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#### Publications and Presentations Arising from this Study

#### Articles Submitted

Habitual Physical Activity among an African Cohort of Type-2 Diabetics in a South African Resource-Poor Community Setting. Submitted to the Journal of Public Health Nutrition. (Chapter 2).

Effects Of Progressive Resistance Exercise On Glycosylated Haemoglobin (HbA<sub>1C</sub>) And Lipid Profiles In Subjects With Type 2 Diabetes Mellitus. Submitted to the British Medical Journal. (Chapter 3).

The Efficacy of a 20-Week Progressive Resistance Training (PRT) Programme on Morphological, Musculoskeletal and Aerobic Fitness in Subjects with Type-2 Diabetes Mellitus. Submitted to the Journal of Exercise Science and Fitness. (Chapter 4).

Influence of a Dietary Education Programme on Diabetes Care Knowledge and Activities among Type-2 Diabetics. Submitted to the International Journal of Diabetes in Developing Countries. (Chapter 5).



#### Papers Presented

12th Asian Federation of Sports Medicine Congress, 1-6 December 2009, Amritsar India. Habitual Physical Activity among an African Cohort of Type 2 Diabetics in a South African Resource-Poor Community Setting.

12th Asian Federation of Sports Medicine Congress, 1-6 December 2009, Amritsar, India. Influence of a Dietary Education Program on Diabetes Care Knowledge and Activities among Type 2 Diabetics.

Pre-Olympic Conference on Science, Education and Medicine in Sport, 1-5 August 2008, Guangzhou, China. Effect of Resistance Exercise on HbA<sub>1c</sub> and Lipid Profiles in Subjects with Type 2 Diabetes Mellitus.

South African Sports Medicine Association Biennial International Conference, 15 & 16 November 2007, Pretoria, South Africa. Efficacy of Progressive Resistance Training on Morphology and Musculoskeletal Fitness in People with Type 2 Diabetes.

South African Sports Medicine Association Biennial International Conference, 15 & 16 November 2007, Pretoria, South Africa. Efficacy of Resistance Training on Aerobic Function and Perceived Exertion in Patients with Type 2 Diabetes Mellitus.

South African Society for Endocrinology and Metabolic Diseases (SEMDSA) Congress, 30 June - 2 July 2007, Bloemfontein, South Africa. Effects of Progressive Resistance Exercise on Glycosylated Haemoglobin (HBA<sub>1C</sub>) and Lipid Profile in Black Subjects with Type 2 Diabetes Mellitus (DM).

South African Sports Medicine Association Biennial International Congress, 28-30 September 2005, Johannesburg, South Africa. Habitual Exercise Practices among African Women with Type 2 Diabetes Mellitus in SA: Mamelodi Diabetes Project.



#### Chapter 1

#### **General Introduction**

#### 1.1 Background, Prevalence, Impact and Aetiology of Diabetes Mellitus

Diabetes mellitus is a chronic disorder of carbohydrate, fat and protein metabolism. Diabetes mellitus represents a heterogeneous group of disorders that have hyperglycemia as a common feature. There are two distinct forms of diabetes, termed type-1 diabetes mellitus formerly labelled as "insulin dependent" and type 2 diabetes mellitus previously known as "non-insulin dependent diabetes mellitus". Type 2 diabetic patients need insulin for their wellbeing but not for The value of this simple and useful classification relies on the survival. recognition of the mechanisms underlying the development of the two types of diabetes mellitus. The identification of diabetes as type-1 diabetes mellitus is primarily achieved by clinical observation and simple investigations, although the condition can be further defined by genetic and immunological markers. Insulin dependence, the hallmark of type-1 diabetes, necessitates insulin injections in order to survive. Type-1 diabetes mellitus appears to be an auto-immune disease in which the body attacks and ultimately destroys insulin-producing pancreatic beta cells in an inflammatory reaction [1]. The pathogenesis in type 2 diabetes mellitus is such that although the pancreas produces insulin, the body does not utilise the insulin correctly. This is primarily due to insulin resistance in peripheral tissue, where the insulin-receptors within the body cells are insensitive to insulin resulting in glucose not readily entering the tissues [2], thus ultimately leading to hyperglycemia or elevated blood glucose concentrations [3]. This increase in blood glucose in turn stimulates the beta cells of the pancreas to secrete more insulin in an attempt to maintain a normal blood glucose concentration. Insulin resistance is often associated with hypertension, lipid disturbances and obesity [4]. Apart from genetic dispositions, diet and obesity, animal experiments as well as epidemiological data suggest that a lack of physical activity may contribute to insulin resistance [5].



In comparison to type-1 diabetes mellitus much less is known about the potential pathogenesis of type 2 diabetes mellitus, despite it being the most common type. There is no evidence that auto-immune mechanisms are involved. Lifestyle clearly plays a role and obesity has been identified as a co-morbidity of type 2 diabetes mellitus [6, 7]. Although considered to be a disease in adulthood, there has been an epidemic increase in the incidence of type 2 diabetes mellitus in obese children, particularly among Black Africans, Hispanics, Native Americans, and Asians [4]. Diabetes has been called the "new world syndrome" [8], a symptom of globalization with social, cultural, economic and political significance [9]. Apart from the impact on health, the economic cost of diabetes mellitus and its complications, the impact is enormous both in health-care and loss of productivity to society [9]. Diabetes mellitus will, in the future, constitute a heavy burden both for individuals affected and for the society in which they live [10].

#### Prevalence of Diabetes Mellitus

The incidence of type 2 diabetes mellitus is increasing markedly in adult populations around the world [11]. This is viewed as a growing chronic health problem, the complications of which cause significant morbidity and mortality [12]. Diabetes mellitus constitutes a growing global public health problem, with an increasing incidence from 30 million people ten years ago to about 135 million today [13] to an estimated 300 million in 2025 [14, 15]. As populations age and urbanize, and as obesity becomes more prevalent [16, 17], the incidence of type 2 diabetes mellitus increases proportionally.

The prevalence of type 2 diabetes mellitus is at its highest among the Pima Indians living in Arizona [18] and Polynesians. South Asians and West Africans are in the middle range, with European populations in the lowest range. Europeans could reflect a population predisposition to genetic susceptibility, and/or exposure to environmental factors [19]. The persistent elevated rates of type 2 mellitus among South Asian migrants several generations after migration to the UK, suggest that genetic factors play an important role [20].



A similar elevation in type 2 prevalence rates among urbanized Indian, Chinese and African migrants in Mauritius is testimony to the importance of environmental (lifestyle) factors [10], as does the five-fold difference in type 2 diabetes mellitus prevalence between rural and urban populations in Tamil Nadu in South India [20].

Care of diabetics in the African continent is fraught with numerous problems. The prevalence of diabetes mellitus among African adults appears to be lower than that reported in most industrial countries, however it has been estimated that at least one million people in Africa suffer from type 2 diabetes mellitus [21]. The continents identified with the largest potential future increase are Asia and Africa, where diabetes mellitus could increase two to three fold [13]. South Africa has diabetes mellitus prevalence of 4.5% and an impaired glucose tolerance prevalence of 51% [22]. Recent studies have indicated that the prevalence of type 2 diabetes mellitus is an increasing health concern among black South Africans. The age-adjusted prevalence of diabetes in urban settings in 2001 was found to be 8% in Cape Town and 5.3% in Durban [23]. Among peri-urban Xhosa speakers, the age-adjusted prevalence was found to be 4.5% [22] and in rural Kwa-Zulu Natal, 4.2% [24]. Diabetes care in South Africa is incongruent with the greatest need for care. From observation, highly trained health-care workers tend to be concentrated in metropolitan areas and render service to the affluent minority as opposed to rendering service in the rural, resource-poor areas of the country.

#### Aetiology of Type 2 Diabetes Mellitus

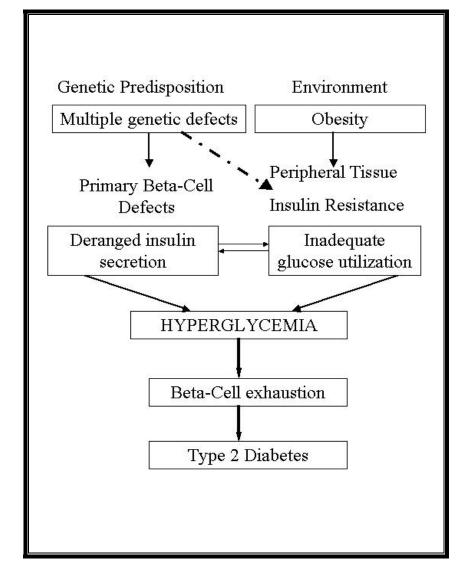
The main factors associated with the development of type 2 diabetes mellitus are genetic predisposition, increasing age, increasing body fat and environmental factors, such as urbanization and industrialization [25, 26]. Increased longevity and changes in lifestyle from a traditional healthy and active life to a modern, sedentary, stressful life coupled with the overconsumption of energy-dense food [11] [9], is also part of the aetiology.



Despite the variation in the prevalence of type 2 diabetes mellitus between populations and at the individual level, the most overt environmentally mediated epidemiological feature of type 2 diabetes mellitus is the strong positive correlation with relative body fat (Figure 1). Genetic factors exacerbate this condition and epidemiological studies indicate that type 2 diabetes mellitus appears to stem from a collection of multiple genetic defects, each contributing to its own pre-disposing risk and each modified by environmental factors. The two metabolic defects that characterize type 2 diabetes mellitus are a derangement in beta-cell secretion of insulin and an inability of peripheral tissue to respond to insulin (insulin resistance) [4].

Type 2 diabetes mellitus is generally viewed as a lifestyle disorder, most prevalent among populations with heightened genetic susceptibility [27]. Recent epidemiological evidence indicates that a majority of the world's population are prone to type 2 diabetes mellitus in the wake of increasing obesity [28], with Caucasians being a possible exception. This plausible evolutionary explanation relies on the old concept of hunter-gatherer genes that accounts for the rapid rise of type 2 diabetes in some populations. Neel (1962) postulated the theory of the existence of the "thrifty gene" [29]. According to Neel's theory early people lived in feast-famine cycles and the thrifty gene would have had selective advantages because it increased the ability of the body to store fat (energy) that could later be metabolized during periods of food shortage [30]. Accordingly, the 'thrifty" genotype would have been advantageous for hunter-gatherer populations, especially child-bearing women, because it would allow them to fatten more quickly during times of abundance. Individuals carrying the thrifty genes would thus better survive in times of food-scarcity. However, in modern societies with a constant abundance of food, this genotype efficiently prepares individuals for a famine that never comes. The result is widespread chronic obesity and predisposition to related health problems like diabetes.





