascular disease (Warren, 2004). Prescribed lifestyle changes are the cornerstones in the management of type 2 diabetes and therefore, helps in preventing and/or delaying diabetic complications by improving and maintaining glycaemic control (HbAIC < 7%). Hence, strategies for lifestyle changes for people with type 2 diabetes must be incorporated in primary care settings and should include – individual and group interventions, inter-disciplinary approach (i.e. joint care between the family physician, and referral to others such as dieticians, diabetes nurses, diabetes educators, behavior consultants, and exercise experts), and community resources.

However, effective diabetes management including adherence to the prescribed lifestyle changes seeks to prevent and/or delay complications of diabetes, but not usually restore normoglycaemia

or eliminate all the adverse consequences (The DPPR Group, 2002). The single most crucial factor in lowering microvascular complications of diabetes is to promote strict glycaemic control, HbA1c less than 7%. Glycosylated haemoglobin (HbA1c) level of 7% or greater should serve as a call to action to initiate or change therapy with the aim of achieving a level as close to the non-diabetic range as possible (Nathan *et al*, 2006). This suggests that an increasing number of people with type 2 diabetes will require intensive therapy in the future that includes appropriate diet and increasing physical activity (Warren, 2004).

At every patient's encounter, family physician must ensure an appropriate lifestyle choice towards diabetic management in order to achieve and maintain glycaemic control. Appropriate program of diet and exercise tailored to the needs of the individual patients would enhance adherence to therapeutic lifestyle modification recommendations. Although, family physician have an important role in promoting healthy diet and exercise to people with type 2 diabetes, but have identified this role as being challenging (Larme & Pugh, 1998, Wylie *et al*, 2002). The challenges include increasing non-adherence to lifestyle modification recommendations, limited evidence to support lifestyle interventions delivered and lack of tools to evaluate impacts of lifestyle interventions delivered at the primary care settings (Larme & Pugh, 1998, Harris *et al*, 2003).

2.10 Lifestyle modification recommendations (diet and exercise) and glycaemic control

Lifestyle modification in the context of diabetes management involves the giving up of certain pleasures or unhealthy lifestyle behaviors in order to prevent and/or delay diabetic complications and to achieve desirable glycaemic control at HbA1C < 7% (Peterson, 2002). This intervention encompasses weight control for normal weight individuals or weight loss for overweight and obese patients, exercise programs (i.e. increase aerobic physical activity in form of cycling, brisk walking, jogging and any other sporting activities), stop smoking or avoid starting at all, moderate consumption of alcohol, and healthy diet. Healthy dietary habits include eating more fruit and vegetables; nuts and whole grains, moving from saturated animal based fats to unsaturated vegetable-oil based fats and low fatty and sugary foods (WHO, 2003). People with type 2 diabetes should limit consumption of snacks that have high levels of fat, sugar, or salt (for example, potato chips, fast food, soda, desserts) and having their meal plan developed by a registered dietician, diabetes educator, diabetes nurse, or physician that must include low-fat and high-fiber foods, small portion sizes, and fewer beverages with high sugar content (for example, soda, juice). Patient and their family must be taught how carbohydrates (for example, breads, paste, rice and e.t.c.) can affect blood sugar levels using inter-disciplinary approach. Moderate physical activity should be in form of gentle aerobic exercise such as 30 minutes brisk walking for at least five times per week, but patients should be encouraged to exercise every day, if possible and convenient. Patients should aim to accumulate at least 150 minutes (2.5 hours) per week and physical activity declines with age (Davidson, 2005).

The importance of lifestyle modification recommendations such as regular moderate aerobic exercise, eating healthy diets and moderate alcohol consumption should not be under-estimated in improving and maintaining glycaemic control, but many people, particularly the middle aged and elderly, extremely find them difficult to initiate and sustain (Davidson, 2005). It is also important to encourage patient to stop smoking or not initiating smoking at all. This is substantiated by the study undertaken by Sargeant *et al.* (2001) that found an independent association between cigarette smoking and glycosylated hemoglobin-HbA1c concentration in men and women i.e. individuals who smoked had a higher risk of developing diabetes than those who had never smoked. Evidence also suggests that stopping smoking reduces the risk of microvascular and macrovascular complications in people diagnosed with type 2 diabetes mellitus (Tuomilehto, 2005). Lifestyle modification recommendations in conjunction with anti-diabetic medications have been proven to be effective therapeutic intervention in the prevention and management of diabetes and its associated complications. It thus appears that therapeutic lifestyle modification recommendations are add-on interventions to improve and maintain good glycaemic control in order to minimize diabetic complications.

The cornerstone of type 2 diabetes mellitus treatment regimen, and the first step toward disease management, is a tailored program of diet and physical activity, and this approach may be monitored through regular measurements of weight and blood sugar (ADA, 2003). Strict adherence to therapeutic diet and exercise can improve insulin sensitivity and glycaemic control and thereby, decrease and/or postpone the need for oral medications and/or insulin (Nelson et al, 2002). Therefore, regular and moderate- intensity aerobic physical activity for 30 minutes at least 5 times per week or accumulation of 150 minutes per week is recommended for individuals diagnosed with type 2 diabetes (The DPPR Group, 2002). For example, moderate-intensity exercise corresponds to physical activity that elicits 60-70% of maximal heart rate and 45-60% of maximal oxygen uptake (Miller et al, 1993). This is corresponds to a heart rate of 110 to 125 beats/min irrespective of gender, and can be achieved by cycling on a stationary bicycle at 75 to 100 W or walking briskly, at 5 to 6 km/h (Cleroux et al, 1999). Vessby et al. (2001) demonstrated that monounsaturated or polyunsaturated fats appears to have more beneficial effects on insulin action, whereas saturated fats and diets with high total fat content appear to decrease insulin sensitivity. Similarly, an inverse association exists between dietary fiber intake (increase intake of vegetable fat, fruits and non-starch polysaccharides), whole-grain consumption and risk of developing type 2 diabetes mellitus (Bazzano et al, 2005). This finding means that increasing dietary fiber and whole-grain intake may decrease the development of type 2 diabetes mellitus in the general population.

The remarkable effect of weight loss via concerted efforts of adhering to healthy diets and increased physical activity has been demonstrated in the Diabetes Prevention Program Research in the United States of America (U.S.A.) to benefit particularly the over 60s, in whom nearly

three-quarters of new cases of diabetes were prevented (The DPPR Group, 2002, IDF Diabetes Atlas, 2006). This finding provides hope to those with impaired glucose tolerance (IGT) and people diagnosed with type 2 diabetes. The Diabetes Prevention Program suggests that dietary and physical activity changes to produce a 5-7% weight loss can successfully reduce the incidence of type 2 diabetes, improves and maintains glycaemic control in people diagnosed with type 2 diabetes. Reduction in fat and caloric intake accompanied by 30 minutes of brisk walking or any other forms of exercise per day has been demonstrated to lower the incidence of type 2 diabetes by 58% among studied age group (25-85 years). However, great success has been achieved among people over 60 years, reducing the development of diabetes in that high-risk age group by 71% (The DPPR Group, 2002, IDF Diabetes Atlas, 2006).

In a Swedish uncontrolled study, it was reported that moderate weight loss through increase in physical activity, and diet constituting low simple carbohydrate, more complex carbohydrate, low saturated fats and high fibers reduced the incidence of type 2 diabetes by 63% in middleaged men with impaired glucose tolerance – IGT (Burnet et al, 2005 & Uusitupa, 2002). In the Finnish Diabetes Prevention Study, Tuomilehto et al. (2001) reported 47% (P<0.001); 33% (P<0.03); and 58% (P<0.001); overall reduction risk of type 2 diabetes over 4 years, following supervised aerobic exercise only, diet therapy only aimed to achieve weight loss of $\geq 5\%$, and both diet regimen and exercise respectively. The main goals of this study are – to achieve 30 minutes moderate intensity physical activity per day; and daily diet that constitutes < 30% kcal from fat, < 10% saturated fat and ≥ 15 g fiber/1000 kcal (Tuomilehto et al, 2001, Burnet et al, 2005). Therefore, health care providers must emphasize the key role of weight loss, increasing physical activity, and healthy diet in the prevention and management of type 2 diabetes in order to translate findings into clinical practice (Uusitupa, 2002). This finding is also substantiated by Bazzano et al. (2005) who demonstrated that weight loss alone may reverse the course of insulin resistance and normalize blood glucose concentrations in people with type 2 diabetes or at risk individuals. However, sustaining weight loss is an extremely difficult task to accomplish, but even modest weight loss may confer substantial clinical benefits for diabetes management.

In a prospective study undertaken by Manso $et\ al.\ (1992)$, it was demonstrated that low risk lifestyle behavior can slow onset of type 2 diabetes in both adult men and women. Findings from several large, long-term randomized controlled trials (RCTs) across the globe provide convincing evidence that changes made in dietary habits and physical activity levels are effective in delaying, and possibly, preventing progression from impaired glucose tolerance to frank type 2 diabetes. For examples, Pan $et\ al.\ (1997)$ in Da Qing study have demonstrated a 42% (P<0.005) reduction in progression of impaired glucose tolerance to diabetes over 6 years, based on intensive regimen of exercise and diet therapy (55-60% of caloric intake from carbohydrates and 10-15% from protein); and the Diabetes Prevention Program Trial (2002) in the United States, further substantiated that lifestyle changes for both men and women using a vigorous program of healthy diets (i.e. low fat diet to achieve loss of \geq 5%-7% of body weight) and exercise therapy

(i.e. 30 minutes per day, every day of brisk walking or other moderate intensity exercise expending ≥ 700 kcal per week) reduced overall incidence of type 2 diabetes by 58% (95% CI, 48%-66%, NNT=7 & P<0.001) during the 3 years of follow-up, as compared with metformin by 31% (95% CI, 17%-43%). This finding suggests that physical activity in form of brisk walking increases insulin sensitivity. The Diabetes Prevention Program Research was based on two major goals: to achieve a minimum of 150 minutes (2.5 hours) of moderate physical activity, similar in intensity to brisk walking and a minimum of 7% weight loss and maintenance per week. However, participants who wished to be more active (i.e. achieve more than minimum) were strongly encouraged to do so, provided no medical contraindications (The DPPR Group, 2002).

Weight loss through fat and caloric restrictions initially improves glycaemic control, but the amount of improvement is proportionately related to the magnitude of weight loss and duration of improvement (Harris et al, 2003). For example, in UKPDS (1990), the study suggest that programs that achieved close to a 7% decrease in body weight produced substantial changes in fasting blood sugar, approximately 11 mmol/liter at baseline to 8.3 mmol/liter following 3-6 months of weight loss. Similarly, in a meta-analysis conducted by Boule et al. (2001), it was concluded that the weighted mean difference in post-intervention HbAIc was clinically relevant, with respect to a significant decrease in the risk of diabetic complications, hence, supported moderate exercise interventions on their own (not solely as an avenue for weight loss) in the management of people diagnosed with type 2 diabetes. The intervention goal consisted of three work-outs per week with a mean of 53 (SD 17) minutes in duration, for 18 (SD 15) weeks, with moderate aerobic intensity usually consisting of brisk walking or cycling.). Harris et al. (2003) therefore concluded that patients diagnosed with type 2 diabetes should aim to accumulate at least 150 minutes of moderate-intensity aerobic exercise each week, spread out over at least 5 nonconsecutive days. If patients are willing, they should be encouraged to accumulate 4 hours or more of exercise weekly, and all patients with type 2 diabetes should receive individual advice on nutrition from a dietician.

Although, a strong body of evidence emphasizes the health benefits of lifestyle modification recommendations for people with type 2 diabetes, but far less is known about the effectiveness of primary care based strategies for achieving the dietary and physical activity changes necessary to acquire these benefits (Clark, 1997, Petrella & Lattanzio, 2002). Peterson *et al.* (2007) have shown that diet and exercise alone are effective for metabolic control in less than 10 percent of youths with type 2 diabetes mellitus. In addition, adherence to lifestyle changes have been shown to have substantial collateral benefits, including decreased blood pressure, improved blood lipid levels, better health-related quality of life (CDC & Prevention, 2004). Evidence also suggests that lifestyle changes reduce the risk of cardiovascular disease, improve psychological wellbeing and self esteem in individuals with type 2 diabetes (Gu *et al*, 1999, Fox *et al*, 1999).