# Figure 1: Pathogenesis of type 2 diabetes mellitus. Genetic predisposition and environmental influences converge to cause hyperglycemia and overt diabetes (Redrawn from Kumar, 2003)

In summary, type 2 diabetes mellitus has a heterogeneous and multi-genetic, complex aetiology [8, 31]. Most people who have type 2 diabetes mellitus are obese, have disturbances in lipid metabolism and suffer from hypertension [32, 33]. Diabetes mellitus needs to be treated using a holistic approach embracing dietary adjustments, physical activity and exercise, medication (if needed) and education.



#### 1.2 General Exercise Guidelines in Type 2 Diabetes Mellitus

The therapeutic role of exercise in type 2 diabetes mellitus is different to that in type-1 diabetes. Approximately 80% of people with type 2 diabetes are obese and insulin resistant and only about 35% require insulin therapy. Physicians often prescribe exercise in combination with diet and oral antidiabetic agents to achieve and maintain weight reduction and improve glycaemic control. Research has proven that regular physical activity protects against the development of type 2 diabetes in high-risk populations [34, 35]. Together with the treatment and prevention of obesity by dietary restriction, increased physical activity is an important component of lifestyle modification for people with impaired glucose tolerance, with a family history of type 2 diabetes, or with other risk factors for its development [36]. Exercise induced hypoglycemia and acute regulation of blood glucose are less of a problem in type 2 diabetes than in type-1 diabetes, however cardiovascular disease and musculoskeletal injuries are generally greater. People with type 2 diabetes mellitus can develop the same diabetes complications as those with type-1 diabetes mellitus, including retinopathy, nephropathy, neuropathy, and macrovascular disease, and must be screened for conditions before starting an exercise program [36].

# 1.2.1 Guidelines for General Exercise Training and Prescription: Effects on the Exercise Response

Under normal circumstances, in people without diabetes there is coordination between the hormonal and metabolic events which results in the maintenance of glucose homeostasis. Insulin and counter-regulatory hormone concentrations in people with diabetes do not respond to exercise in the normal manner and the balance between peripheral glucose utilization and hepatic glucose production may be disturbed [37]. The effects of diabetes on a single exercise session is dependant on several factors, including: use and type of medication to lower blood glucose levels (oral or insulin hypoglycemic agents); timing of medication administration; blood glucose level prior to exercise; timing, amount, and type of previous food intake, presence and severity of diabetic complications; use of other



medication secondary to diabetic complications and the intensity, duration and type of exercise [37].

#### 1.2.2 General Recommendations for Exercise Prescription

Exercise prescription for people with diabetes must be individualized according to medication usage schedule, presence and severity of diabetes complications, and goals and expected benefits of the exercise program [37]. Physical activity for those without significant complications or limitations should include appropriate endurance and resistance exercise for developing and maintaining cardiorespiratory fitness, body composition, and muscular strength and endurance. In general, one hour of exercise requires an additional of 15g of carbohydrate either before or after exercise. If exercising is vigorous and of long duration, an additional 15 to 30g of carbohydrate is needed every hour. Exercise is a contraindication if: there is active retinal hemorrhage or there has been recent therapy for retinopathy; illness or infection is present; blood glucose is above 13.8mmol/l (250mg/dl) and ketones are present (blood glucose should be lowered before initiation of exercise); or blood glucose is 4.4 to 5.5 mmol/l (80 to 100 mg/dl) because the risk of hypoglycemia is great (in this situation, carbohydrate should be eaten and blood glucose allowed to increase before initiation of exercise). Exercise precautions includes the following: keeping a source of rapidly acting carbohydrate available during exercise; consuming adequate fluids before, during and after exercise; practicing good foot care by wearing proper shoes and cotton socks, and inspecting feet after exercise; and carrying medical identification [37].

## 1.3 General Effects of Acute Exercise in Patients with Type 2 Diabetes Mellitus

#### 1.3.1 Blood Glucose Levels and Insulin Sensitivity

In healthy non-diabetic individuals, exercise has very little impact on blood glucose levels. In individuals with type 2 diabetes mellitus, exercise with either



moderate or heavy intensity is associated with decreases in blood glucose levels. A single bout of exercise often decreases plasma glucose levels [38], which progresses into the post-exercise periods. The blood glucose lowering effect of exercise in individuals with type 2 diabetes mellitus can be explained by the insulin-dependent activation of glucose transportation by exercise [39], as well as increased insulin sensitivity.

#### 1.3.2 Hormone Levels

Moderate to heavy exercise reduces insulin secretion and inversely the plasma insulin levels are reduced [38]. Glucagon and adrenaline levels increase during exercise. Glucose homeostasis is generally maintained during exercise because the increase in glucose utilization is matched by an increase in hepatic glucose production. The exercise-induced increase in glucagon and the fall in insulin levels can control the increase in glucose production. The important role of pancreatic hormones is the control of hepatic glucose production during exercise, the increase in glucose uptake in peripheral tissues is controlled primarily by insulin-independent mechanisms [4].

#### 1.3.3 Glucose Transport

The total skeletal muscle glucose transporter protein (GLUT 4) levels are increased in exercise trained middle aged individuals with either normal glucose tolerance or in individuals with type 2 diabetes mellitus, compared to sedentary individuals [40]. These individuals have improved insulin sensitivity, which is explained by increased GLUT 4 expression. Exercise is also a stimulator of glucose transportation [39]. In humans, insulin sensitivity is related to the degree of physical activity [36]. Exercise also enhances insulin sensitivity in obese individuals and those with type 2 diabetes mellitus [41]. In patients with type 2 diabetes mellitus, regular exercise training may enhance cellular glucose uptake. This improvement in insulin sensitivity may overcome defects in the insulin signal transduction pathway, seen in muscle tissue taken from individuals with type 2 diabetes mellitus [42].





## 1.4 General Long Term Effects of Exercise in Patients with Type 2 Diabetes Mellitus

#### 1.4.1 Metabolic Control and Insulin Sensitivity

Aerobic power is inversely related to modest, favorable changes in glycosylated haemoglobin and glucose tolerance [38, 43]. In certain studies [44-48], duration of physical activity ranged from 6 weeks to 12 months, and improved glucose tolerance was shown in early stages of type 2 diabetes [49]. Some studies also showed that mild-to-moderate physical activity ranging from 12 weeks up to 2 years did not improve glucose control in type 2 diabetic subjects [50, 51]. It was also noted that older diabetic individuals (e.g., over 55years) may not show the same exercise-induced blood glucose changes as usually seen in younger diabetic individuals [52]. Favorable changes in glucose tolerance usually deteriorates within 72 hours of the last exercise bout in those with type 2 diabetes [53] and are a reflection of the last individual exercise bout, rather than training per se [54]. Hence, regular physical activity is recommended for persons with type 2 diabetes to sustain glucose-lowering effects.

#### 1.4.2 Body Weight

In individuals with type 2 diabetes mellitus and obesity a diet-induced decrease in body weight is associated with the beneficial effect of improved metabolic control and reduced risk of ischaemic heart disease [55]. Patient compliance with weight loss programmes is often low and diet therapy alone is generally not sufficient to maintain weight loss on a long term basis [56]. Programmes which combine diet therapy and exercise are more successful in achieving bodyweight reduction in participants [43, 57].

#### 1.4.3 Cardiovascular Risk Factors

Exercise is associated with a decrease in serum triglycerides levels, particularly very low-density lipoproteins, and an increase in high density lipoprotein



cholesterol [38]. Physical activity has also been reported to lower blood pressure in hypertensive individuals [38, 43]. The latter adaptation occurs independent of weight loss and changes in body composition. Physical training has also shown to increase cardiovascular fitness and physical working capacity in individuals with type 2 diabetes mellitus [58].

#### **1.5** Resistance Training for the Management of Type 2 Diabetes Mellitus

Resistance training has been recognised as a useful therapeutic tool for the treatment of a number of chronic diseases [59-64], and has been demonstrated to be safe and efficacious for the elderly [65] and obese [66] individuals. Resistance training has been reported to enhance insulin sensitivity [67, 68], daily energy expenditure [68, 69], and quality of life [70]. Resistance training also has the potential for increasing muscle strength [69, 71], lean muscle mass [72], and bone mineral density [73] which could enhance functional status and glycaemic control and assist in the prevention of osteoporosis and sarcopenia. Resistance training requires equipment, knowledge of exercise techniques and initial instruction, unlike aerobic exercise, such as walking. Tesch et al. [74] demonstrated that muscle biopsy specimens form resistance-trained, non-diabetic men contained glycogen concentration 50-100% higher than those of physically inactive men in the general population. Certain exercise studies have shown that as little as 4 weeks of resistance training increases muscle glycogen synthesis in elderly, previously sedentary and healthy individuals [75]. Resistance training could help in the management of diabetes mellitus by increasing skeletal muscle mass, since muscle is the principal source of glucose disposal [76, 77]. In a cross-sectional study comparing healthy male athletes with sedentary control subjects, a significant correlation (r=0.54) was observed between muscle mass and insulin sensitivity [78]. Resistance training clearly produces significant skeletal muscle hypertrophy even in elderly individuals [79], with associated increases in insulin sensitivity [78].



#### 1.6 Statement of the Problem

Disease prevention not only entails stopping the development of the disease before it occurs, but also includes measures aimed at slowing down the progression of the established disease. Primary prevention should focus on health promotion. Diabetes mellitus should be seen as an interacting occurrence between people and their environment. Thus the primary concern in prevention and treatment of type 2 diabetes mellitus should include changes in those structural, social and economic factors that are important determinants of lifestyle [80]. Exercise has long been a cornerstone in the management of diabetes based on its potential to improve metabolic control and diminish complications [81]. Presently the lack of understanding pertaining to exercise and its benefits, associated with type 2 diabetes mellitus as well as the absence of education and intervention programmes makes good diabetes management difficult to achieve [82]. Exercise is undervalued in the management of type 2 diabetes mellitus. This may be due to a lack of understanding and motivation on the part of the person with diabetes mellitus as well as the absence of clear recommendations, encouragement and follow-up actions by health-care workers. Health-care workers should address these issues because most people with type 2 diabetes mellitus have the potential to derive benefit from regular, moderate levels of exercise.