Significant weight losses of $\geq 10\%$ are generally associated with greater improvements in glycosylated hemoglobin – HbA1c in people with type 2 diabetes (Wadden *et al*, 2006). This can be achieved with very low calorie diets (including high fiber) and ≥ 175 min/wk of moderately intense physical activity (Wadden *et al*, 2006). Higher levels of physical activity greatly improve the maintenance of lost weight in order to sustain good glycaemic control, maintains adequate blood pressure control, and lipid levels (Wadden *et al*, 2006). Increasing lifestyle activity like using stairs rather than elevators and walking rather than riding are as effective as programmed (aerobic) activity in inducing and maintaining weight loss and in improving cardiovascular risk factors in people with diagnosed type 2 diabetes (Wadden *et al*, 2006).

2.11 Non-adherence to Diet and Exercise Recommendations

Adherence implies to follow closely or without deviation mutually agreed collaborative approach to care including lifestyle modification recommendations in form of partnership between the patient and health care provider. Adherence to treatment is referred to as the characteristics of the behavior that defines the extent to which a patient follows a medical prescription including therapeutic lifestyle measures (Garay-Sevilla et al, 1995 & Mash, 2005). Adherence to therapeutic lifestyle modification recommendations reduces the risk of complications associated with type 2 diabetes. Non-adherence to lifestyle modification recommendations occurs when patient deviates partially or completely (i.e. below acceptable level of adherence) from the mutually agreed collaborative approach to behavior/lifestyle changes that are known to improve health status. For example, non-adherence to prescribed physical activity is defined as engaging in less than 75% of prescribed physical activity goals across a four week period (Wadden et al, 2006) i.e. achieving less than 150 minutes of physical activity per week or less than 30 minutes of physical activity spread over 5 or less days for four consecutive weeks. Non-adherence to therapeutic lifestyle measures can worsen the quality of life and add to the cost of medical care including accelerating the development of new complications, and worsen existing ones (Serour et al, 2007). Therefore, improving the adherence to the lifestyle intervention recommendations would increase its cost-effectiveness substantially and subsequently, improves glycaemic control and reduce diabetic complications (Tuomilehto, 2005).

Adherence to lifestyle modification recommendations may vary with age and could affect the effectiveness of diabetes prevention and management in older individuals (Crandall *et al*, 2006). But sustained lifestyle changes is exceptionally effective in preventing and managing diabetes in older individuals, this finding was largely explained by greater weight loss and increasing physical activity (Crandall *et al*, 2006) i.e. lifestyle modification seems to be more effective with increasing age. This means that a program of modest weight loss through moderate aerobic exercise and diet should be recommended for older individuals at high risk for type 2 diabetes and those diagnosed with the disease (Crandall *et al*, 2006). Harris *et al*. (1987) stated that adherence to a prescribed diet and exercise was associated with the benefit perceived in people

diagnosed with type 2 diabetes. Similarly, adherence is associated with open frank discussion about diabetes i.e. acceptance of the disease, supporting behavior-family and social supports, family's structures and functioning, and patient's knowledge on diabetes (Garay-Sevilla *et al*, 1995). In same study by Garay-Sevilla *et al* (1995), year since diagnosis of diabetes was found to be the main determinant of adherence to diet. This is because, after years of suffering the disease, attitudes of denial are reduced, and patients progressively accept treatment including dietary change.

Type 2 diabetes is a chronic disease for which lifestyle modification is crucial for disease management. The impact of the disease on a patient's lifestyle can be very dramatic, and adhering to lifestyle modification recommendations often requires substantial time and effort from the patient (Fitzgerald *et al*, 1995). Effectiveness of positive changes in eating habits and physical activity in the management of diabetes cannot be over emphasized. These changes greatly improve and maintain glycaemic control, thereby preventing and delaying diabetic complications. Evidence also suggests that moderate physical activity can reduce HbA1c by 0.6% among individuals with type 2 diabetes (Boule *et al*, 2002). The potentially most effective, but most difficult step is to change patients' lifestyles and to achieve a clinically meaningful and long lasting weight loss (Heine *et al*, 2006). Despite difficulty and disappointing long term results, people with type 2 diabetes should be persuaded to engage in modest exercise and reduce energy intake, especially as relatively modest targets have been proven to be clinically effective (Heine *et al*, 2006). It therefore means that achieving and sustaining a more favorable glycaemic control requires strict adherence to lifestyle changes on exercise and diet.

Patient adherence, especially to the rapeutic lifestyle measures and behavior modification recommendations, is notoriously difficult to achieve, but essential to the success of managing chronic diseases including type 2 diabetes mellitus (Cawood, 2006). The problem of poor adherence to lifestyle modification recommendations among patients with type 2 diabetes is very complex and multi-faceted in nature. Improving levels of healthy nutrition and physical activity is achievable, but often requires fairly intensive and continuous interventions specific to each lifestyle modification recommendation (Lin et al, 2006). Strict adherence to lifestyle changes and the extent to which recommendations are followed present difficult and complex challenges as patients can find lifestyle behaviors (for example, diet and physical activity) hard to change and maintain for long periods (Serour et al, 2007). Adhering to the apeutic lifestyle prescription is becoming a more complex issue, especially when psychological, emotional, social and family characteristics of living with chronic diseases come into play (Cawood, 2006). Similarly, adherence to lifestyle modification recommendations are hard for patients to initiate and even harder to maintain especially among middle age and elderly (Garay-Sevilla et al. 1995 & Cawood, 2006). Rapid socioeconomic development, urbanization, globalization, and an expanding number of fast food outlets, leading to unusual consumption and over dependence, may be contributing to factors influencing adherence to therapeutic lifestyle modification

recommendations amongst type 2 diabetes mellitus patients. Similarly, socio-cultural needs of patients, beliefs and patient's perceptions about their own health as well as economic factors, may hinder adherence to lifestyle modification recommendations.

Brief behavior change counseling strategies can be effectively incorporated into patient encounters and counseling messages must be individualized to the patient's readiness to change (Burnet *et al*, 2005). Behavioral counseling to enhance adherence to lifestyle changes can be guided by the Five A's model that involve assessing the patient's lifestyle risk factors and readiness to change; advising specific behavior change; agreeing on behavior change goals; assisting the patient in acquiring information, skills, and confidence required to progress toward goals; and arranging follow – up with the physician, dietician, nurse or behavior expert (Burnet *et al*, 2005). This Five A's model is based on the principle of motivational interviewing rooted in patient centered approach that elicits behavior change by helping patients address their ambivalence regarding recommended changes (Burnet *et al*, 2002). This motivational interviewing should emphasize rapport building, eliciting patient's belief and perception, barriers, and self-efficacy for change (ACC/AHA, 2002). For example, patient's readiness, knowledge and current diet and exercise can be assessed in a non-judgmental manner (Burnet *et al*, 2005).

2.12 Rates of Non-adherence to Diet and Exercise

Rates of non-adherent patients to therapeutic lifestyle modification recommendations have been reported to range from 40 to 50% and some experts estimate that non-adherence to lifestyle measures is even higher (Cawood, 2006). Similar study reports rates of non-adherence to diet plan and exercise recommendations from 35 to 75% and 70 to 81% respectively (Rowley, 1999). In people with type 2 diabetes, non-adherence to lifestyle modification recommendations ranged from 35 to 75% for either diets or physical activity alone or combined measures together, and some patients justified their non-adherence on basis of economic factors, interpersonal problems with spouses and families i.e. lack of spouses and families supports, and other factors (Garay-Sevilla et al, 1995). In another recent study, rates of non-adherence to dietary and exercise recommendations were estimated as 63.5% and 64.4% respectively (Serour et al, 2007). Ary et al. (1986) reported rates of non-adherence to diets and exercise amongst type 2 diabetes patients as 50% and 47% respectively. Study undertaken by Wanko et al. (2004) reported rate of nonadherence to exercise as 52%; and the reasons for having difficulty exercising are as follow: body pain i.e. negative physical reactions (41%); no time to exercise (39%); no willpower (27%); health not good enough (21%); lack of information i.e. don't know what kind of exercise to do (17%); lacking exercise partner i.e. no one to exercise with (15%); no convenient or close place to exercise (11%); nowhere safe to exercise (5%); and felt exercise was not important (1%).

Fitzgerald *et al.* (1997) showed that self-reported adherence to exercising was higher for men than women; while women were more likely to report adherence to diet. This is probably due to the fact that more men reported that they were told to exercise than did women (Fitzgerald *et al*, 1995). Study by Nelson *et al* (2002) reported rates of non-adherence to diet and physical activity as 62% and 69% respectively. This study demonstrated that about a third of people with type 2 diabetes eat healthy diet and exercise regularly, however, up to one third of adults with the diabetes are completely sedentary. Thomas *et al.* (2004) also reported rate of non-adherence to exercise as 66% of the individuals sampled; which represents two third of people with type 2 diabetes. It is estimated that about 60% of the world population and more than 50% of American adults do not attain the minimum levels of physical activity recommended by the American College of Sports Medicine and the Centers for Disease Control and Prevention, namely; 30 minutes of moderate physical activity for at least five days a week (Hudon *et al*, 2008). Also, the current guidelines of the Dutch College of General Practitioners in Welschen *et al.* (2007) demonstrates 70% of people with type 2 diabetes had little or no physical activity.

2.13 Reasons for Non-adherence to Diet and Exercise

Serour et al. (2007) reported that understanding the barriers to adherence to lifestyle changes can help family physicians to plan and implement more intensive interventions to assist patients facing the long-term task of achieving beneficial lifestyle changes. Non-adherent patients may be experiencing some sort of barriers to adhering to the recommended lifestyle modifications as part of the interventions in managing chronic diseases including type 2 diabetes mellitus. The barriers may include lack of communicative relationship between the patient and health care providers, lack of psychosocial and emotional supports, health beliefs and perceptions that are incompatible with the recommendations, socio-economic factors, and stressful environment (Rowley, 1999). Factors influencing diet adherence may include frequent gatherings with extended families and friends; whereby patients consumes more fat, meat, sugar, rice and wheat flour than usual pattern, and over-dependent on fast meals. Climatic conditions like dry desert with intensely hot summers and brief, cool winters may also discourage patients from adhering to the recommended physical activity (Serour et al, 2007). Botswana's climate is like that of dry desert with about 2-3 months of intense and cool winter, which may discourage individuals from engaging in preventive and therapeutic exercise recommendations. Serour et al. (2007) identified the following as barriers to adherence to diet-unwillingness (48.6%); difficulty in following a diet regimen different from that of the rest of the family (30.2%); high frequency of social gatherings (13.7%); no advice given by health care providers (4.2%); workload (3.3%) and other causes (6.9%). Similarly, barriers to adherence to regular exercise include lack of time - always being busy (39.0%); coexisting disease-mainly osteoarthritis and asthma (35.6%); intensely hot summer whether (27.8%); lack of exercise partner (3.7%); cultural difficulties for Kuwait's women (3.7%); and other causes (2.8%) (Serour et al, 2007). While overall factors influencing adherence to lifestyle measures (both diet and exercise) are traditional Kuwaiti food, which is

high in fat and calories (79.9%); stress (70.7%); a high consumption of fast food (54.5%); high frequency of social gatherings (59.6%); abundance of maids (54.1%), and excessive use of cars (83.8%).

Ary *et al.* (1986) reported the following reasons for non-adherence to diets (caloric intake): inappropriate offers from others (42%); restaurants or eating out (26%); situations at home i.e. eating unhealthy diets when alone at home (19%); challenging conditions i.e. non-supportive family members, spouse and friends (19%); criticism by others (13%); granting self-permission (10%); and poor self-control (10%). Similarly, barriers to non-adherence to exercise (physical activity) reported are negative physical reactions i.e. sickness and chest pain (34%); criticism by others (24%); being too busy (17%); weather (17%); suggesting interfering activities (15%); lack of exercise partner (11%); specific locations away from home (10%); and on a trip (10%) (Ary *et al*, 1986). Other social variables influencing adherence to therapeutic lifestyle measures may include individual's behaviors with diabetes, previous experience with chronic disease(s), actions of family members, friends and colleagues at work, acceptance/denial of diabetic condition, and self-beliefs and knowledge of individuals with chronic illness such as type 2 diabetes. About 75% of patients with type 2 diabetes had been told to limit caloric intake (diet) and to exercise regularly, but only about 20% and 73% had been given written instructions regarding physical activity and caloric intake respectively (Ary *et al*, 1986).