Despite evidence pointing to the benefits of exercise there is still a lack of participation among patients who are at risk of or who have type 2 diabetes mellitus. The reasons for the non-participation in regular exercise includes the patients' lack of knowledge about the benefits of exercise, a lack of motivation and the absence of clear guidelines from health-care professionals. Clinicians should view the need to encourage regular exercise as an essential part of diabetes management therefore specific instructions should be given to persons with type 2 diabetes mellitus rather than general advice, which does not encourage compliance. In most South African communities the rate of diabetes is on the increase and is becoming unmanageable due to a lack of education and proper interventional programmes. A study undertaken by Paul [83], investigated the



knowledge, attitudes, beliefs and practices relating to exercise among type-1 diabetes mellitus patients in government hospitals in Kwa-Zulu Natal. The study showed that patients visiting government hospitals were provided with a basic check-up, including glucose capillary tests and blood pressure measurement and were very briefly advised on exercise, if at all. It was also noted that no education relating to diet or medication was provided. The results showed that even though many people were positive about exercising, they were unable to exercise due to the lack of knowledge on the appropriate type, duration and frequency. Furthermore there are no qualified exercise practitioners in public-sector government hospitals in South Africa, to recommend and monitor exercise programs for patients. It was also noted that when doctors and nurses recommended exercise in hospitals they very often referred to the use of sophisticated exercise apparatus, disregarding the fact that not all people were able to access gymnasia and commercial health programs. This misplaced counseling was the result of most of the global and local [23, 84] research on the benefits of exercise on diabetes management having focused on aerobic exercise in well-resourced settings. This study, however, has focused on progressive resistance training (PRT) utilizing basic affordable equipment and/or the use of own body weight in a resource-poor setting.

#### 1.7 Significance of the Study

The research is interdisciplinary, involving experts from the field of epidemiology, exercise physiology, nutrition, as well as support from other academic institutions and industry. Previous diabetes related study in South Africa has been limited to risk profiles of various populations [24, 85, 86] and dietary habits [23] of diabetics. A more directly related intervention study [84] investigating diabetes and exercise focused on aerobic training and relaxation exercises in a resource poor setting but no study in South African has investigated the efficacy of resistance exercise on a diabetic patient. The desired outcome of this study was to observe a significant change (1%) in glycosylated haemoglobin and lipid profiles, and a significant potential improvement in morphological, musculoskeletal and cardio-respiratory health-related fitness. Ultimately all persons with diabetes, irrespective of



geographic and/or socio-economic settings should have the opportunity to benefit from the many valuable therapeutic effects of exercise [87].

#### 1.8 Aims of the Study

The study was designed to determine the effect of a community-based exercise (progressive resistance training) and lifestyle (dietary education) intervention on health outcomes in persons with type 2 diabetes mellitus, in a resource-poor setting.

#### 1.9 Research Objectives

The following objectives were set out in accordance with the above stated aim of this study:

- 1. To describe the physical activity profile of subjects at baseline;
- 2. To investigate changes in glycosylated haemoglobin and lipid profiles of subjects;
- 3. To investigate changes in morphological, musculoskeletal and cardiorespiratory health-related fitness of subjects; and
- 4. To investigate the profile and changes in diabetes care activities among subjects.

#### 1.10 Delimitations of the Research

As the study entailed a community-based trial undertaken in and confined to the under- resourced area of Mamelodi, in the city of Tshwane, Gauteng, South Africa, there was an ethnic focus on subjects of African heritage. Furthermore, only persons with type 2 diabetes mellitus on oral medication were included in the study.



#### 1.11 Structure of the Thesis

In accordance with the aim and objectives of the study the chapters of the thesis are structured as follows:

#### Chapter 1:

General introduction

#### Chapter 2:

Habitual physical activity among an African cohort of persons with Type 2 Diabetes Mellitus in a South African resource-poor community setting.

#### Chapter 3:

Effects of progressive resistance exercise on glycosylated haemoglobin (HbA1c) and lipid profiles in participants with Type 2 Diabetes Mellitus.

#### Chapter 4:

The efficacy of a 20-week progressive resistance training programme on morphological, musculoskeletal and aerobic fitness in participants with Type 2 Diabetes Mellitus.

#### Chapter 5:

Influence of a dietary education programme on diabetes care, knowledge and activities among Type 2 Diabetics.

#### Chapter 6:

Summary, general conclusions and recommendations.



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#### Chapter 2

## Habitual Physical Activity among an African Cohort of Persons with Type 2 Diabetes Mellitus in a South African Resource-Poor Community Setting

#### Abstract

**Background:** Despite positive evidence that physical activity (PA) can preserve mobility in older adults there is a trend for PA to decrease with advancing age. Therefore measuring the prevalence of inactivity has become increasingly pertinent in South African societies, particularly those affected by or at risk of chronic disease.

**Aims:** The purpose of the study was to describe the physical activity profile of a cohort of 80 male and female type 2 diabetics from ages 40-65 years. Participants were of African heritage and were recruited in a resource-poor setting from the outpatients' clinic at the Mamelodi hospital in Gauteng, South Africa.

**Method:** A cross-sectional baseline evaluation was done on a group of patients selected for a randomized controlled clinical trial using the short version of the International Physical Activity Questionnaire (IPAQ). This study reports on firstly: the physical activity profile in three exercising categories i.e. low, moderate and vigorous categories, secondly: their energy expenditure (METS) and lastly the sitting time (sedentary activity) on one weekday. The effect of age, gender and body mass index (BMI) on physical activity was also assessed.

**Results:** The cohort showed a distribution of 16 (20.0%) subjects in the low activity category, 49 (61.25%) in the moderate activity category and 15 (18.75%) in the vigorous activity category, respectively. The median baseline weekly energy expenditure (METS) was 2052.5 (p25 - p75; 677 - 2793). Gender had a differentiating effect on physical inactivity (sitting time) with males (median 180 minutes) spending significantly (p=0.02) more time sitting than females (median 120 minutes). However gender, age, and BMI had no significant differentiating effect on categories of physical activity or energy expenditure. Similarly age and BMI did not influence levels of physical inactivity (sitting time).



**Conclusion:** The prevalence of physical inactivity at baseline among the cohort of patients studied was moderately high. Most subjects reported doing physical activity of a moderate nature, with low energy expenditure. Males were more inactive than females. Efforts are needed to encourage active living and discourage sedentary habits, among patients with type-2 DM.

## Keywords: International Physical Activity Questionnaire, Inactivity, Exercise, Health Promotion, IPAQ



## 2.1 Introduction

Physical activity is an important aspect of lifestyle with beneficial effects on wellbeing and health and, in particular, cardiovascular morbidity, mortality and longevity [1, 2]. As such, physical inactivity is a risk factor for cardiovascular disease and a variety of other chronic diseases [1-3]. Current advice recommends daily exercise to combat chronic disease. Studies done by Pate *et al.* [3], discussed these recommendations, focusing on the amount of activity needed to avoid the adverse health consequences of a sedentary lifestyle. Despite positive evidence that physical activity can preserve mobility in older adults there is a trend for physical activity to decrease with advancing age. This decline is more evident in women, low-income earners and in those with poor education [4, 5].

Recent cross-sectional studies in peri-urban communities of the Western Cape in South Africa highlighted that the most sedentary individuals were young women aged from 15-24 years and men and women over the age of 55 years [6]. Therefore measuring the prevalence of inactivity has become increasingly important in South African societies, particularly those affected by or at risk of chronic disease. South African data on the level of physical activity in older adults as obtained from the regional cross-sectional risk factor surveys suggest that persons over age 55 have the lowest levels of self-reported moderate and vigorous physical activity. In a study of older South African adults from historically disadvantaged backgrounds, the Yale Physical Activity Survey for Older Adults (YPAS) described patterns of weekly activity spent on housework, gardening and yard work, care-giving, exercise and recreation [7]. Results from this study suggested that South African seniors spent an average of 2583 kcal/wk (± 3027 kcal/wk) on physical activity, 65% less than reported in a sample of North Americans of the same age [8]. This has also been well documented in other developed countries [9]. In two studies conducted in South Africa on older adults from peri-urban communities [7, 10] current levels of physical activity were dissociated from various indicators of morbidity, such as blood pressure (BP), waist circumference and body mass index (BMI), as well as prevalence of hypertension, diabetes and hypercholesterolemia. This may be explained, in part, by a "healthy



survivor" effect. On the other hand, moderate-lifetime occupational physical activity levels recalled for the ages from 14-49 years using a historical activity questionnaire, were significantly and inversely associated with current systolic blood pressure (r=-0.24, p<0.05) [11]. The inverse correlations between physical activity and cardiovascular disease (CVD) risk factors have been found in a number of cross-sectional studies [12, 13], and intervention studies have established that CVD risk factors can, to some extent, be modified through exercise [14, 15]. Physical inactivity is an independent CVD risk factor, since epidemiological studies find inverse relationships between physical activity level and cardiovascular as well as all cause mortality [16].

The purpose of the present paper is to report on the baseline data regarding the daily habitual physical activity among an African cohort of type-2 diabetics in a resource-poor community setting. This baseline analysis formed part of a clinical trial evaluating the efficacy of a physical activity and lifestyle intervention on health outcomes in persons with type 2 diabetes.