Physical or material barriers to exercise in people with type 2 diabetes include women rarely left their houses due to fear of physical attack and religious restrictions or ethnic customs; lack of information and advice; financial hardship; exercise as potentially exacerbating illness or causing physical weakness; absence of exercise parks; dirty pavements and street crime (Greenhalgh et al, 1998). Results from study by Wens et al. (2005) suggest patient's deficient knowledge and diabetes; lack of communication skills by the attending physician; lack of multidisciplinary support; over-reliance on modern/alternative medicine; fear of social isolation; minimizing of the disease i.e. patients underestimating diabetic conditions; opposition to change; and lack of patient's motivations as some of the barriers to treatment adherence including therapeutic diets and exercise in people living with type 2 diabetes. Clement (1995) demonstrated significant knowledge and skill deficits in 50-80% of patients with type 2 diabetes. Patient's knowledge; attitude towards diabetic conditions; ideas; belief and experiences; as well as those of family members and friends; have also been shown to correlate with adherence (Wens et al, 2005). However, scheduled consultations based on patient-centeredness; multi-disciplinary teamwork; shared decision making based on patient's participation and partnership; and motivational counseling have been proven to encourage better adherence to treatment including diets and exercise in people with type 2 diabetes (Wens et al, 2005).

In another study by Thomas *et al.* (2004), the main factors influencing physical activity include lack of confidence- 60%; poor weather-56%; tiredness-54%; other plans with friends-50%; lack

of local facilities-26%; lack of spare time-25%; cost of exercise-23%; associated serious illness-20%; changing job-9%; having children-4%; lack of exercise partner; distraction by good television programmes; and fear of hypoglycemia. Patient's attitude and the attitudes of people important to the patient, for example, their spouse, friends, colleagues or physician towards following a diabetic diet would influence that patient's adherence to change and maintain a diet (Fitzgerald *et al*, 1995).

Adherence level is directly proportional to the degree of patient's attitude, for example, patient with more adherence levels had more favorable attitudes toward diabetes (Fitzgerald *et al*, 1995). Hudon et al. (2008) shows that levels of physical activity are lower among low income earners; low socioeconomic status, low educational status; decrease with age; and among people with functional incapacities. Finally, physical activity is directly related to psychological distress perceived health status and employment (Hudon *et al*, 2008).

Wadden *et al.* (2006) demonstrates lack of self monitoring; injuries from physical activity; ongoing medical problems i.e. concurrent medical and surgical illness; and emotional or psychiatric problems as reasons for not adhering to therapeutic lifestyle interventions. However, counseling using cognitive re-structuring and motivational interviewing techniques based on interdisciplinary approach may help people with type 2 diabetes mellitus to cope with exercise and dietary recommendations. Similarly, patient non-adherence can be changed by improving diabetic education, perception, motivation and self-management.

2.14 Patient's Perceptions about Diet and Exercise

From patient's perceptive, lifestyle modification recommendations constitute the larger part of self care tasks in the management of type 2 diabetes and perceived to be time consuming. Russell *et al.* (2005) estimated that about 2 hours per day is required for performing the American Diabetes Association-recommended self-care tasks among patients taking oral hypoglycemic agents, and physical activity and healthy nutrition are the most time consuming daily tasks. These are behaviors requiring the greatest alteration in individual's lifestyles (Ary *et al*, 1986).

The study by Serour *et al.* (2007) stated that most patients (69.1%) had strong beliefs that adherence to a diet regimen and regular exercise could have a positive effect on their diabetic condition. Self-perceptions, beliefs and responses to diabetic condition significantly influence adherence to lifestyle measures. For example, adherence may be compromised if people with type 2 diabetes do not believe that lifestyle modification recommendations-healthy diets and physical activity affects their glycaemic control.

Study by Thomas *et al.* (2004) found that more than two third of individuals with diabetes believe strenuous exercise would improve their diabetic control; but majority find it difficult to

initiate and sustain. Farmer *et al.* (2005) categorized beliefs about illness in terms of whether they relate to symptoms, cause, consequences, time lines, treatment and control/cure. However, beliefs about the consequences and controllability of diabetes, and the perceived effectiveness of intervention can predict patient adherence to lifestyle measure recommendations (Farmer *et al*, 2005).

2.15 Summary of Literature Reviewed

Abundant literature supports the beneficial effects of diet and exercise recommendations for improving and maintaining glycaemic level of people with diagnosed type 2 diabetes mellitus. Adherence to lifestyle modification recommendations is considered adequate when patients with type 2 diabetes achieves at least 150 minutes of exercise per week for four consecutive weeks and strictly restrict fat and calories intake. Patient adherence to therapeutic lifestyle measures recommendations is notoriously difficult to achieve, but essential to the success of managing type 2 diabetes mellitus. The problem of poor adherence to lifestyle measure recommendations amongst patients with type 2 diabetes is very complex and multi-faceted in nature.

The rates of non-adherence to diet and exercise recommendations ranged from 35% -75% and 35%-81% respectively. Frequently reported reasons for not adhering to diet include inappropriate offers from others, lack of communication/information, lack of supports, health beliefs and perceptions, eating out, previous experience with chronic diseases, financial hardship, and e.t.c. But, the most common barriers for exercise non-adherence were negative physical reactions (e.g. body pain), no will-power, poor health, associated co-morbidities, lack of exercise partner, lack of communication/information, poor weather, lack of time, and e.t.c.

Finally, more than 50% of the people with type 2 diabetes believe that adherence to diet and exercise recommendations would improve their diabetic condition, but greater proportion find it difficult to initiate and sustain. However, patient non-adherence can be enhanced by improving diabetic education, perception, motivation, and self-management.

Chapter 3

Methods

3.1 Introduction

This chapter is about methods applied in the study on non-adherence to lifestyle modification recommendations (diet and exercise) amongst type 2 diabetes mellitus patients attending Extension II clinic in Gaborone, Botswana.

3.2 Aim, Objectives, Research Question, and Epistemological Approach

3.2.1 Aim

The study aims to investigate non-adherence to diet and exercise recommendations amongst type 2 diabetes mellitus patients attending Extension II clinic in Gaborone, Botswana.

3.2.2 Objectives

- To determine prevalence of non-adherence to lifestyle modification recommendations (diet and exercise) in type 2 diabetes mellitus patients;
- To establish the reasons non-adhering patients give for not adhering to diet and exercise; and
- To establish the perceptions of patients on the role of lifestyle modification recommendations in the management of type 2 diabetes mellitus.

3.2.3 Research Question

Why are type 2 diabetes mellitus patients not-adhering to lifestyle modification recommendations (diet and exercise) at Extension II clinic in Gaborone, Botswana?

3.2.4 Epistemological Approach

This study takes a positivistic approach in realizing its aim and objectives using a quantitative method. This approach has its root in the enlightenment era (Bruce *et al*, 2008), which aims to find out the prevalence of non-adherence, perceptions of patients, and reasons for not adhering to lifestyle modification recommendations. It is based on the assumption that this can be achieved by analyzing the quantitative data generated from a self-administered questionnaire.

3.3 Study design

This was a descriptive cross-sectional study using self-administered questionnaires.

3.4 Study Population

All individuals 30 years or older diagnosed with type 2 diabetes mellitus and on clinic care for two or more years attending Extension II Clinic from 1st July to 30th September 2008 formed the study population. This age-group was targeted because most of the people diagnosed with type 2 diabetes in my practice (Extension II clinic) were aged 30 years and above (GCC, 2006).

3.4.1 Inclusion criteria

- 1) Participants had to have type 2 diabetes mellitus, diagnosed two or more years and on clinic care
- 2) Participants had to be aged 30 years or older.

3.4.2 Exclusion criteria

- 1) People with type 1 diabetes mellitus
- 2) Age < 30 years
- 3) Non-clinic attendants type 2 diabetic mellitus patients
- 4) Less than 2 years of diagnosed with type 2 diabetes mellitus

3.5 Sample Size and Selection

With a study population of 40 patients per month on follow up care, using a confidence level of 95% and power of 80%, the estimated sample size was 96 (at default population size of 999999) over a period of 3 successive months i.e. 32 patients per month for 3 successive months. For ease of calculation, sample size of 35 participants per month was recruited from the sample population; hence the study sample size was 105 over a period of three successive months. Convenience sampling method was used to select 35 subjects per month, over a period of three successive months and a total of 105 participants were recruited into the study, made up of 44 men and 61 women.

During the process of sample selection, each questionnaire was coded using participant's initials and this was cross-checked with initials on the signed informed consent form in order to ensure that the same participant was not selected more than once.

3.6 Recruitment of Study Participants

Type 2 diabetes patients were recruited from Extension II clinic in Gaborone, over a period of 3 successive months to participate in the study. Patients suitable for study inclusion were identified from routine follow-up consultations and eligible patients were approached to participate. Information related to the study was provided including aim and objectives, informed consent

signed, accompanied by self-administered questionnaire and assistance was rendered to the participants by the research assistant – 'C' (trained by the researcher), where necessary.

3.7 Data Collection

Data was collected from July – September, 2008 using self-administered questionnaire. The questionnaire was formulated according to a model established during literature review and also, from related studies (modified to suit study locality), and was written in two languages- English and local language (Setswana) versions.

The questionnaire comprised close-ended and multiple-choice questions. Clarification of questions was provided in local language when necessary, and patients with poor educational background were assisted in completing the questionnaire by trained research assistant "C". Participants' responses were reviewed and verified on completion, and average of 25 minutes was used to complete all the questions. All participants consented to complete the questionnaire; after being duly informed about the study and signing the consent form.

However, a pilot study to test the questionnaire was not done because permission was difficult to obtain from the Ministry of Health Botswana without MCREC ethical clearance certificate.

3.8 Data Analysis

Data was captured, edited and cleaned using SPSS 14.0 for windows software, then exported to Microsoft excel for statistical analysis. Descriptive statistics were used to measure general baseline participants' characteristics. The proportions (prevalence rates) of respondents not adhering to healthy dietary habits and exercise, and those perceiving lifestyle modifications recommendations (i.e. healthy diets and exercise) as important in the management of type 2 diabetes mellitus were estimated. Finally, the proportions of individual reasons for not adhering to either healthy diets or exercise were measured. Data tabulations, percentages and bar charts were used to illustrate relevant and important aspects of the study findings. Confidence intervals around the proportions were measured in order to determine statistically significance findings.

3.9 Reliability and Validity

Reliability is the extent to which test scores are accurate, consistent or stable (Struwig & Stead, 2004). The synonymous terms are 'reproducibility and repeatability' (Bruce *et al*, 2008). Validity refers to 'the capacity of a test, instrument or question to give a true result' (Bruce *et al*, 2008).

Reliability and validity of the study was enhanced by translating and back translating of questionnaire and responses in both English and Setswana languages. The English version was translated by translator 'A' to a local language (Setswana) and for reliability purposes, an independent translator 'B' was given the Setswana version of the questionnaire for back translation to English and linguistics was compared, which produced same meaning. The interpretation and back translation was done by an expert in linguistics in order to ensure accuracy and consistency of the translation.

The inclusion of patients diagnosed two or more years ago on clinic care may have led to the recruitment of participants with relative insight into the disease condition and understanding the implication of adhering to lifestyle modification recommendations. Extraneous variables were controlled by homogeneous group of participants (those diagnosed two or more years ago and on clinic care) and selection of sample over a period of 3 months.

3.10 Bias

Bias is defined as a systematic error in sampling or measurement that leads to an incorrect conclusion (Bruce *et al*, 2008).

3.10.1 Selection Bias

The restriction of participants to those aged \geq 30 years, with type 2 diabetes 2 or more years and on clinic care may have presented selection bias that may limit generalization of the study findings due to inability to capture the views of participants aged < 30 years and those diagnosed less than 2 years. However, this was minimized by the use of convenience sampling method and statistically powered (80%) of a representative sample size.

3.10.2 Participant Bias

The possible impact of the researcher's expectation from the participants may have had a Hawthorne's effect, but this was minimized by self-administration of questionnaire, the use of an independent research assistant "C" and the assured anonymity of responses.

3.10.3 Language Bias

The researcher has little knowledge about the local language (Setswana) which may have introduced bias in understanding the participants' views, but this was minimized by the use of a trained local research assistant – 'C' (trained by the researcher).

3.11 Ethical Considerations

Permission to conduct the study was granted by the Research Committee of the Department of Family Medicine and Primary Health Care at the University of Limpopo (Medunsa Campus), Republic of South Africa.

Ethical approval for this study was obtained from the following research and ethics committees:

- Medunsa Campus Research Ethics Committee (MCREC) of the University of Limpopo, Republic of South Africa (MCREC/M/12/2008: PG),
- Health Research Unit of the Ministry of Health, Botswana {PPME-13/18/1 PS Vol. III (20)},
- Finally, permission for data collection was sought from the District Health Team of the Gaborone City Council, Botswana (GCC/H/8).

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Results

4.1 Introduction

This section focuses on results of the study that investigated non-adherence to diet and exercise recommendations amongst type 2 diabetes patients attending Extension II clinic in Gaborone, Botswana.

4.2 Sample

A total of 105 questionnaires were distributed, of which 104 were correctly completed, resulting in a response rate of 99% of the recruited study population included in the data analysis.

4.3 Baseline characteristics of the study participants

Table I displays socio-demographic characteristics of recruited individuals with type 2 diabetes mellitus - gender, age range in years, marital status, educational level, and employment status. Of the 104 participants, 59% were female and 41% were male. 26.9% (n=28) of the participants were 50-59 year age group, this is closely followed by 21.2% (n=22) of the participants aged 40-49 year, and the lowest proportion was noted among participants aged 30-39 year. 41% (n=43) of the participants were married at the time of data collection, 26% (n=27) reported to be single, and 14.4% (n=15) were co-habiting or living-in. About 84% of the participants had attended school with a range of education- 22.1% of the participants had attended primary school, while 32.7% and 28.8% had attained secondary and tertiary education respectively.

Table I: Background characteristics of 104 participants studied

Variable		Frequency (n)	Percent (%)
Gender	Male	43	41.3
	Female	61	58.7
Age (years)	30 - 39	15	14.4
	40 - 49	22	21.2
	50 - 59	28	26.9
	60 - 69	20	19.2
	70 & above	19	18.3
Marital status	Single	27	26.0
	Married	43	41.3

	Divorced	05	4.8
	Separated	03	2.9
	Co-habiting	15	14.4
	Windowed	11	10.6
Educational level	None	17	16.4
	Primary	23	22.1
	Secondary	34	32.7
	Tertiary	30	28.8
Employment status	Unemployed	16	15.4
5.00.0	Employed	57	54.8
	Pensioner	19	18.3
	Housewife	12	11.5

According to table I above, over 50% (n=57) of the participants were employed at the time of data collection, 15.4% (n=16) were unemployed and 11.5% (n=12) reported to be housewife.

4.4 Prevalence of non-adherence to lifestyle measures - diet and exercise recommendations

Table II shows that about one third (n = 38, 37.4 %; 95% CI, 27.7 - 46.3) and nearly half (n = 54, 52 %; 95% CI, 42.4 - 61.6) of the participants were not adhering to diet and exercise regimens respectively.

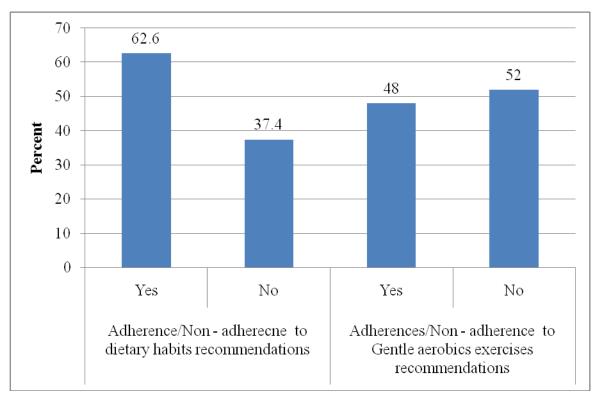


Figure 1: Prevalence rates of non-adherence to diet and exercise recommendations

NB: Yes - depicts participants adhering to diet/exercise

No - depicts participants not adhering to diet/exercise

Figure I show bars chart representing prevalence rates of non-adherence to diet and exercise recommendations.

Table II: Non-adherence to lifestyle measures and barriers for not adhering to diet and exercise

Variable ↓		Proportion (%)	95% Confidence Interval (C.I)
Non-adherence to diet		37.4	27.7 - 46.3
Barriers to diet	Eating out	31.7	23.0 – 41.0
	Financial constraints	28.8	20.3 – 37.7
	Poor self control	26.9	18.5 – 35.5
	Granting self	36.5	27.7 – 46.3

	permission		
	Another's home	18.3	10.6 – 25.4
	Situation at home	6.7	2.1 – 11.9
	Lack of information	33.3	24.0 – 42.2
Non-adherence	to exercise	52	42.4 - 61.6
Barriers to exercise	Weather	15.4	8.1 - 21.8
CACICISC	Lack of exercise partner	24	15.8 – 32.2
	Specific location	18	10.6 – 25.4
	Criticism	1.9	-0.69 – 4.69
	Lack of information	65.7	56.1 – 75.0
	Exercise exacerbating illness	57.6	48.5 – 67.5
Overall barrier to diet and exercise	Spouse	54.1	44.4 – 63.4
i.e. lack of moral and emotional	Family members	44.8	35.4 – 54.6
supports from	Friends	58.7	49.6 – 68.5

From table III, majority of the participants adhering to dietary recommendations indicated that they engaged in low saturated fats and caloric intake, high starchy and fibre diets, vegetable and fruits, regulated alcohol intake and smoking cessation. Similarly, there was a range of exercise preference amongst participants who indicated that they exercised; brisk walking was the most frequently selected option (83.3%), followed by sport activities, cycling, and jogging as the least

chosen option. About four fifth (83%) of the adherers stated that they engaged in exercise for at least 3 times per week and each session lasting for 30 minutes or more.

Table III: Summary of characteristic of the participants adhering to diet and exercise

Variable \	Proportion (%)	
Dietary habits	High starchy & fibre diets	51.0
	Low saturated fats and caloric	48.1
	Fruits & vegetables	42.2
	Regulated alcohol intake & smoking cessation	15.4
	High sugar, CHO & fatty meals	1.0
Exercise preference	Brisk walking	83.3
	Sport activities	6.3
	Cycling	6.3
	Jogging	4.2
Frequency of exercise	≥ 3 times/week	83.0
	< 3 times/week	17.0
Duration of exercise/session	≥ 30 minutes	74.5
exercise/session	< 30 minutes	25.5

4.5 Reasons for not adhering to lifestyle modification recommendations

4.5.1 Reasons for not adhering to diet

According to table II, the main perceived reasons for not adhering to diet recommendations were granting self permission (36.5%; 95% CI, 27.7 - 46.3), lack of information (33.3%; 95% CI, 24.0 - 42.2), eating out (31.7%; 95% CI, 23.03 - 40.97), financial constraints (28.8%; 95% CI, 20.3 – 37.7), and poor self control (26.9%; 95% CI, 18.5 - 35.5). And the least perceived reason was situation at home-eating unhealthy diets when alone (6.7%; 95% CI, 2.1 - 11.9). Similarly, figure 2 show bars chart representing perceived barriers to adherence to diet.

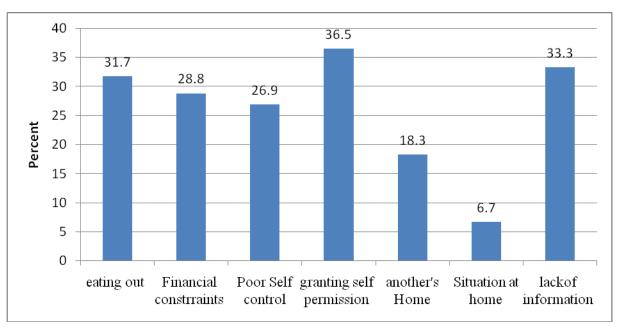


Figure 2: Bars chart showing perceived reasons for not adhering to diet recommendation

4.5.2 Reasons for not adhering to exercise

Table II shows that fifty-two percent of the participants were not adhering to exercise and the top five reasons for having difficulty to engage in regular moderate intensity exercise include lack of information (65.7%; 95% CI, 56.1 - 75.0%), exercise as potentially exacerbating illness (57.6%; 95% CI, 48.5 - 67.5%), lack of exercise partner (24%; 95% CI, 15.8 - 32.2), specific locations away from home such as cattle posts, official trips (18%; 95% CI, 10.6 - 25.4), and intensely cold winter weather (15.4%; 95% CI, 8.1 - 21.8). The least perceived reason for not adhering to exercise was criticism by others (1.9%; 95% CI, -0.69 - 4.69) and was not statistically significant because the confidence interval crosses line of no difference -1.00 (i.e. a unity).

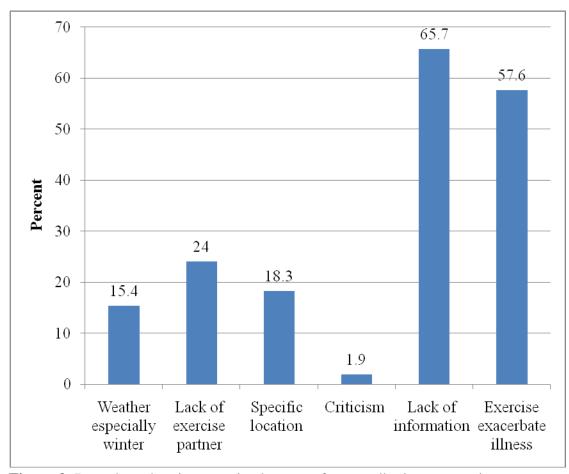


Figure 3: Bars chart showing perceived reasons for not adhering to exercise recommendation

Similarly, figure 3 show bars chart representing perceived reasons for non-adherence to regular exercise. Finally, the 95% confidence interval used demonstrates that the researcher is 95% confident that the true estimated value lies within the two confidence limits.

4.5.3 Overall barriers to diet and exercise recommendations

Among non-adherents to diet and exercise, reported overall reasons that interfered with adherence to diet and exercise recommendations were lack of moral and emotional supports from the spouse/partner (54.1%; 95% CI, 44.4-63.4), family members (44.8%; 95% CI, 35.4-54.6), and friends (58.7%; 95% CI, 49.6-68.5).

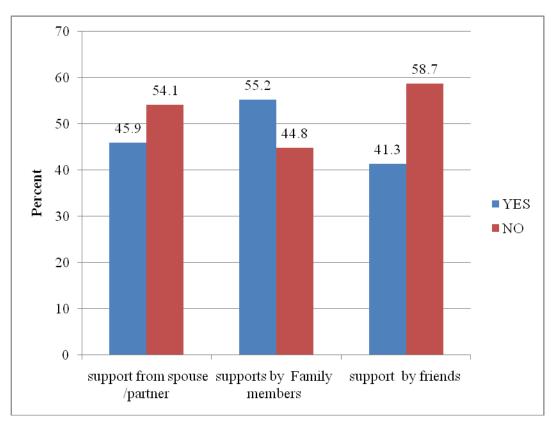


Figure 4: Bars chart demonstrating moral and emotional supports from spouse/partner, family members and friends.

NB: Yes- represents respondents who had received moral and emotional supports. No- represents respondents who had not received moral and emotional supports

Figure 4 shows proportion of individuals who had received and had not received moral and emotional supports from spouse/partner, family members, and friends among non-adherers to diet and exercise.