## 2.2 Materials and Methods

#### 2.2.1 Participants

The study was undertaken in Mamelodi, a suburb in the city of Tshwane in the province of Gauteng, South Africa. The study participants (n=80) included black male and female participants between the ages 40-65 years with type-2 DM without complications and a known duration of the disease for at least one year. Most participants were recruited from the outpatient clinic at the Mamelodi government hospital as well as from local churches in the Mamelodi area. The following exclusion criteria were used: Cardiovascular contraindications Unstable angina, untreated severe left main coronary artery disease, angina, hypotension, or arrhythmias provoked by resistance training, acute myocardial infarction, end-stage congestive heart failure, severe valvular heart disease, malignant or unstable arrhythmias, large or expanding aortic aneurysm, known cerebral aneurysm, acute deep venous thrombosis, acute pulmonary embolism or infarction, and recent



intracerebral or subdural hemorrhage; Musculoskeletal contraindications: Significant exacerbation of musculoskeletal pain with resistance training, unstable or acutely injured joints, tendons or ligaments, fracture within the last 6 months (delayed union), acute inflammatory joint disease; Other contraindications: Rapidly progressive or unstable neurological disease, failure to thrive, terminal illness, uncontrolled systemic disease, symptomatic or large abdominal or inguinal hernia, hemorrhoids, severe dementia/behavioral disturbance, acute alcohol or drug intoxication, acute retinal bleeding, detachment/severe proliferative diabetic retinopathy, recent ophthalmic surgery, severe cognitive impairment, uncontrolled chronic obstructive pulmonary disease, prosthesis instability, severe (systolic >160mmHg and diastolic >100mmHg) and malignant hypertension, and signs and symptoms suggestive of immuno-suppression.

#### 2.2.2 **Ethical Clearance**

The protocol was approved by the Research Ethics Committees of the Faculties of Humanities and Health Sciences at University of Pretoria (Number 66/2004). The chief executive officer, superintendent and physician providing medical services as well as the health-care workers at the diabetes mellitus (DM) out-patient clinic of the Mamelodi Hospital also consented to the diabetes mellitus study being conducted.

#### 2.3 **Study Design**

A descriptive survey was used with quantitative data captured by means of the International Physical Activity Questionnaire (IPAQ).

#### 2.4 Instrumentation

In epidemiological studies, information about physical activity is often collected using questionnaires as this indirect method is a more feasible method in large studies [17]. The IPAQ (Appendix 1), which was designed by a multinational working group, is a standardized instrument that can be used internationally to





obtain comparable population estimates of health-enhancing physical activity from surveillance system data [18]. IPAQ has 2 versions, namely a short (9-item) and a long (31-item) format. Both formats are designed to assess physical activity over a 7-day period or during a "typical week" and they can be administered by telephonic interviews or self-administered. The IPAQ was subjected to reliability and validity studies carried out in 14 centres' in 12 countries including South Africa during 2000. This demonstrated that the IPAQ instruments have acceptable measurements properties for monitoring population levels of physical activity among 18 to 65 year-old adults in diverse settings [18, 19]. It was reported that in South Africa, which was classified as a developing country, the reliability of the long and short IPAQ was 0.79 and 0.85 respectively [20]. The long and short version of the IPAQ questionnaire were further validated by Bohlmann et al. [21] among urban and peri-urban South Africans from various socio-economic backgrounds and divergent languages. The IPAQ was again cross validated among older adults in South Africa by Kolbe-Alexander et al. [20]. In this study physical activity was assessed using the English version of the short IPAQ available on www.ipaq.ki.se. The short version IPAQ deals with three specific types of activity undertaken in four domains namely: leisure activity, domestic and gardening activity, work related (occupational) activity and transport related physical activity. The specific types of activity assessed are walking, moderate-intensity activity and vigorous intensity activities. IPAQ defines moderate-physical activities as those that produce a moderate-increase in respiration rate, heart rate and sweating for at least 10 minute duration, which is equivalent to 3-6 metabolic equivalents (METS) based on the compendium of physical activity [22]. Vigorous physical activity is defined as those that produce a vigorous increase in respiration rate, heart rate and perspiration for at least 10 minutes duration where the metabolic equivalent value is above 6 METS [22]. Inactivity was also determined assessed using the IPAQ and is described as time spent sitting in an ordinary weekday.

#### Administration of the Questionnaire

A pilot study was conducted to pre-test the English version of the short IPAQ questionnaire. The questionnaires were administered by the primary researcher.



While most participants indicated their preference to have the questionnaire administered in English, where necessary, the resident hospital dietician was available during the administration to serve as a translator in case participants required clarity in a preferred African language.

## 2.5 Statistical Analysis

Data was checked for any outliers according to the guidelines from IPAQ (<u>www.ipaq.ki.se</u>). Data was screened for missing values and where the answers "don't know" or "not sure" appeared a "0" response was allocated to such answers. Data was analyzed using Stata 10 software programme [23]. Data was summarised using standard descriptive techniques of mean, median, frequency, percentage and range. The categories, baseline METS and sitting time in the group as a whole as well as in categories of age, gender and body mass index (BMI) (3 quantiles of BMI) were analysed. Groups were compared with either the Mann Whitney or Kruskal Wallis tests. A p value of ≤0.05 was regarded as statistically significant.

## 2.6 Results

The results are presented in the following order:

Pooled data of the entire cohort, categories of age, gender and BMI, pooled baseline METS, baseline METS by age, gender and BMI categories and pooled data regarding time spent sitting by the cohort and sitting time by age, gender and BMI categories.

## Table 1: Overall Categories of Physical Activity

Category	Total C	ohort (n=80)
	Ν	%
Low (1)	16	20.0
Moderate (2)	49	61.25
Vigorous (3)	15	18.75



The total cohort of 80 subjects is shown in table 1. The categories 1, 2, and 3 represent the low, moderate and vigorous activity levels that the patients indicated on the IPAQ questionnaire. As seen in table 1, there were 16 (20.0%) subjects distributed in the low activity category, 49 (61.25%) subjects distributed in the moderate activity category and 15 (18.75%) subjects distributed in the vigorous activity category. The majority of subjects 49 (61.25%) were distributed in the moderate activity category.

	Categories (n=80)							
Age (Years)	Low	Low		Moderate		Vigorous		otal
	N	%	N	%	Ν	%	Ν	%
40-50 years	6	35	8	47	3	17	17	21
51-60 years	5	15	22	66	6	18	33	41
61-70 years	5	16	19	63	6	20	30	38
Total	16	20	49	61	15	19	80	100
p-value		0.54						

## Table 2: Categories of Physical Activity by Age

Physical activity was further categorized in the different age categories of the cohort. As seen in table 2, 6 subjects within the age category 40-50 years, 5 subjects in the 51-60 years and 5 subjects in the 61-70 year age category, thus totaling to 16 subjects, fell into the low activity category. In the moderate category the were 8 subject in the 40-50 years, 22 subjects in the 51-60 years and 19 subjects in the 61-70 years category, thus totaling to 49 subjects in the moderate activity category. Similarly there were 3 subjects in the 40-50 years category that were classed as being vigorously active, 6 subjects in the 51-60 years category and 6 subjects in the 61-70 years category, thus totaling 15 subjects in the vigorous activity category. There was no-significant difference (p=0.54) when comparing the subjects physical activity within age categories.



Gender	Categories							
Gender	Lo	w	Moderate		Vigorous		Total	
	Ν	%	N	%	Ν	%	Ν	%
Males	4	24	11	65	2	12	17	21
Females	12	19	38	60	13	21	63	79
Total	16	20	49	61	15	19	80	100
p-value		0.79						

## Table 3: Categories of Physical Activity by Gender

In the gender category highlighted in table 3 there were 4 males and 12 females in the low category, 11 males and 38 females in the moderate category and 2 males and 13 females in the vigorous category. There was no significant difference (p=0.79) in the gender category. As seen in table 3 the majority of females and males fell in the moderate physical activity category.

		Categories							
Quantiles of BMI	Lo	w	Mod	Moderate		Vigorous		Total	
	Ν	%	Ν	%	Ν	%	Ν	%	
Lowest (Mean 26.3)	4	14	19	68	5	18	28	35	
Moderate (Mean 31.1)	5	18	17	65	4	15	26	33	
Highest (Mean 39.6)	7	25	13	50	6	23	26	33	
Total	16	20	49	61	15	19	80	100	
p-value		0.69							

### Table 4: Categories of Physical Activity by Body Mass Index

In the above BMI table the subjects are categorized according to the 3 quantiles of BMI ranging from lowest to highest quantile of BMI. As seen in the low activity level, 4 subjects fell within the lowest quantile, 5 subjects in the moderate quantile and seven subjects in the upper quantile. In the moderate activity levels, 19



subjects fell in the lowest quantile, 17 in the moderate quantile and 13 in the highest quantile. In the vigorous activity level, 5 subjects fell in the lowest, 4 in the moderate and 6 subjects fell in the highest quantile of BMI. There was no significant difference (p=0.69) when comparing the BMI to the categories of physical activity. A greater proportion of subjects in the highest quantile of BMI reported the lowest physical activity; however, as stated this was not statistically significant.

The distribution of baseline METS by category (i.e. age, gender and BMI) is shown in tables 5-8.

METS		))	
	Median	p25	p75
Total METS	1392	677	2793

## Table 5: Overall Energy Expenditure

Table 5 shows the median in energy expenditure (METS) of the entire cohort of 80 subjects. The median METS was 1392 (p25=677) and (p75=2793). Most training studies [24] suggest that 150–400 kcal per day should be expended daily for those starting an exercise program. The lower end of range is considered the minimal threshold and should be considered an initial goal for persons initiating physical activity. If performed daily this should result in an energy expenditure of ±1000 kcal/week [24].



## Table 6: Energy Expenditure by Age

	Pre-intervention METS (n=80)				
Age (Years)	Median	p25	p75		
40-50 years	838	325	1674		
51-60 years	1537.5	742.5	2970		
61-70 years	1392	660	2844		
p-value	0.33				

Table 6 shows the distribution of METS according to the age category. In the age range of 40-50 years the mean METS was 838 with p25=325 and p75=1674. In the 51-60 age range the total METS averaged 1537.5 with p25=742.5 and p75=2970 and in the age range 61-70 years the average total METS was 1392 with p25=660 and p75=2844. It is seen from the data that the average METS is higher in the age range 51-60 years, meaning that they are more physically active than the other two age ranges. However, among the entire cohort, there was no significant difference (p=0.33) when comparing the different age ranges at baseline.

## Table 7: Energy Expenditure by Gender

	Pre-intervention METS (n=80)				
Gender	Median	p25	p75		
Males	1155	462	1884		
Females	1404	693	2970		
p-value	0.54				

Table 7 shows the average baseline METS distribution among the males and females of the entire cohort of subjects. Based on the gender distribution the males averaged baseline METS of 1155 with p25=462 and p75=1884, while the females averaged a higher energy expenditure with a baseline METS of 1404 with



p25=693 and p75=2970. There was, however, no significant differences (p=0.54) between the mean METS of males and females.

	METS (n=80)				
Quantiles of BMI	Median	p25	p75		
Lowest (Mean 26.3)	1189.5	717.8	2658.5		
Moderate (Mean 31.1)	1521.25	693	2970		
Highest (Mean 39.6)	1536	325	2970		
p-value	0.99				

## Table 8: Energy Expenditure by Body Mass Index

The distribution of total METS at baseline into the quantiles of BMI showed that a total METS of 1189.5 fell in the lowest BMI quantile with p25=717.8 and p75=2658.5. However in the moderate BMI quantile the total METS averaged 1521.25 with p25=693 and p75=2970, and lastly in the highest BMI quantile category the total METS averaged 1536 with p25=325 and p75=2970. The differences observed were not statistically significant (p=0.99).

## Table 9: Overall Levels of Physical Inactivity

	Total Cohort (n=80)			
Daily Time Spent Sitting (minutes)	Median	p25	p75	
	129.3	90	180	

The total time spent sitting on one weekday is shown for the overall cohort of 80 subjects in table 9. As observed, the average time sat was just over 2 hours (129 minutes with p25-75, 90-180 minutes). Thus the cohort basically sat for a minimum of 1.5 hrs which can be viewed as substantial sedentary activity, but is less when compared to other clerical office workers [18].



## Table 10: Physical Inactivity by Age

	Time Spent S	itting (min) at Pre-inter	rvention (n=80)
Age (Years)	Median	p25	p75
40-50 years	100	90	180
51-60 years	150	90	180
61-70 years	120	80	180
p-value		0.81	

Physical inactivity among the cohort was further categorized into age ranges as shown in table 10. The proportion of inactive subjects was more or less equally distributed among the three age range groups with a median of 100min (p25=90min and p75=180min) in age range 40-50 years, a median of 150min (p25=90min and p75=180min) in age range 51-60 years and lastly with a median of 120min (p25=80 min and p75=180min) also in the age range 61-70 years. Inactivity seems to be higher in the age range 51-60 years with the median sitting time equaling to 150 minutes. There was no significant differences (p=0.81) by age category at baseline.

## Table 11: Physical Inactivity by Gender

Gender	Time Spent Sitting (min) at Pre-intervention (n=80)				
Gender	Median	p25	p75		
Males	180	120	180		
Females	120	90	180		
p-value		0.02			

Table 11 shows the cohort of subjects distributed into gender categories regarding the time spent sitting at baseline on one specific weekday. From the data males spent more time sitting (180minutes) with a p25=120 min and p75=180 min, as compared to females who sat on average 120 minutes with a p25=90 min and p75=180 min. When comparing the males and females at baseline there was a



significant difference (p=0.02) in the gender category, with males being more sedentary.

Quantiles of BMI	Time Spent Sitting (min) at Pre-intervention (n=80)				
Quantiles of Dim	Median	p25	р75		
Lowest	180	90	180		
(Mean 26.3)	100	90	100		
Moderate	120	100	180		
(Mean 31.1)	120	100	100		
Highest	100	60	180		
(Mean 39.6)	100	00	100		
p-value		0.08			

## Table 12: Physical Inactivity by Body Mass Index

Table 12 shows the 3 quantiles of BMI associated with the time spent sitting. In the 1st BMI quantile the median = 180 min with the p25= 90min and p75= 180 min, in the 2nd quantile the median=120 min with p25=100 min and p75= 180 min, and in the 3rd quantile the median = 100 with p25= 60 and p75= 180.

## 2.7 Discussion

The present study was a cross sectional evaluation done at the baseline of a clinical study to report on the physical activity profile of persons with type 2 DM in a resource-poor setting of South Africa using the internationally validated physical activity questionnaire (IPAQ - short version). The IPAQ is supported by many Health organizations including the World Health Organization, the US Centers for Disease Control and Prevention and the American College of Sports Medicine [18]. Regular participation is a key concept included in current public health guidelines for physical activity. This study reported on firstly: the overall physical activity profile of the pooled cohort of subjects in the 3 exercising categories i.e. low, moderate and vigorous categories as well as physical activity with respect to the age, gender and BMI. Energy expenditure (METS) as well as the baseline METS by categories age, gender and BMI was also reported and lastly physical inactivity



reported by sitting time (sedentary activity) on one weekday, and the sitting time by categories i.e. age, gender and BMI was observed. The main significant finding in the baseline data was the amount of physical inactivity (time spent sitting) in the gender comparison. Although inactivity levels were high in both males and females the finding reflects that males spent more time (median of 180 minutes) sitting doing no physical activity on one weekday than the females, with a lower median of 120 minutes. In another recent study undertaken by Cook [25], the IPAQ was used to focus on the prevalence of cardiovascular risk factors and physical inactivity in a rural South African population. It was reported that most participants followed an inactive lifestyle.

The finding in the present report that females spent less time sitting than males deserves some comment. The IPAQ component also assessed components of physical activity including moderate intensity activities done at home such as carrying loads (e.g. babies, washing clothes) scrubbing floors and sweeping. These types of domestic activities are most likely to be performed by females. Cultural beliefs and practices of the subjects suffering with type 2 DM, also plays and important role in their participation in physical activity which could attribute to the more time spent sitting by males than females. According to Bopape [26], beliefs held by an individual may influence their decision to comply with preventative action. According to Tshabalala and Gill, 1997 [27], "older people are usually excluded from exercise by virtue of their senior status. They usually sit in the sun, while the young do the hard work". This could thus be a possible explanation for the increased time spent sitting by the men, which was significantly greater (p=0.02) when comparing genders. One would have expected subjects with low BMI values to be less sedentary and vice-versa. The data shows the inverse but, essentially there was no statistical difference (p=0.08) in the sitting time between the quantiles of BMI.

Although there was no significant difference (p=0.81) in the sitting time and the age category, several reports have shown such a relationship [28]. Data from the Behavioral Risk Factors Surveillance System (BRFSS) study indicated that inactivity increased with advancing age from 18 to 29 years to 70+ in both sexes



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[29]. A study done by Al-Hazzaa, (2007) [30], dealt with inactivity levels of Saudi males between ages 19 to 68 years and found a curvilinear relationship between inactivity prevalence and age [30]. This study showed an inactivity prevalence (sitting doing no physical activity) reaching its highest level in the age group of 30 to 49 years, and the lowest level in the age group 60 years and above. Again all the above studies assessed mainly leisure-type physical activity and this could explain the difference in results regarding inactivity levels.

A Brazilian survey using the IPAQ short version found an inactivity prevalence of 41% among Brazilian adults aged 20 years and above [31]. Data from the Behavioral Risk Factors Surveillance System (BRFSS) in the United States indicated that the majority (54%) of US adults were not physically active enough to meet the current recommendations of at least 30 minutes of moderate-intensity activity on most days of the week [32]. In another report analyzing 1988-2002 BRFSS data in the USA, it was revealed that leisure time physical inactivity had decreased especially after 1996 in both men and women [29]. However, the US national health objective for 2010 calls for a reduction in the prevalence of leisure time physical inactivity to 20% [29].

South Africa is a country undergoing rapid epidemiological transition, with a dual burden of infectious diseases and chronic diseases related to lifestyle. Results from the 1998 Demographic and Health Survey suggest that overweight and obesity affect more than 55% of South African women [33]. This high prevalence of overweight and obesity among South African women, particularly from the indigenous (black) population groups has dire health consequences, as it is associated with increased risk for chronic disease related to lifestyles. The relationship between Body Mass Index (BMI) and physical activity was investigated in 530 black women living in the North West Province as part of the 'Transition and Health during Urbanization of South Africans (THUSA) study [34]. Kruger *et al.* [34], reported that physical activity was significantly and inversely associated with BMI (r = -0.14; p = 0.001) and waist circumference (r = -0.15;  $p \le 0.00001$ ). Furthermore, the women who were in the highest tertile for physical activity were 62% less likely to be obese compared to those who were the least active (r = 0.38;



95% CI: 0.22 - 0.66). Similarly, the women in the second tertile for physical activity had approximately half the risk of obesity when compared to those who were least active (r=0.52; 95% CI: 0.31-0.86). These findings therefore underscore the importance of the role of physical activity in the prevention of obesity and overweight in women. This is particularly important since 54% of the women participating in the study were classified as either overweight (BMI >24.9 and <30) or obese (BMI >29.9) [34].

From the present study in table 1 we can observe that the majority (n=49; 61.25%) of the subjects were classified into the moderate activity category where physical activity was done for five or more days per week and walking activities for at least 30 minutes or more per day. It has to be noted that these activities were not structured and any type of movement would have generated METS which contributed to the "physical activity status".

In South Africa the Ministry of Health has initiated a consultative process to develop a series of guidelines for the prevention or management of chronic disease related to lifestyles (separate guidelines are available for the prevention and management of diabetes, hypertension, hyperlipidaemia, and overweight). The directorate has also recognized the need to encourage physical activity, in particular, among older adults and initiated guidelines for promoting "active" ageing [35]. More recently, in November 2004, the Directorate of Health Promotions, within the Department of Health, launched an inter-sectoral strategy aimed at the promotion of healthy lifestyles and change from high-risk behaviour, particularly among the youth. This forms part of the plan for comprehensive health care in South Africa, and is one of the strategic priorities for the period 2004 - 2009. The original successful initiative advocating physical activity in developing countries was the implementation of Agita Mundo in Brazil [36]. The Agita Mundo programme was formulated in response to the high prevalence of chronic diseases of lifestyle among Brazilian men and women. Agita Mundo translated means, "Move for Health", and the main aim of this campaign was to educate individuals on the health and fitness benefits of exercise and to promote the implementation of physical activity programmes. This programme, which started in Sao Paulo, spread to the rest of Brazil, and then



to the rest of the Americas, has subsequently been recognised as a model to promote mass participation in physical activity programmes [37]. Consequently, the World Health Assembly has mandated its member states, of which South Africa is one, to celebrate "Move for Health" annually. The core message of "Move for Health" is to encourage individuals to accumulate 30 minutes of moderate-physical activity on most days (at least 5) of the week. The South African campaign has been named, "Vuka South Africa – Move for your Health", which means "Wake up South Africa, move for your health". The National Department of Health, together with its partners (National Departments of Education and Sport and Recreation South Africa; private companies, tertiary institutions and non-governmental organisations) launched the "Vuka" South Africa – Move for your Health campaign in May 2005. Since its inception, there have been numerous planning meetings, culminating in a stakeholders' workshop that was held in September 2005. This workshop served as a platform for the future implementation of the Move for Health programme, together with the monitoring and evaluation of the campaign [11].