4.6 Patient's understanding and perceptions of diet and exercise recommendations

From table IV, almost 50% of the participants understood lifestyle modification recommendations as healthy dietary habits and exercise, while 36.5% and 15.4% understood lifestyle intervention as healthy dietary habits and exercise only respectively.

Table IV: Patient's understanding and perceptions of diet and exercise recommendations

Variable ↓		Frequency (n)	Percent (%)
Understanding of lifestyle	Diet only	38	36.5
recommendations	Exercise only	16	15.4
	Both diet and exercise	50	48.1
Perceives diet helps to control	Yes	99	95.2
sugar level	No	05	4.8
Perceives exercise helps to	Yes	70	67.3
control sugar	No	34	32.7

Table IV demonstrates that almost all the participants felt that diets could positively affect their diabetic condition i.e. 95% of the patients stated that healthy dietary habits could help to control and maintain their glucose (sugar) levels. Similarly, about two-third (67.3%) of the participants had reported that exercise could improve and maintain their diabetic control, while nearly one-third perceived that exercise could not help to control and maintain glucose levels.

Figure 5 show bars chart representing self-perceptions of diet and exercise recommendations amongst participants sampled.

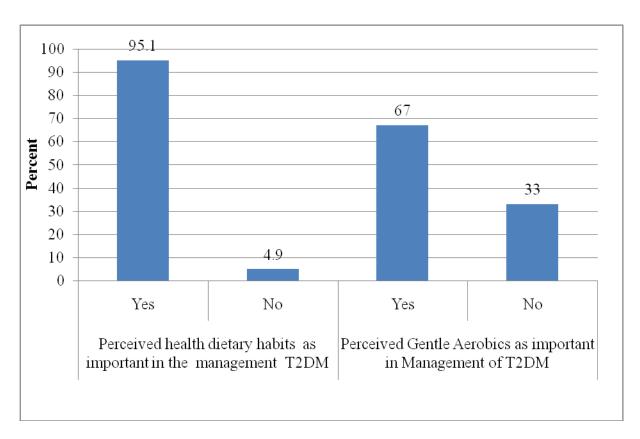


Figure 5: Self-perceptions of diet and exercise recommendations

Discussion

5.1 Introduction

This section describes findings of the study that investigated non-adherence to diet and exercise recommendations amongst type 2 diabetes patients attending Extension II clinic in Gaborone, Botswana. These findings would be compared with previous research based on literature review in order to demonstrate relevant and important aspects of the results including similarities, differences and deviations. It provides a robust estimate of rates of non-adherence, reasons for not adhering and patients' perceptions of lifestyle measure recommendations in the management of their diabetic condition. Effectively developing and targeting lifestyle measures among type 2 diabetes patient populations require a better understanding of their perceptions and beliefs as well as perceived potential reasons for not adhering to diets and exercise recommendations.

This study will make an important contribution to the prescription of diet and exercise measures in the management of type 2 diabetes at primary health care settings in Gaborone, Botswana. Informing health care providers about the study findings would increase their commitment to the inclusion of therapeutic lifestyle measures as part of the interventions to be used in managing people with type 2 diabetes mellitus.

5.2 Prevalence rates of non-adherence to diet and exercise recommendations

Adherence to a prescribed diet and aerobic exercise is important for both diabetes prevention and optimal glycaemic control in people with diagnosed type 2 diabetes mellitus. Therefore, efforts should be made to explore patient's background behaviour, knowledge, moral and emotional supports (from spouse, family and friends), ability, barriers, and readiness to initiate and sustain lifestyle changes that influence patients' adherence to therapeutic lifestyle measures. Promoting healthy dietary habits and modest regular exercise can improve the quality of life for all people with type 2 diabetes, improve productivity, prevent burden of the disease, and may invariably reduces direct health care costs dramatically (Harris *et al*, 2003, Bazzano *et al*, 2005, Burnet *et al*, 2005)

More than one third (37%) and nearly half (52%) of the participants were not adhering to diet and exercise recommendations respectively. Non-adhering to exercise programmes is far more prevalent than diet non-adherence amongst participants sampled. This can partly be explained by higher level of perceptions noted amongst participants that diet significantly helps to achieve and maintain good glycaemic control. Other strong reasons that might be responsible for differential rates include-majority of the participants understood lifestyle measures to include dietary advice, more than half (57.6%) of non-adherers wrongly viewed exercise as potentially exacerbating illness such as body pain, and two third of the non-adherers seems to have been informed about

dietary recommendations as opposed to only one third aware of exercise programmes i.e. about one third and two third of the non-adherers were not informed about diet and exercise regimens respectively. An overview of literature shows that individual's understanding, self-perceptions and belief about lifestyle measures greatly influence adherence to a prescribed diet and exercise regimens in people with diagnosed type 2 diabetes mellitus (Rowley, 1999, Thomas *et al*, 2004, Serour *et al*, 2007).

The rates of non-adherence to diet and exercise in this study are consistent with that reported in previous overseas studies undertaken by Garay -Sevilla et al. (1995) (both diet and exercise, 35-75%); Rowley (1999) (diet only, 35-75%); and Cawood (2006) (both diet and exercise, 40-50%). Similarly, rate of non-adherence to exercise in this study tend to agree with the findings of Ary et al. (1986) (47%) and Wanko et al. (2004) (52%). However, rates of non-adherence in this study were lower than that reported in studies authored by Ary et al. (1986) (diet only, 50%); Rowley (1999) (exercise only, 70-81%); Nelson et al. (2002) (diet, 62%; exercise, 69%); Thomas et al. (2004) (exercise only, 66%); and Serour *et al.* (2007) (diet, 63.5%; exercise, 64.4%). This is probably due to smaller sample size used in this study when compared to studies that reported higher rates of non-adherence, since the larger the sample size the more precise study findings. Also, nearly one third of participants that reported higher rates of non-adherence in overseas studies authored by Nelson et al. (2002), Thomas et al. (2004), and Serour et al. (2007) had other chronic conditions such as hypertension, obesity and osteoarthritis that interfered with adherence to lifestyle measures especially exercise adherence. Therapeutic lifestyle measures must be tailored to the individual needs in order to accommodate pre-existing co-morbidities, since each individual patient is unique in background and lifestyle, and therefore, no one program fits any two patients' needs completely.

Nevertheless, estimated rates are statistically significant since 95% confidence interval did not include a unity-1.00 i.e. 95% CI for estimated rates never crossed line of no difference.

5.3 Reasons for not adhering to diet and exercise recommendations

Despite the fact that most participants perceived diet and exercise as important to achieve and maintain good glycaemic control, majority still reported a range of reasons for not adhering. The most frequent reasons for not adhering to dietary recommendations are granting self permission (e.g. just this once, a little won't hurt), lack of information, eating out (especially fast food, social gathering, restaurant, family and friends' homes), financial constraints to buy idea healthy diet, poor self control and another's home in the villages. The top 5 reported reasons for not adhering to exercise are lack of information, viewed exercise to be causing negative physical reactions (for examples, chest pain, extreme weakness, ageing and sickness), lack of exercise partner, specific locations away from home (such as social and official trips, cattle post), and intensely cold winter weather. The reasons for not adhering to diet and exercise in this study are consistent

with that reported in previous non-adherence studies conducted by Ary *et al.* (1986), Thomas *et al.* (2004) and Serour *et al.* (2007) .

The overall reasons negatively influencing adherence to both diet and exercise recommendations are lack of moral and emotional supports from the spouse, family members, and friends. This makes adherence to a specific diet and exercise regimen extremely difficult, especially between and within family members including spouse. This finding is similar to the results of previous overseas studies undertaken by Ary *et al.* (1986), Garay-Sevilla *et al.* (1995), Rowley (1999), and Thomas *et al.* (2004). They found that good supports from spouse, family members and friends positively predict adherence to diet and exercise recommendations. However, adherence to diet may require stronger support from the patients' relatives, considering that meals are usually shared by all members in a family, especially in traditional societies (including African countries) (Garay-Sevilla *et al.* 1995). These barriers should be addressed when planning diet and exercise regimens during diabetes education.

In this study, lack of information (i.e. detailed written instruction) between the patients and health care providers appeared to be the most frequently reported reason for diet and exercise non-adherence, when comparing with other reasons for not adhering to lifestyle modification recommendations. This barrier is far more prevalent for exercise non-adherence (65.7%) and approximately doubles that of diet non-adherence (33.3%). This finding agrees with studies undertaken by Greenhalgh et al. (1998), Rowley (1999) and Wens et al. (2005). The overall effects of lack of lifestyle measures information would include knowledge and skill deficits and thus, leading to poor glycaemic control. This suggests the need for diabetes educational programme to improve diet and exercise adherence. It is the professional responsibility of the health care provider to the diabetic patient, to provide robust information on diet and exercise regimens as part of the total health care to be delivered. People with diabetes may not strictly adhere to lifestyle measures unless they are thoroughly educated and informed by the health care providers including family physician. Individualized lifestyle measures may be achieved through: 'assessment of the patient's knowledge and needs; education of the patient; anticipation of the individual's future barriers' (Dudley, 1980); and identification of support structures. Identifying individual's reasons for non-adherence to diet and exercise measures will prepare the patient mentally to deal with the situations effectively.

This study confirms that another's home and specific locations away from home are part of the reasons responsible for diet and exercise non-adherence respectively. This finding is consistent with cultural norms in the Republic of Botswana, whereby an individual has more than one home such as city home, village home and home at the cattle post. Therefore, it is important to examine and address the influence of alternative homes on adherence to diet and exercise regimens during diabetic education. This observation agrees with that of Ary *et al.* (1986), who demonstrated that

another's home (14%); and specific locations away from home (20%); were part of frequently reported reasons for non-adherence to diet and exercise respectively.

5.4 Patients' understanding and perceptions of lifestyle modification recommendations

This study has established that most of the participants sampled in this study perceived diet and exercise as indispensable lifestyle measures that would improve their diabetic control. A possible explanation might be that participants had relative insight into their disease condition, high uptake level of health care service, and a relatively high level of school education amongst participants sampled (i.e. 84% had attained one form of school education with a minimum of primary education). This positive finding should be seen as an advantage by health care provider when planning diet and exercise regimens during diabetes education, since self-perception of lifestyle measures is highly associated with higher level of adherence. This finding is consistent with other studies conducted by Thomas *et al.* (2004) and Serour *et al.* (2007), they reported that more than two third of individuals with type 2 diabetes felt that diet and exercise could have a positive effect on their glycaemic control. However, this study showed higher level of positive self-perception of diet (95.2%), when compared with that reported by Thomas *et al.* (2004) (66%) and Serour *et al.* (2007) (69.1%), probably due to smaller sample size in this study.

5.5 Strengths and limitations of the study

This study investigated an important and previously under-researched area in diabetes research in Gaborone, Botswana. The study was conducted in a primary care setting, which makes it more relevant to the field of a family physician. And reported perceived reasons in this study represent the likely range of everyday barriers for non-adherence to diet and exercise measures amongst people diagnosed with type 2 diabetes mellitus in Gaborone.

However, sample does have some limitations. In recruiting participants from the study setting; researcher excluded people diagnosed less than 2 years, and setting was limited to only one primary care centre out of 15 general practice centres in Gaborone. Therefore, findings of the study may not be necessarily generalizable for the whole population of type 2 diabetic patients and statements about generalizability must await the findings of the research in additional settings. A nationwide study or one covering all the 15 primary care centres in Gaborone is needed. However, findings may not have shown any significant difference, since most people diagnosed with type 2 diabetes in the city usually attends Extension II clinic for their routine monthly follow-up consultations. Finally, measure of diabetic control i.e. glycosylated hemoglobin (HbA1c) was not assessed, which makes it difficult to relate individual's perceived reasons for not adhering to diet and exercise recommendations to level of glucose control.

5.6 Implications for policy and practice

The researcher suggests diabetes education which must be tailored to the individual needs and perceived reasons for non-adherence in a culturally acceptable manner. This study has important implications for current levels of clinical practice in the country, and public health burden of the disease may be reduced significantly with implementation of effective and sustainable diet and exercise programs. This is because strict adherence to diets and exercise recommendations, an integral part of comprehensive diabetes care has been proven to enhance clinically meaningful glycaemic control.

Finally, informing policy makers about the study findings would increase their commitments to the recruitment of dieticians, diabetic nurses and educators in our primary care centres. Potential focus for future interventions must include public health policy to support promotion of modest regular exercise, food labeling, and increase public awareness on the fatal consequences of not adhering to lifestyle modification recommendations, since health policy and legislation play an important role in implementing lifestyle measures.

5.7 Summary

This study has demonstrated high rates of non-adherence to diet and exercise recommendations amongst people diagnosed with type 2 diabetes mellitus in Gaborone, Botswana. It also revealed that there is no single reason for diet and exercise non-adherence. For example, for diet, granting self permission and lack of information were consistently reported as the most frequently reasons for non-adherence. While lack of information and exercise as potentially exacerbating illness were the most frequently reported reasons for non-adherence to exercise. Therefore, intensive and repeated diabetic education should be incorporated as part of routine diabetes care in the primary care setting.

Chapter 6

Conclusion and recommendations

6.1 Conclusion

The rates of non-adherence to diet and exercise recommendations are relatively high, but exercise non-adherence is far more prevalent amongst studied population. The most common reasons for non-adherence to diet were granting self permission, lack of information, eating out, financial constraints, poor self control, and another's home(s). In contrast; lack of information, exercise as potentially exacerbating illness (i.e. negative physical reactions such as body pain, physical weakness, sickness or ageing), lack of exercise partner, cold winter weather and specific location away from home were the most frequently reported reasons for not adhering to exercise. While lack of moral and emotional supports from the spouse, family members and friends were the reported overall reasons for diet and exercise non-adherence. Additional measures including diabetes education are needed to improve dietary habits and enhance regular modest exercise in this population.

6.2 Recommendations

- 1) Information on diet and exercise must be provided to each diabetic patient through a robust diabetes education program using a motivational interviewing model in form of counseling sessions. This must be tailored to the individual needs and understandings. Dietary information must take into account locally available food and exercise preference must also be taken into consideration.
- 2) Comprehensive and robust strategies for diet and exercise recommendations should be incorporated as part of total primary health care for people with type 2 diabetes. These strategies must be based on multi-disciplinary team and collaborative approach, and should include individual and group interventions, inter-disciplinary focus including referral to non-primary care physician (such as dieticians, diabetes nurses and educators, and exercise experts) for ongoing patient's support and maintenance, and community resources.
- 3) People with diagnosed type 2 diabetes must be encouraged to express their concerns on lifestyle modification recommendations, especially, understanding and self-perceptions of lifestyle measures and perceived reasons for non-adherence. In the same vain, indoor exercise must be encouraged during intensely cold winter weather.
- 4) The health educator and primary care physician must ensured that people with type 2 diabetes identify their own support structures such as family members, spouse, friends and colleagues at work. It is the duty of health care provider to ensure that diabetic patient and their social support attends at least one session (preferably, first session) of adherence counseling on diet and exercise regimens. For example, inviting spouses to

- join sessions, especially if responsible for shopping and cooking at home (Burnet *et al*, 2005). Several studies demonstrated that the presence of social supports greatly improves adherence to therapeutic lifestyle measures.
- 5) The health educator and primary care physician must interpret (preferably in patient's language), for each diabetic patient, the short and long-term benefits of adhering to diet and exercise recommendations. Interpretations must be focusing on good glycaemic control, preventing and/or delaying diabetic complications, less frequent follow-up visits to health care facility, and good quality of life.
- 6) Healthy eating habits and gentle aerobic exercise should be encouraged as adjunctive therapy for people with type 2 diabetes. This recommendation must be incorporated as part of a total diabetes care and must be adapted to individual's ability, needs and limitations. People with type 2 diabetes should engage in 30-45 minutes of moderate aerobic exercise, such as brisk walking or cycling, at least 5 times per week in order to achieve and maintains good glycaemic control. Similarly, self-monitoring of fat and calorie intake should be encouraged using structured meal plans and locally available meal replacement. This strategy is known to improve adherence to lifestyle measures.

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APPENDIX ONE

RESEARCH PROTOCOL

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RESEARCH TITLE

NON-ADHERENCE TO LIFESTYLE MODIFICATION RECOMMENDATIONS (DIET & EXERCISE) AMONGST TYPE 2 DIABETES MELLITUS PATIENTS ATTENDING EXTENSION II CLINIC IN GABORONE, BOTSWANA

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TABLE OF CONTENTS

		Page
1.	INTRODUCTION:REASON AND MOTIVATION	54
2.	LITERATURE REVIEW	55-57
3.	AIM AND OBJECTIVES OF THE STUDY	58
4.	RESEARCH QUESTION	58
5.	METHODS	59-61
6.	ETHICAL CONSIDERATIONS	62
7.	REFERENCES	63

8.	APPENDIX I (QUESTIONNAIRE- ENGLISH & SETSWANA)64-77
9.	CONSENT FORM (MODIFIED)78-79
10.	CLEARANCE CERTIFICATES80-82
11.	IMPLEMENTATION TIME FRAME83
12.	RESEARCH BUDGET ESTIMATE8

INTRODUCTION

REASON AND MOTIVATION

The researcher in this study intends to investigate non-adherence to lifestyle modification (dietary habits and exercise) amongst type 2 diabetes mellitus patients at Extension II clinic in Gaborone, Botswana. The trigger for conducting this study was an observation by him at his practice, that most patients with type 2 diabetes mellitus were non-adherent to lifestyle modification and therefore, presented with poor glycaemic control.

Diabetes afflicts large numbers of people of all social class throughout the world. The personal and public health problem of diabetes, already of vast proportions, continues to grow despite exciting advances in the past few years in virtually every field of diabetes research and in patient care (e.g. improved treatment, protection against complications, improved lifestyles and even primary prevention of some form of diabetes)¹. Type 2 diabetes constitutes about 85% to 95% of all diabetes in developed countries and account for even a higher percentage in developing countries.² Studies have shown that lifestyle modification such as healthy diet and exercise are the cornerstones of type 2 diabetes management. Similar studies support diet and exercise as interventions to improve and maintain glycaemic control for people with diagnosed type 2 diabetes.

LITERATURE REVIEW

Diabetes Mellitus is recognized as a group of heterogeneous disorders with the common elements of hyperglycemia and glucose intolerance due to insulin deficiency, impaired effective insulin action, or both. Type 2 diabetes is characterized by insulin resistance and relative insulin deficiency, either of which may be present at the time that diabetes become clinically manifest. The specific reasons for the development of these abnormalities are not yet known.²

Diabetes Mellitus is rapidly emerging as a major public health problem. It is a chronic debilitating disease, but early detection and effective management may be associated with a

normal lifespan and quality of life. It is a multi-faceted disorder and inflicts a tremendous economic burden on patients, families and health care providers³ and a common, costly condition associated with significant morbidity and mortality. It is now one of the most common non-communicable diseases globally. Diabetes is the fourth or fifth leading cause of death in most developed countries and there is substantial evidence that it is epidemic in many developing countries including Botswana, and newly industrialized nations.²

About 194 million people worldwide or 5.1% in the age group 20-79 was estimated to have diabetes in 2003. This estimate is expected to increase to some 333 million, or 6.3% of the adult populations by 2025. The largest proportional and absolute increase will occur in developing countries where the prevalence will rise from 4.2% to 5.6%. By 2025, the adult diabetic population is expected to double in India to about 72 million and in china to 46 million. At the same time, diabetes prevalence is expected to increase to 2.8% of the adult population in Africa and 7.2% in South and Central America. The European region, with 48 million and Western Pacific region with 43 million currently have the highest number of people with diabetes.²

Type 2 diabetes is now a common and serious global health problem, which for most countries, has evolved in association with rapid cultural and social changes, ageing populations, increasing urbanization, dietary changes, reduced physical activity and other unhealthy lifestyle and behavior patterns.²

ADHERENCE/NON-ADHERENCE TO LIFESTYLE MODICATION

Adherence implies to follow closely or without deviation mutually agreed collaborative approach to care (including lifestyle modification recommendations) in form of a partnership between the patient and health care provider. Adherence to treatment is referred to as the characteristics of the behavior that defines the extent to which a patient follows a medical treatment⁴. Non-adherence to lifestyle modification recommendations occurs when patient deviates completely (i.e. below acceptable level of adherence) from mutually agreed collaborative approach to behavior/lifestyle changes. Patient adherence, especially to recommended behavioral interventions and lifestyle modifications, is notoriously difficult to achieve, but essential to the success of managing chronic diseases including type 2 diabetes mellitus⁵. Lifestyle modification encompasses weight control/weight loss for overweight and obese patients, exercise program/increase physical activity, stop smoking or avoid starting at all, and healthy diet including reduction in alcohol intake, are hard for patient to initiate and even harder to maintain especially middle age and elderly^{5,7}. Adherence becomes a more complex issue when psychological, emotional, social and family characteristics of living with chronic diseases including type 2 diabetes mellitus come into play⁵.

Rate of non-adherent patients to lifestyle modification recommendations have been reported to range from 40 to 50% and some experts estimate that non-adherence to lifestyle changes is even higher⁵. Similar study reports rates of non-adherence to diet plan and exercise recommendations from 35 to 75% and 70 to 81% respectively⁶. In type 2 diabetes patients, non- adherence to lifestyle modification ranged from 35% to 75% and some patients justify their non- adherence on

basis of economic factors, interpersonal problems with spouses and families, and other factors.⁷ Non- adherent patients may be experiencing some sort of barrier to adhering to the recommended lifestyle modification. Such barriers may include 'lack of communicative relationship between the patient and health care professional, lack of psychosocial and emotional supports, health beliefs that are incompatible with the recommendations, socio-economic factors, stressful environment' and e.t.c.

AIM AND OBJECTIVES OF STUDY

AIM

To investigate non-adherence to lifestyle modification recommendations in type 2 diabetes mellitus patients at Extension II clinic in Gaborone, Botswana.

OBJECTIVES

- To determine the prevalence of non-adherence to lifestyle modification recommendations (diet & exercise) in type 2 diabetes mellitus patients;
- To establish the reasons non-adhering patients give for not adhering; and
- To establish the perceptions of patients on the role of lifestyle modification (diet & exercise) in the management of type 2 diabetes mellitus.

RESEARCH QUESTION

Why are type 2 diabetes mellitus patients non-adherent to lifestyle modification recommendations at Extension II clinic in Gaborone, Botswana?

METHODS

- **5.1: STUDY DESIGN-** A descriptive quantitative study using self-administered questionnaire.
- **5.2: STUDY POPULATION** -Consenting adults diagnosed with type 2 diabetes mellitus on clinic care for two or more years. Adult here refers to age from 30years and above.

Inclusion criteria are type 2 diabetes mellitus diagnosed two or more years on clinic care.

Exclusion criteria include type 1 diabetes; type 2 diabetes diagnosed less than 2 years and nonclinic attendants.

5.3: SAMPLE SIZE - With a study population of 40 patients per month, using a confidence level of 95% and power of 80%, the sample size will be 96 (at default population size of 999999) over 3 successive months. For ease of calculation, sample size of 35 per month will be drawn

from the study population; hence the study sample size will be 105 over a period of 3 successive months.

5.4: SAMPLE SELECTION - Convenience sampling method will be used in the study. Over a period of 3 months, guided by the inclusion criteria every patient consulted will be requested to participate in the study. This process will continue until sample size of 105 is accumulated over a period of 3 months (i.e. 35 participants per month). In the event of dissent by approached patient, successive consenting patient will be selected to fill the gap and then the selection continues.

5.5: DATA COLLECTION - Self-administered questionnaire will be used in the study. The questions will be formulated according to a model established during the literature study and from related study (modified questions). The questionnaire will comprise yes/no and multiple – choice with or without closed – ended questions. Demographic data excluding name will be included to contextualize responses. The questionnaire will be handed over to the respondents to complete (with the help of a research assistant) after an informed consent and their willingness to participate.