In conclusion, while the short IPAQ provides reasonable specific measures of physical activity but its sensitivity to classify inactive people correctly, is limited. The present study is subject to the following potential limitations. Firstly the study used the short IPAQ. As is the case with any questionnaire, the respondents could have suffered from recall bias. Second limitation was that the sample of subjects to whom the IPAQ was administered to at baseline was not a random sample and there were small numbers in the analysis of age, gender and BMI specific outcomes.

From the findings of the current study we can conclude that the prevalence of physical inactivity at baseline among the cohort of patients studied was moderately high, but it is commonly acknowledged that inactivity increases with advancing age. This is reflected by the fact that majority of the participants were classified in the moderate physical activity category. Therefore health policies [38] in South Africa, should focus on active living and discourage sedentary habits. Health care workers should promote physical activity among the general population more, and in the context of this study, also among patients with type-2 DM. A limitation of this study



is that the survey sample was small and inferring the results to a larger population should therefore be done with caution. There is a need for a national study with a representative sample to address the issue of physical activity in South Africans suffering from diabetes mellitus.



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#### **Chapter 3**

# Effects of Progressive Resistance Training (PRT) on Glycosylated Haemoglobin (HbA<sub>1c</sub>) and Lipid Profiles in Participants with Type 2 Diabetes Mellitus.

#### Abstract

**Background:** The influence on different types of exercise on risk factors for cardiovascular diseases have rarely been investigated in south African setting, however numerous trials worldwide have demonstrated that supervised resistance training may be a viable effective exercise modality for the improvement of glycaemic control and lipid profiles in persons type 2 diabetes mellitus.

**Aims:** The purpose of the study was to determine the efficacy of a 20 week progressive resistance training (PRT) and a dietary education programme on baseline blood glucose and lipid profiles in a cohort of 80 male and female type 2 diabetics from ages 40-65 years. Participants were of African heritage and were recruited in a resource-poor setting from the outpatients' clinic at the Mamelodi Hospital in Gauteng, South Africa.

**Methods:** A randomised controlled trial design was adopted for the study. Subjects were assigned to a PRT group (n=40) and control group (n=40). Participants in the PRT group were exposed to progressive resistance training and dietary education whilst the control group (CT) where only exposed to dietary education. The outcome measures entailed an assessment of glycosylated haemoglobin (HbA<sub>1c</sub>), high-density lipoprotein (HDL), low-density lipoprotein (LDL), triglycerides (TG) and total cholesterol (TC) count.

**Results:** The following pre-post intervention changes (mean (SD) were found for the PRT vs. CT for HbA<sub>1c</sub> (PRT: pre 9.01 (3.1) vs. post 8.47 (2.4); p=0.04 vs. CT: pre 9.32 (2.3) vs. post 9.17 (2.5)%: p=0.72), TC (PRT: pre 4.92 (1.10) vs. post 4.69 (0.81); p=0.11 vs. CT: pre 5.08 (0.84) vs. post 5.04 (1.02) mmol/L: p=0.09), LDL (PRT: pre 3.05 (0.97) vs. post 2.89 (0.74); p=0.19 vs. CT: pre 3.17 (0.86) vs. post 3.11 (0.93) mmol/L: p=0.19), HDL (PRT: pre 1.05 (0.25) vs. post 1.09 (0.28); p=0.13 vs. CT: pre 1.27 (1.11) vs. post 1.09 (0.52) mmol/L: p=0.87), TG (PRT: pre 1.06



(0.84-1.74) vs. post 1.04 (0.79-1.52); p=0.16 vs. CT: pre 1.29 (1.1-1.9) vs. post 1.2 (0.95-2.03) mmol/L: p=0.73). However, none of these changes within the PRT group were significantly better (p>0.05) than that in the control (dietary intervention only) group.

**Conclusion:** The PRT and dietary education program combined failed to show a better improvement in metabolic parameters, than a dietary education program alone. Although this study failed to demonstrate a statistically significant change of at least 1% in the HbA<sub>1c</sub> it is important to note that even the 0.5% difference achieved, can be considered as clinically significant. PRT needs to be of sufficient frequency and intensity to be effective as a treatment modality in persons with type 2 diabetes.

**Keywords:** Resistance training, glycosylated haemoglobin (HbA<sub>1c</sub>), Lipid Profile, Type 2 diabetes mellitus, community setting.





## 3.1 Introduction

Diabetes Mellitus (DM) is a chronic disorder of carbohydrate, fat and protein metabolism. DM represents a heterogeneous group of disorders that have hyperglycemia as a common feature which is often associated with poor lifestyle and obesity [1, 2]. The incidence of type 2 DM is increasing markedly in adult populations around the world [3]. As populations age and become urbanised, and as obesity becomes more prevalent [4, 5], the incidence of type 2 DM rises. The striking epidemiological features of type 2 DM is the wide variation in population and individual prevalence and the strong positive correlation with relative body fat [6, 7] as well as socio-economic deprivation which, in turn, is associated with poor diet and other adverse lifestyle factors [8]. The main underlying factors associated with type 2 DM include genetic and environmental factors. These factors are urbanisation and industrialisation, increased longevity and changes in lifestyle from a traditional healthy and active way of life to a modern, sedentary and stressful life characterised by the overconsumption of energy-dense food [3].

The key factor in managing body weight is energy balance. When energy expenditure equates to energy intake, body weight is maintained, thus preventing initial weight gain or weight regain after weight loss. To promote weight loss it is necessary to create an energy imbalance that elicits an energy deficit. Structural physical activity contributes to energy deficit by increasing total energy expenditure, which thus promotes weight loss [9].

All patients with type 2 DM require active dietary management because this is an essential component of successful diabetic care [10, 11]. Dietary control involves balancing complex issues and needs, that are tailored to lifestyle, cultural and religious customs and to the overall diabetic management strategy of each individual patient [11]. There are three important goals related to dietary habits, i.e. essential nutrition, prevention of vascular complications and adaptation to metabolic problems. An optimal diet should provide all the essential nutrients bearing in mind that the person with type 2 DM needs the same essential nutrients as the general population. A balanced diet aims to reduce central obesity improve serum lipid



profile and lower blood pressure, all of which contribute to increased morbidity and mortality in a person with diabetes [12]. Food intake in type 2 DM patients must be balanced with exercise and hypoglycemic treatment [13], to avoid the twin perils of hypoglycemia and hyperglycemia. Most patients with type 2 DM are overweight; therefore they need to limit their energy intake.

Glycated haemoglobin provides an accurate and objective measure of glycaemic control over a period of weeks to months. Components of adult haemoglobin (HbA<sub>1</sub>) can be separated from unmodified haemoglobin (HbA<sub>0</sub>) by ion-exchange chromatography, and these haemoglobin moieties are increased in diabetes by the slow non-enzymatic covalent attachment of glucose and other sugars (glycation) [14]. The rate of formation of glycated haemoglobin is directly proportional to the ambient blood glucose concentration; a rise of 1% in glycated haemoglobin corresponds to an approximately 2 mmol/l increase in average blood glucose. Glycated haemoglobin concentration reflects integrated blood glucose control over the lifespan of the erythrocytes (120 days). Estimation is weighted by changes in glycaemic control occurring in the month before measurement (representing 50% of the glycated haemoglobin concentration). When initially diagnosed, type 2 DM can be controlled with diet and exercise because both contribute to weight loss. As weight is reduced insulin receptor numbers increase and insulin resistance is diminished. Exercise also contributes to weight loss by creating an increased demand for glucose in skeletal muscle and exercise promoting an increase in insulin receptors [15].

Strict blood glucose control in type 2 DM is essential because this is a critical factor in reducing the risk of chronic diabetic complications [13]. Research has suggested that in addition to good dietary habits, exercise is one of the cornerstones of DM management [16]. Exercise is often seen as a desirable means to manage excessive weight gain associated with type 2 DM and for its beneficial effect in increasing insulin sensitivity. Because muscle is a major site for insulin-induced glucose disposal and because muscle responds to exercise training, it is reasonable to assume that such changes in muscle tissue might contribute to reduced insulin resistance in people with type 2 diabetes [17-19]. Exercise can have



both long-term and short-term effects on insulin action. A strenuous session of exercise improves muscle glucose transport, which reverses rapidly when exercise is stopped [20]. This is then replaced by a marked increase in the sensitivity of the receptors to insulin [21]. The exercising muscle may increase the uptake of glucose by 7 to 20 fold during the first 30-40 minutes, depending on the intensity of the exercise session. Insulin receptors thus become more sensitive to the lower amount of insulin available during exercise. This improvement in insulin receptor sensitivity can last for many hours after the exercise bout is over, even for as long as 2 days if the exercise session was of sufficient intensity and duration [22].

### Exercise and Insulin Sensitivity

Bjorntorp and colleagues [23], suggested the use of physical exercise to treat the insulin resistance associated with obesity and type 2 diabetes. They [23] have noted that active middle-aged men had significantly lower fasting insulin concentrations and lower insulin responses to oral glucose than untrained men of the same age and body weight. These findings suggested that regular physical activity is associated with increased insulin sensitivity which led them to study the effects of physical training in obese patients with normal glucose tolerance but insulin resistance. After 12 weeks of moderate intensity aerobic exercise (30-60 minutes, 5 days/week), there was no change in the subjects blood glucose responses but insulin levels were significantly lower, both fasting and following glucose administration [24]. The increase in insulin sensitivity and responsiveness associated with physical conditioning rapidly disappears when exercise is discontinued. Burstein *et al.* [25], found that much of the effect is gone within 60 hours; other researchers demonstrated that the effect is no longer present after 5 to 7 days without exercise.