The research assistant (a nurse will be trained by the researcher for the study), an indigene will help to clarify in local language any instruction(s) or item(s) not understood by the participants. The English version of the questionnaire was translated by translator 'A' to a local language (Setswana) and for reliability purposes, an independent translator 'B' was given the Setswana version of the questionnaire to translate to English and linguistics was compared, which produced same meaning. The interpretation will be done by an expert in linguistics who will also do back translation to ensure accuracy and consistency of the translation.

5.6: PILOT STUDY- The researcher had intended conducting a pilot study. However, obtaining permission with Ministry of Health in Botswana without MCREC certificate is very difficult. It is in that light, that it has been abandoned.

5.7: DATA ANALYSIS - Descriptive statistics will be used to get baseline data. Results will be carefully selected and organized into summary tables and graphs (Data tabulation, Frequency table and percentage, bar chart) to demonstrate relevant and important aspects of the results including trends, similarity, differences, and deviations across the respondents. The researcher will determine the prevalence of non-adherence to lifestyle modification recommendations in type 2 diabetes mellitus patients. SPSS 14.0 for windows software will be used to analysis the data.

5.8: RELIABILITY AND VALIDITY- Reliability is the extent to which test scores are accurate, consistent or stable. Validity refers to the extent to which a research design is scientifically sound or appropriately conducted.⁸ Congruity in response and interpretation will be maintained by translating and back translating of questionnaire and responses in local language (Setswana).

The choice of study participants on care for two or more years, achieves recruitment of those with relative insight into the disease-condition and implication of lifestyle modification to form testable perception. Extraneous variables will be controlled by adhering to sample size of 105 participants, homogenous group of participants (those diagnosed two or more years) and selection of sample over a period of 3months.

5.9: BIAS- SELECTION BIAS- The restriction of participants to those diagnosed over 2 years and attending clinic may present selection bias that may limit generalization of findings and

study's inability to capture the views of those diagnosed less than 2 years. However, this will be checked by the use of convenience sampling method and statically power of a representative sample size.

PARTICIPANT'S BIAS- The possible impact of researcher's expectation of the participants may have a Hawthorne's effect but will be reduced by self administration of questionnaire and anonymity, the assured anonymity of response.

LANGUAGE BIAS- The researcher has little knowledge about the local language (Setswana) which may introduce bias in understanding the participants' views but this will be checked by the use of a local research assistant.

ETHICAL CONSIDERATIONS: I will explain the purpose of the research study, seeks informed consent, respecting confidentiality of research participants as well as making participation voluntary. Permission from relevant authorities will be sought; Botswana Research and Ethic Committees will be requested to grant clearance to conduct the study. Permission will also be sought from the Research Committee of the Department of Family Medicine and Primary Health Care, and Medunsa Campus Research Ethics Committee (MCREC) of the University of Limpopo.

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APPENDIX TWO

INSTRUMENT FOR DATA COLLECTON: QUESTIONNAIRE (ENGLISH VERSION) RESEARCH TITLE

Non-adherence to lifestyle modification recommendations (healthy dietary habits and exercise) amongst type 2 diabetes mellitus patient attending Extension II clinic in Gaborone, Botswana.

QUESTIONNAIRE TOOL

NB: You have agreed to answer questions on non-adherence to lifestyle modification recommendations in type 2 diabetes mellitus patients. Before proceeding with answering questions, you are reminded that your participation is completely voluntary and your responses will be handled confidentially. Information given will not bear your name or will not be traced to you in any form but will only be identified to be from an individual diagnosed with type 2 diabetes mellitus on clinic care for two or more years, so nobody will know that you are the one who answered these questions. When the study is completed and the data have been analyzed, these questions will be destroyed.

However, dissent or assent to participate will neither affect your care nor is there any immediate benefit to you from participating, but study if beneficial may directly improves the management of type 2 diabetes mellitus.

If you agree to this, you may return with this questionnaire to the registry where an assistant will direct you and clarify any instruction(s) or item(s) not understood.

SECTION A: DEMOGRAPHICS

Please tick the appropriate response inside the box.

1.	Please indicate your sex. Male	_
	Female	_
2.	Please indicate your age group by ticking the appropriate box. 30 – 39 years	
	40 – 49 years	
	50 – 59 years	
	60 – 69 years	
	70years and above	
2		
3.	Please indicate your marital status. Single	
	Married	
	Divorced	
	Separated	
	Widowed	
	Co-habiting/living- in	
4.	Please indicate your highest educational level.	
	None	
	Primary	
	Secondary	
	Tertiary	
5.	Please indicate your employment status. Unemployed	

	Pensioner			
	Housewife			
SECT	ION B: PERCEPTIONS RELATED TO LIFESTYLE MODIF	<u>ICATION</u>		
RECO	OMMENDATIONS (DIET & EXERCISE			
	This section contains questions to determine the perceptions of patients on the role of lifestyle modification recommendation in the management of type 2 diabetes mellitus.			
6)	Please indicate below your understanding of lifestyle modification the management of type 2 diabetes mellitus.	on recommendations in		
	Gentle aerobic exercise only			
	Healthy dietary habits only			
	Both gentle aerobic exercise & Healthy dietary habits			
	Other			
7)	Do you feel that gentle aerobic exercise has a role to play in the diabetes mellitus? Yes	e management of type 2		
	No			
	If NO, please proceed to question 9.			
8)	Do you think that gentle aerobic exercise helps to control and n level?	naintain glucose (sugar)		
	Yes			

Employed _____

	No	
	Do you feel that healthy dietary habit has a role to play in the management of type diabetes mellitus?	e 2
	Yes	
	No	
	If NO, please proceed to question 11	
	Do you think that healthy dietary habit helps to control and maintain glucose (suglevel? Yes	ar)
ar ari	No	
	ON C: ADHERENCE/NON-ADHERENCE TO LIFESTYLE MODIFICATION	
RECO	<u>MMENDATIONS</u>	
	ction contains questions to establish whether or not type 2 diabetes mellitus patients g to lifestyle modification recommendations (diet and exercise)	are
Please t	ick the appropriate option inside the box.	
	Do you adhere to any form of gentle aerobic exercise recommendations (i.e. do y exercise for a minimum of 30 minutes per day for at least 3 days/week)? Yes	/ou
	No	
	If NO, please proceed to question 15.	
	If YES, what kind of gentle aerobic exercise recommendations are you adhering to? Brisk walking	
	Cycling	
	Jogging	
	Sport activities	
	Other	
13)	How often do you adhere to gentle aerobic exercise recommendations?	

Once daily	
Once weekly	
At least thrice weekly	
Once monthly	
Other	H
14) What is the duration of your gentle aerobic exercise per session? Less than 10 minutes	
10 – 19 minutes	
20- 29 minutes	
30 – 39 minutes	
40 minutes and above	
15) Do you adhere to any form of healthy dietary habit recommendation Yes	ns?
No	-
If NO, please proceed to question 18.	
16) If YES, what kind of healthy dietary habit recommendations are you	ou adhering to?
(You may tick more than one option)	
High starch and fiber diets	
Low saturated fat and caloric intake	
Fruits & vegetables	
Regulated alcohol intake and smoking cessation	
Eat more of sugar, Carbohydrate and fat meals	
Eat any kinds of food	
Other	
17) How often do you adhere to healthy dietary habit recommendations	s?

Once weekly
At least thrice weekly
Once monthly
Other
SECTION D: TO BE ANSWERED BY NON-ADHERERS
SOCIO – ENVIRONMENTAL VARIABLES I.E. REASONS FOR NON-ADHERING TO LIFE STYLE MODIFICATION (DIET & EXERCISE)
Please tick the option (s) that expresses your view about each of the statements describing reasons for non-adherence to lifestyle modification (i.e. what is preventing you?) You may tick more than one option.
18. From the following list, Please indicate reason(s) for non-adherence to exercise.
Too busy schedule
Weather (especially during winter)
Lacking exercise partner/spouse
Specific locations away from home (e.g. Cattle post, trips)
Criticism (presence of others make you uncomfortable)
Others
19) From the following list, please indicate reason (s) for non-adherence to dietary habits/prescriptions.
Eating out (restaurant, ceremonies, work, family & friends' homes)
Inappropriate dietary habits (e.g. eating snacks in-between meals)
Financial constraints (to procure idea healthy diets)
Poor self control

Once daily_____

Granting self permission (e.g. just this once, a little won't hurt)
Another's home (e.g. Cattle post, on trips)
Situations at home (e.g. I eat non-healthy diets when alone)
Other
Please tick the appropriate option inside the box.
20) Do you view exercise as potentially exacerbating illness i.e.as negative physical reactions such as physical weakness, body pain, sickness or ageing?
Yes
No
21) Have you ever received detailed written instruction regarding exercise programs from any health care provider?
Yes
No
22) Have you ever received detailed written instruction regarding healthy dietary habits from any health care provider?
Yes
No
23) Do you enjoy any form of moral and/or emotional supports from your spouse/partner towards adhering to lifestyle modification recommendations?
Yes
No
24) Do you consistently receive moral and/or emotional supports from your family members towards adhering to lifestyle modification recommendations?
Yes

No
25) Do you consistently receive friends' support towards adhering to lifestyle modification recommendations?
Yes
No
Thank you very much for your participation and completing this questionnaire.
QUESTIONNAIRE: SETSWANA VERSION
SEDIRISIWA SA GO TSAA MAELE- POTSOLOSO
Go tlhoka go fetola botshelo/boitshwaro mo balwetseng ba bolwetse jwa sukiri ya mofuta wa bobedi mo kokelwaneng ya Ext 2 mo Gaborone, Botswana.
SEDIRISIWA SA POTSOLOSO
LEMOGA: O dumalane go araba dipotso mo mabakeng a go tlhoka go fetola maitsholo a botshelo mo balwetseng ba mohuta wa bobedi wa bolwetse jwa sukiri. Pele fa o tswelela le go araba dipotso, o gakololwa gore go tsaa karolo ga gago ke ga boithaopo, tota le dikarabo tsa gajo e tla nna sephiri. Polelo e e tla fiwang ga e na go nna le maina a gago kgotsa ga e na go salwa morago mabapi le wena, ka tsela epe, mme e tla kaiwa e tswa mo mongweng yo o lwalangolwetsi jwa sukiri jwa mohuta wa bobedi mo tlhokomelong ya kokelo mo dingwageng tse pedi kgotsa go feta, jalo ga gona ope yo o tla itseng gore ke wena yo o arabileng dipotso tse. Fa dipatlisiso tse di sena go nna di dirwa le polelo e sena go sekasekiwa, dipotso tse di tla senngwa
Le fa go ntse jalo, go gana kgotsa go dumalana le go tsaa karolo ga gago ga gona go ama tlhoko melo ya gago ka gope e bile ga gona sepe se o tla se neelwang mo go tseeng karolo, mme dipatlisiso fa e le gore di ka nna mosola di ka tokafatsa kalafi ya bolwetse jwa sukiri.
Fa o dumalana le se o ka nna wa busetsa pampiri e ya potsoloso ko bokwaleding ko mothusi a tl go kaelang a bo a tlhalosa ditaelo tse o sa di tlhaloganyang mo puong ya setswana.
KAROLO YA NTLHA: POLELO KA WENA
Γswee tswee supa ka go tshwaa mo lebokosong se se tshwanetseng.
1) Supa bong jwa gago. Rre

2)	Supa setlhopha sa dingwaga tsa gago Dingwaga; 30 -39	
	Diligwaga, 30 -39	_
	40 -49	
	50 -59	_
	60 -69	
	70 – Le go feta	
		_
3)	Supa maemo a gago a lenyalo.	
	O nosi	
	O nyetswe/nyetse	
	O tlhadilwe	
	Le kgaogane	
	O tlhokafaletswe	
	Le nna mmogo	
4)	Supa maemo a gago a thuto Ga ke a tsena sekolo	
	Sekolo se sebotlana	
	Se se golwane	
	Se segolo	
5)	Supa maemo a gago a mmereko. Ga ke bereke	
	Ke a bereka	
	Dituelo tsa bogodi	
	Mme wa mo lwapeng	

KAROLO YA BOBEDI

BOITSHWARO/DITIRO TSE DI AMANANG LE KA FA MOTHO AKA TSHELANG KA TENG GO TOKAFATSA BOTSHELO JWA GAGWE

Karolwana e ena le dipotso tse dika supang gore a balwetse ba ba sukiri ba fetola seemo sa botshelo jwa bone kgotsa jang

Tshwaa karabo ee lebaneng

6)	Tswee tswee tshwaa ka fa o tlhaloganyang boitshwaro jwa gago ka teng mabapi le Mofuta wa bobedi wa sukiri.
	Go itshidila mo go motlhofo
	Go ja dijo tse di itekanetseng
	Go itshidila le go ja dijo tsedi itekanetseng
	Tse dingwe
7)	A o ikutlwa fa go itshidila mo go itekanetseng go na le mosola mo go alafeng bolwetse jwa sukiri ya mofuta wa bobedi?
	Ee
	Nnyaa
	Fa o rile nnyaa fetela ko potsong ya bofera bongwe
8)	A o akanya gore go itshidila mo go le kanetseng go ka laola selekanyo sa sukiri?
	Nnyaa
9)	A o akanya gore go ja dijo tsedi itekanetseng go ka thusa mo go alafeng bolwetse Jwa sukiri ya mofuta wa bobedi?
	Ee
	Nnyaa
	Fa o rile nnyaa, fetela ko potsong ya lesome le bongwe
10)	A o akanya gore dijo tse di itekanetseng di ka thusa go laola selekanyo sa sukiri?
	Nnyaa

KAROLO YA BORARO:GO ITSHWARA SENTLE KANA GOSA ITSHWARENG SENTLE MABAPI LE KA FA O TSHELANG KA TENG

Karolo e ena le dipotso tse ka tsone o ka itseng gore a balwetse ba mofuta wa sukiri wa bobedi baka kgona go fetola ka fa ba tshelang ka teng

Tswee tswee tlhopa mo go siameng.