Mikines and associates [26], observed that a single bout of aerobic exercise increased the sensitivity and responsiveness of insulin-stimulated glucose uptake in untrained individuals. The effect lasted 2 days but was not observed after 5 days. In addition, physically trained individuals (as compared to untrained individuals) had increased individual action 15 hours after their last training session. Five days after



their last training session, insulin responsiveness remained elevated compared with that of untrained subjects, suggesting that training results in a long-term adaptative increase in whole-body responsiveness to insulin [27]. Although the mechanism of this increase is not known, it may be related to increased capillary density in skeletal muscle, enhanced oxidative capacity or other adaptive capacity of skeletal muscle and to other adaptations to training such as elevated skeletal muscle GLUT 4 content [28]. An increase in insulin-stimulated glucose uptake can last 5 to 7 days following cessation of exercise in previously trained subjects, patients with type 2 DM do not have improved fasting blood glucose concentrations during this same period. Some researchers have observed that physical training is associated with lower glycosylated hemoglobin levels [29]. The cumulative result of decreased blood glucose concentrations during and after aerobic exercise rather than a specific effect of physical training is of importance. Since moderate-intensity aerobic exercise usually lowers blood glucose concentrations towards normal in hyperglycemic patients with type 2 diabetes, and since increased insulin-stimulated glucose disposal persists for many hours following a single bout of exercise, it is likely that regular exercise 4 to 7 days a week may decrease blood glucose and glycohemoglobin concentrations without a significant effect on fasting blood glucose or glucose response to meals. The net effect of exercise repeated on a regular basis would improve long-term glucose control in patients with type 2 diabetes [30].

#### Effects of Exercise on Lipid Control

Regular physical activity leads to reduced risks of cardiovascular disease [31, 32], an effect which is likely due to the beneficial effect on lipid metabolism [32]. Physical inactivity has adverse consequences on cardiovascular risk, due to the detrimental effects on serum lipoprotein concentrations. There are a number of studies that have considered the effects of exercise on lipid profile but there seems to be some uncertainty as to how much exercise is sufficient for health benefits and how much inactivity acts to worsen risk profiles [33]. Research done by Slentz *et al.* [32], referred to as the STRIDDE study (Studies Targeting Risk Reduction Interventions through Defined Exercise) examined one of many factors dealing with the effects of different amounts and intensities of exercise training on lipoproteins.



It was noted that many of the beneficial effects of exercise on lipids and lipoprotein was not observed in the typical lipid profile, but rather it was observed in the effects of exercise on the particle size and particle number. This was an important finding in that the concentrations of low density lipoprotein (LDL) particles, large high density lipoprotein (HDL) particles and large very low density lipoprotein (VLDL) particles are better indicators of cardiovascular risk than are the elements of the traditional lipid profile [34, 35]. In diabetes the plasma cholesterol level is usually elevated and this plays an important role in the development of atherosclerotic vascular disease which is a long term complication of diabetes in humans. The rise in plasma cholesterol level is due to an increase in the plasma concentration of VLDL and LDL [36]. The most common pattern of dyslipidaemia is hypertriglyceridemia and reduced HDL cholesterol levels. DM in itself does not increase levels of LDL, but the small dense LDL particles found in type 2 DM are more arterogenic because they are more easily glycated and susceptible to oxidation [37]. Physical training is associated with a decrease in serum triglycerides levels, particularly very low density lipoproteins, and an increase in high density lipoproteins-2 cholesterol [38].

The American College of Sports Medicine [39, 40] advises a combination of both aerobic and resistance training as part of an exercise regime. In general exercises with higher intensities are associated with poorer compliance [41]. Post-intervention compliance with lifestyle activity involving high intensity aerobic programmes is poor. Furthermore, aerobic training is not ideal for many type 2 patients because of advancing age, obesity and other co-morbid conditions [6, 42, 43]. On the other hand, resistance training leads to improved glycosylated haemoglobin (HbA<sub>1C</sub>) levels [44] and increases in lean body mass [45-47]. Although this mode of exercise is generally safe, it is often erroneously neglected or absent from exercise programmes. Resistance training has additional benefits apart from improving glycaemic control and insulin sensitivity, such as building muscle mass, strength, endurance and mobility. Circuit-type resistance training thus appears to be a feasible and effective therapeutic modality in moderately obese, sedentary patients with type 2 DM [42].



## 3.2 Aims

The primary focus of this research was to establish the effectiveness of a progressive resistance exercise and dietary education intervention programme on baseline  $HbA_{1C}$  and lipid profiles in a cohort of African participants with type 2 DM.

## 3.3 Hypothesis

To implement a progressive resistance training intervention programme and to establish its efficacy based on the primary and secondary hypothesis.

## 3.3.1 **Primary Hypothesis:**

The implementation of a progressive resistance training programme would decrease the glycosylated haemoglobin (HbA<sub>1c</sub>) by 1% given a standard deviation of 2.23% with  $\alpha$ =0.05 and  $\beta$ =0.10 in a sample of 80 participants comprising of males and females with type 2 DM.

## 3.3.2 Secondary Hypothesis:

The implementation of a progressive resistance training programme would yield a significant change in lipid profile comprising low-density lipoprotein, high-density lipoprotein, total cholesterol and triglycerides.

## 3.4 Material and Methods

## 3.4.1 Participants

The study was undertaken in Mamelodi, a suburb in the City of Tshwane Metropolitan Municipality in the province of Gauteng, South Africa. The participants (n=80) included black male (6=control group and 11=exercise group) and female (34=control and 29=exercise group) participants from 40-65 years with type 2 DM without complications and a known duration of the disease for at least one year.



Most participants were recruited from the outpatient clinic at the Mamelodi government hospital whilst they were waiting to be seen by a doctor. Participants were also recruited from local churches in the Mamelodi area. Participants were excluded according to the following criteria: Cardiovascular contraindications: Unstable angina, untreated severe left main coronary artery disease, angina, hypotension or arrhythmias provoked by resistance training, acute myocardial infarction, end-stage congestive heart failure, severe valvular heart disease, malignant or unstable arrhythmias, large or expanding aortic aneurysm, known cerebral aneurysm, acute deep venous thrombosis, acute pulmonary embolism or infarction, and recent intracerebral or subdural hemorrhage; Musculoskeletal contra-indications: Significant exacerbation of musculoskeletal pain with resistance training as well as unstable or acutely injured joints, tendons or ligaments, fracture within the last 6 months (delayed union) and acute inflammatory joint disease; Other contra-indications: Rapidly progressive or unstable neurological disease, failure to thrive, terminal illness, uncontrolled systemic disease, symptomatic or large abdominal or inguinal hernia, hemorrhoids, severe dementia/behavioural acute alcohol or drug intoxication, acute retinal disturbance. bleeding. detachment/severe proliferative diabetic retinopathy, recent ophthalmic surgery, severe cognitive impairment, uncontrolled chronic obstructive pulmonary disease, prosthesis instability, severe (readings: systolic >160 mmHg and diastolic >100 mmHg) and malignant hypertension, as well as signs and symptoms suggestive of immuno-suppression.

#### 3.4.2 Design, Randomization and Procedures

The experimental design comprised a pre-test post-test randomised controlled trial. The study comprised of two groups, a control group (no PRT with dietary education only) and an experimental group (received supervised PRT and dietary education). Participants who volunteered for baseline testing were randomised by means of block randomization, using a computerised programme (http://www.randomization.com) [48]. However due to the relatively small sample size, important potential confounders such as age, gender and BMI were not matched or balanced and were adjusted for in the analysis.



The principal investigator was not blinded to the randomization of the participants, and trained university student assistants were recruited to assist in basic administrative work, however, the subjects were blinded to randomization. One hundred opaque sealed envelopes were used for the randomization process. Each envelope was numbered according to the randomization programme and a label was placed inside each one. The options were: (1=A=Exercise or 2=B=Control group). The letter A represented exercise and B represented control. On the appointed day, each of the participants who reported at the YMCA Hall at 08h30 was required to select an envelope indicating the group to which each had been assigned. At this session all participants were again briefed on the aim of the study. After being randomly assigned the participants were asked to fill out the consent forms.

#### 3.5 Ethical Clearance

The protocol was approved by the Research Ethics Committees of the Faculties of Humanities and Health Sciences at University of Pretoria (Number 66/2004). The chief executive officer, superintendent and physician providing medical services as well as the health-care workers at the DM out-patient clinic of the Mamelodi Hospital, also consented. On reporting for baseline-testing participants received information on the study in their own language as well as in English and had the opportunity to ask questions. If they were sufficiently interested in the study the prospective participants provided their signed, written, informed consent. Before commencing with the programme individuals had to undergo a thorough medical evaluation by a specialist physician, to be screened for the presence of any contra-indications to exercise.

#### 3.6 Intervention Programme

The duration of the study intervention programme was 20-weeks. Due to availability of subjects the study was staggered and therefore spanned over a period of 18 months in total (February 2004-June 2005), and was conducted in periods of 20 weeks until the targeted number of subjects were obtained. The



YMCA hall in Mamelodi was used to perform the weekly intervention exercise and dietary educational sessions.

## 3.6.1 Dietary Education

Research has suggested that both diet and exercise are cornerstones [16] which play pivotal roles in the control of type 2 DM. Participants who participated in this intervention programme were given dietary education, conducted in a community hall by the resident dietician at the Mamelodi Hospital with a view to educating participants on proper dietary habits. However no attempts were made to change their diet during the study. Before block randomization into exercise and control groups, all participants were given general information on lifestyle changes. The participants from the exercise and control groups had no contact or interaction with Dietary education for the control group was one another during the study. conducted twice a month for 20-weeks whilst the experimental group also received their dietary education twice a month following one of their exercise sessions. The PRT group and control group received their dietary education on different days of the week. Both groups received education in the form of dietary aids (food models), which the resident dieticians used to provide detailed information on portion sizes of food consumed. Educational aids such as pamphlets and diagrams were used to illustrate the preferred types of food selected and to explain the glycaemic indices of food groups. The instructions stressed the need for a reduction in the intake of total energy, total fat and cholesterol-rich foods. An ideal meal was served to all participants after the education sessions to enlighten them on the types of food to be consumed while stressing the preparation methods and portion sizes.