11) A o atle o itshidile mo go lekanetseng?			
Ee			
Nnyaa			
Fa o rile nnyaa, fetela ko potso ya lesome le botlhano.			
12) Fa e le ee, ke mohuta ofe wa mananeo a itshidilo? Go tsamaya tsamaya			
Go dirisa baesekele			
Go tlolatlola			
Tsa metshameko			
Tse dingwe			
13) O itshidila ga kae?			
Gangwe ka letsatsi			
Gangwe ka beke			
Gararo ka beke			
Gangwe mo kgweding			
Tse dingwe			
14) O tsaa lebaka le le kae fa o itshidila?			
Metsotso e e ko tlase ga 10			
Metsotso 10 - 19			
Metsotso 20 - 29			
Metsotso 30 - 39			
Metsotso 40 - le go feta			
15) A o sala dingwe ditaelo tsa go ja morago?			

Ee-		
Nn	yaa	
Fa	ele gore karabo ya gago ya potso ee fa godimo ke nnyaa araba potso 18.	
16) F	a o rile ee, ke mofuta o fe yoo kgonang?	
D	ijo tse dinang le moroko o montsi[
M	lafura a mannye	
N	Maungo le merogo	
C	Gonwa bojwalwa jo bo lekanetseng le go sa gogeng motsoko	
G	o ja dijo tse di sukiri e ntsi, le tse di mafura	
O	ja dijo dingwe le dingwe	
T	se dingwe	
17) O) fetola gole kae go ja ga gago?	
G	angwe ka letsatsi[
G	angwe ka beke	
G	araro mo bekeng	
G	angwe ka kgwedi	
T	se dingwe	
	D D- KAROLO E E TSHWANETSE GO ARABIWA KE BABASA KO DLA BOITSHWARO JWA BONE	ONI
a itshole	elo le tikologo	
ıbaka aa	a itsang go sela ditaelo tsa go fetola ka fa o tshelang ka teng.	
•	a o bonang go supa mabaka a a go itsang gore o ka fetola ka fa o tshelang kag).O ka tshwaya mabaka a le mantsi	ı teng
Mo ma	abakeng a latelang, supa a dirang gore o seka wa kgona go itshidila sentle.	
O nna	o tshwaregile	
Seemo	sa loapi bogolo jang mariga	

O tlhoka molekane yoo ka itshidilang le ene	
O kgakala le ko o nnang teng (moraka kana o ko ntle ka tsa tiro)	
O kgalwa ke batho(ga o nne sentle fa ole mo gare ga batho)	
Tse dingwe	
19) Mo mabakeng a a latelang tshwaya lebaka/mabaka a a dirang gore o palelwe k melawana ya go ja morago Go ja ko marekisetso a dijo, meletlo	
Go sa boneng dijo sentle (mo go ba masika le lelapa)	
Letlhoko la madi (Go ka reka dijo tse di siameng)	
Go palelwa ke go laola keletso ya dijo	
Go ipha tetla (Gore gangwe fela ga go bolae)	
Mabaka a mafelo mangwe (jaaka meraka)	
Mabaka mo lapeng (Fa kele mo lapeng ga je dijo tse di siameng)	
Tse dingwe	
Tshwaa mo go tshwanetseng	
20) A o tsaya go itshidila go go okeletsa bolwetse, go bitsa ditlhabi mo mmeleng Ee	
Nnyaa	
21) Ao kile wa amogela lenaneo la itshidilo mo go ba botsogo	
Ee	
Nnyaa	
21) A o kile wa amogela lenaneo lengwe mo go ba botsogo le le supang ka fa o tshwanetseng go ja ka teng Ee	
Nnyaa	
22) A o itumelela thotloetso gotswa mo molekaneng wa gago ka go fetola botshelo gago?	jwa

Ee		
Nnyaa		
23) Ao bona thotloetso mo go ba lesika ka go fetola boitshwaro jwa botshelo Ee	, <u> </u>	
Nnyaa		
24) A o bona thotloetso mo ditsaleng tsa gago mabapi le go fetola ka fa o tsl Ee		teng?
Nnyaa		

 $\ensuremath{\mathrm{Ke}}$ leboga thata mo go tseyeng karolo mo go arabeng dipotso tse.

Dr.Adewale.B.Ganiyu

APPENDIX THREE

APPROVED CONSENT FORM (MODIFIED)

Iexperimental research stu habits and Exercise) in ty from individual with diag	udy: non-adherenc ype 2 diabetes me	ce to lifestyle mod llitus patients. I un	lificatior nderstan	n recommend ad that study	lations (D participan	vietary nts are
The researcher has expla Research findings, if ber with diagnosed type 2 dia	neficial may direct	•	•		•	
I understand that my part handled confidentially. A	-	• •		•	sponses w	vill be
I know that Medunsa C Limpopo has approved the will be used for scient confidentiality is guarant	his study. I am ful ific purposes and	lly aware that resu	ilts obta ned. I a	ined at the en	nd of this , provide	study ed my
Participant's Signature			W	itness (Resea		
-	Place	Date				
STATEMENT BY THE	<u>RESEARCHER</u>					
I provided verbal inform pertaining to this study as		•	-	-	uture que	stions

Signature Place Date

<u>NB:</u>

1) For information on the rights of the participants in the study, please contact. Ms G. Tubatsi

Health research Unit

Ministry of Health, Gaborone

+267-3632466

2) For information related to research study, please contact.

Dr Adewale. B. Ganiyu

Department of Primary Health Care/Public Health

Gaborone City Council

+267-72875429

UNIVERSITY OF LIMPOPO

Medunsa Campus



MEDUNSA CAMPUS RESEARCH & ETHICS COMMITTEE

CLEARANCE CERTIFICATE

P O Medunsa Medunsa 0204 SOUTH AFRICA

MEETING:

02/2008

Tel: 012 - 521 4000

PROJECT NUMBER: MCREC/M/12/2008: PG

Fax: 012 - 560 0086

PROJECT:

Title:

Patients' perspectives on reasons for non-adherence

to lifestyle modification (healthy dietary habits and exercise) amongst people with type 2 diabetes mellitus attending

extension II clinic in Gaborone, Botswana

Researcher:

Dr AB Ganiyu

Supervisor:

Dr LH Mabuza Mrs NH Malete

Co-supervisor: Hospital Superintendent:

Dr GM Ilunga (Gaborone City Council Clinics)
Family Medicine & Primary Health Care

Department:

Medicine

School: Degree:

M Med (Fam Med)

DATE CONSIDERED: March 05, 2008

DECISION OF THE COMMITTEE:

MCREC approved the project.

DATE:

March 05, 2008

PROF GA OGUNBANJO

DIRECTOR: RESEARCH & CHAIRPERSON MCREC

Note:

- Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.
- The budget for the research will be considered separately from the protocol. PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.

African Excellence - Global Leadership

APPENDIX FIVE

TELEPHONE: 3632000

FAX:3914467

TELEGRAMS:RABONGAKA TELEX: 2818 CARE BD



MINISTRY OF HEALTH PRIVATE BAG 0038 GABORONE BOTSWANA

REPUBLIC OF BOTSWANA

REFERENCE No: PPME-13/18/1 PS Vol III (20)

June 2, 2008

Dr Adewale B. Ganiyu P.O. Box 80976 Gaborone

Permit: NON ADHERENCE TO LIFESTYLE MODIFICATIONS RECOMMENDATIONS IN TYPE 2 DIABETES MELLITUS PATIENTS AT EXTENSION II CLINIC

Your application for a research permit for the above stated research protocol refers. We note that you have satisfactorily revised the protocol as per our suggestions.

Permission is therefore granted to conduct the above mentioned study. This approval is valid for a period of 1 year effective June 2, 2008.

This permit does not however give you authority to collect data from the selected clinic without prior approval from the management of the clinic. Consent from the identified individuals should be obtained at all times.

The research should be conducted as outlined in the approved proposal. Any changes to the approved proposal will need to be resubmitted to the Health Research Unit in the Ministry of Health.

Furthermore, you are requested to submit at least one hardcopy and an electronic copy of the report to the Health Research Unit, Ministry of Health within 3 months of completion of the study. Approval is for academic fulfilment only.

Thank you,

Mokopakgosi

For/Permanent Secretary Ministry of Health



All correspondence should be addressed to the

TOWN CLERK

Private Bag 0089 Telephones: 3657400 Tel. Add.: 'CIVIC' GABORONE BOTSWANA

Fax: 3900141

Reference: GCC/H/8

Date: June 6, 2008

To: Dr Adewale B. Ganiyu P.O. Box 80976 Gaborone

Re: Permission to conduct a study at Extension 2 Clinic.

Reference is made to your letter dated 2nd June 2008 concerning the recruitment of participants in Extension 2 Clinic for a study on "Non-Adherence to Lifestyle Modification Recommendations in Type 2 Diabetes Mellitus Patients" as fulfillment of the requirements for your Masters Degree in Family Medicine.

Considering the relevance of the study at this period where non-communicable diseases are gaining increasing interest in the Country, and in view of the approval letter authorizing the study by the Health Research Unit, Ministry of Health, Gaborone City Council is hereby granting you permission to recruit study participants in Extension 2 Clinic.

Please be advised that you are not authorized to utilize either for free or for remuneration any Government officer working in the facility as study assistant to administer the questionnaire. Failure to comply with this condition will result in this authorization being nullified.

It goes without say that you are requested to adhere strictly to the ethical conditions of informed consent and confidentiality.

The Matron, Nurse-in-charge and staff of Extension 2 Clinic are hereby informed and requested to allow access and give all the necessary support and cooperation to your study team.

Wishing you good luck,

Dr P. N. Mihigo, MD, MPH Chief Medical Officer

For Town Clerk.

IMPLEMENTATION TIME FRAME

Research Protocol development	_ February 2008				
Approval of the Research Protocol	_ March – April 2008				
Data Collection	_ June – August 2008				
Data Analysis	August - September 2008				
Report Writing	_ January -June 2009				
Submission of Dissertation	_ July 2009.				
RESEARCH BUDGET ESTIMATE					
Materials {including stationeries}	P1200				
Computer work, recording and printing	_ P1300				
Research Assistant (P250 per month)	_ P750				
Project and Transport	_ P300				
Logistics/Miscellaneous	_ P500				
Total	_ P4050 {approx. \$630}				
{P=Pula, Botswana currency, \$=United States dollars}					