## 3.6.2 Exercise Intervention

Exercise sessions took the form of progressive resistance training (PRT) using equipment such as dumbells, elasticized bands, exercise balls and own body weight. The exercise intensities increased on a monthly basis using 5 differently coloured elastised therabands of varying resistance. The colours of the elasticized therabands were yellow (1.5 kg), red (2.0 kg), green (2.7 kg), blue (3.5 kg) and



black (4.5 kg). A bench-press and leg press 1RM test was determined by trial using a sub-sample of 10 subjects (6 females and 4 males) at the physiotherapy gymnasium in the Mamelodi hospital. This was done primarily to determine the initial repetitions per set of exercises than the resistance, as the elasticised tensile resistance (colour) of the theraband was constant for all subjects during each month of the study, with a different theraband (increased resistance) thus being used for each month (X5) of the 20 week program. Dumbells and ankle weights of 2 kg resistance were used, with the repetitions per exercise progressively increasing from 3 sets of 6 repetitions in month 1 to 3 sets of 12 repetitions in month 5. For the first 4 months there was an increase of 2 repetitions each month and in the 5<sup>th</sup> month the repetitions (12 reps) were the same as the fourth month. Between each station the subjects were given 30 seconds rest to move from one station to the other, and repetition of each exercise was done every 4 seconds. In certain instance chairs were substituted for the exercise gym balls. Tables were improvised for exercise benches and door knobs as well as railings in the hall were used to fasten the elastic bands. Participants performed supervised PRT on two non-consecutive days per week (Appendix 5: Exercises). The exercise programme commenced with 30 minute-sessions, progressing to 60 minute-sessions towards the end of the study. Before and after each exercise session blood pressure and glucose levels were measured to ensure that none of the participants was hypoglycaemic (<3.7 mmol/L) prior to exercising or had high blood pressure readings (increase in systolic blood pressure >170 mmHg) that would be contra-If any patients indicated that they did not consume indicative to exercise. prescribed medication they were not allowed to participate in the days activities. All exercise participants congregated in the community hall where they had to do a general warm up and stretching exercises for 20 minutes. The exercising participants which comprised of forty people were divided into four groups with ten participants in each group. The groups then did a circuit workout for the remaining 40 minutes, rotating at each station of the circuit. The groups were then given a further 10-15 minutes which was used as a cool-down period as well as to perform few basic stretching exercises. All the exercises were supervised by qualified exercise science students. An attendance register was kept for each exercise session.





## 3.6.3 Clinical Parameters

A qualified nurse as well as a general medical practitioner at Tshwane District Hospital took blood samples for HbA<sub>1c</sub> and lipid-profile analyses. These samples were taken at baseline and at the end of the study. Blood samples were taken after an overnight fast and collected in EDTA tubes and were transported in ice to a pathology laboratory within six hours of being drawn. The HbA<sub>1c</sub> and lipid profiles were analysed using reagent kits in conjunction with a SYNCHRON<sup>®</sup> and SYNCHRON LX<sup>®</sup> System Lipid Calibrator. The system utilises two unique cartridges Hb and A1<sub>C</sub> to determine the haemoglobin A1c concentration as a percentage of total haemoglobin.

Physical activity/energy expenditure was assessed using the English version of the short International Physical Activity Questionnaire available on <u>www.ipaq.ki.se</u> [49, 50]. The specific types of activity assessed were walking, moderate-intensity activity and vigorous intensity activities. IPAQ defines moderate-physical activities as those that produce a moderate-increase in respiration rate, heart rate and sweating for at least 10 minute duration, which is equivalent to 3-6 metabolic equivalents (METS) based on the compendium of physical activity [51].

Circumferences that were measured with an anthropometric tape measure, were used to determine the derived measures of waist-to-hip ratio (WHR) i.e. ratio of the minimum circumference of the abdomen to the circumference of the buttock at the maximum protuberance. Body mass index (BMI) was calculated from weight in kilogram divided by height in metres squared.

## 3.7 Sample Size

The initial sample consisted of 91 participants, with a subsequent dropout of 11 participants, leaving forty participants in an experimental group (6 males and 34 females) and forty participants in a control group (11 males and 29 females). Progress through the various stages of this study is highlighted in figure 1. The discontinuation of participants as highlighted in figure 1 was due to personal



problem experienced, non-compliance and amputation. Follow–up was done by means of telephone calls and letters that were posted to participants homes or hand delivered while they waited at the diabetes outpatient clinic. Socio-economic problems, psychosocial problems, death in the family and illnesses were given reasons for not attending the exercise and dietary sessions. No adverse effects or side effects were reported in either group.



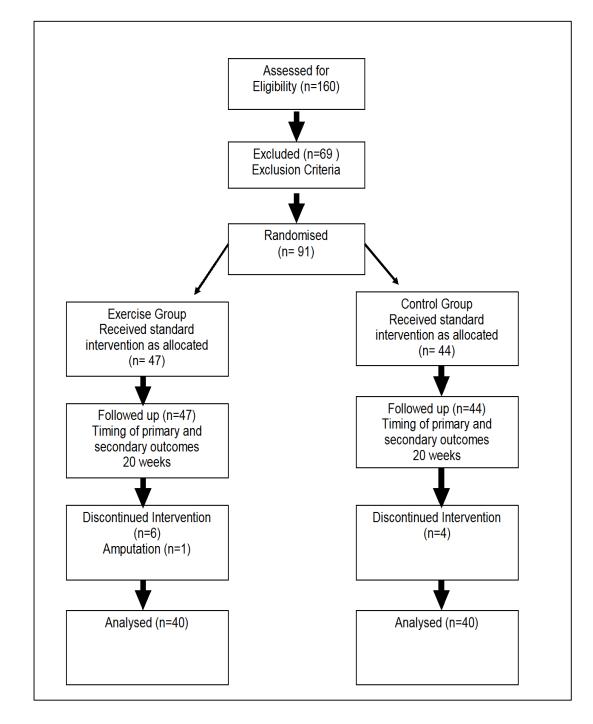


Figure 1: Diagram Showing the Flow of Participants through Each Stage of the Randomized Controlled Trial.



#### 3.8 Statistical Analysis

The analysis of data was done using Stata 10® [52]. Analysis of co-variance was used to assess the post values adjusting for baseline value as well as age, gender and baseline body mass index (age and gender when assessing post body mass index and post waist to hip ratio). Comparison of the pre-post values within groups over time was done using the paired t-test or the Wilcoxon signed-rank test (for triglyceride values). For comparisons between groups over the 20-week period, analysis of co-variance (ANCOVA) was used adjusting for baseline values (using log transformation in the case of the triglycerides) as well as body mass index, gender and age. A p-value  $\leq 0.05$  was regarded as statistically significant.

#### 3.9 Results

The demographics of the sample by gender, age, educational level and employment status are given in Table 1. The sample size consisted of 17 males and 63 females. The ages of the participants ranged from 40-65 years. The majority (52.50%) of the exercise group had passed standard 7 (grade 9) whilst the majority (40%) of the control group had passed standard 10 (grade 12). The employment status indicated that majority (52.5%) in the exercise group were unemployed, whilst the majority (40%) in the control group were pensioners. Formal statistical testing and matching of groups at baseline was not done and such post randomization differences observed were thus due to chance. However, age and gender appear not to have been balanced between the two groups and were thus adjusted for in subsequent analyses.



# Table 1: Frequency Distribution of Demographic Variable

DEMOGRAPHIC VARIABLES		Exercise	e (N=40)	Control (N=40)		
		Ν	%	Ν	%	
	Males	6	15.00	11	27.50	
GENDER	Females	34	85.00	29	72.50	
	40-50	11	27.50	6	15.00	
AGE (Years)	51-60	16	40.00	17	42.50	
	61-70	13	32.50	17	42.50	
	St 1-4	7	17.50	8	20.00	
EDUCATIONAL	St 5-7	21	52.50	12	30.00	
LEVEL	St 8-10	11	27.50	16	40.00	
	NONE	1	2.50	4	10.00	
	Part-time	1	2.50	4	10.00	
EMPLOYMENT STATUS	Full time	1	2.50	5	12.50	
	Pensioner	17	42.50	16	40.00	
	Unemployed	21	52.50	15	37.50	

Table 2 highlights the clinical baseline characteristics of participants in the exercise and control groups. The mean values reflect the control and exercise group to be more or less homogeneous (based on randomization), except for BMI (which was subsequently adjusted for).



# Table 2: Baseline Clinical Data

	Exercise	cise (N=40)		(N=40)
Variable	Mean	SD	Mean	SD
Glycosylated Haemoglobin (%)	9.01	3.11	9.32	2.32
Systolic blood pressure (mmHg)	142	28.55	133	20.66
Diastolic blood pressure (mmHg)	101	25.61	88	14.01
High-density lipoprotein (mmol/L)	1.05	0.25	1.27	1.11
Low-density lipoprotein (mmol/L) Exercise: n=37 Control: n=39	3.05	0.97	3.17	0.85
Total cholesterol (mmol/L)	4.92	1.10	5.08	0.84
Triglycerides* (mmol/L)	1.57 *(0.38-11.78)	1.81	1.66 (0.47-5.00)	1.03
Body Mass Index (kg/m²)	33.53	6.93	30.84	5.36
Waist to Hip Ratio	0.86	0.08	0.88	0.11
Energy expenditure (METS)* (Pre-intervention )	1662	343-3525	1347	714-2578.5

\*Median (min-max)

SD= Standard deviation

N= Number of patients

BMI adjusted at baseline



HbA <sub>1c</sub> (%)	Exercise (N=40)		Control (N=40)	
	Mean	SD	Mean	SD
Pre-intervention	9.01	3.1	9.32	2.3
Post-intervention	8.47	2.4	9.17	2.5
Change within group	-0.54	1.6	-0.15	2.6
p- value at 20 weeks	0.04* 0.72*			'2*
Difference at 20 weeks between exercise and control group	-0.59 (95% CI -1.45 to 0.27, p=0.18)**			

#### Table 3: HbA<sub>1c</sub> Values in Exercise and Control Groups

- \* p for change within group
- \*\* adjusted for BMI, age, gender as well as pre-test values

When comparing changes in glycosylated haemoglobin (HbA<sub>1c</sub>) between exercise and control group over the intervention period, a non-significant difference (p=0.18) was observed. A 0.59% reduction in HbA<sub>1c</sub> levels was seen between groups over the 20 week period (95% CI -1.45 to 0.27). A non-significant (p=0.72) mean (SD) HbA<sub>1c</sub> reduction of 0.15% (2.6) was observed in the control group and whilst a significant (p=0.04) reduction of 0.54% (1.6) was observed in the exercise group.

#### Table 4: High-Density Lipoprotein Values in Exercise and Control Groups

HDL (mmol/L)	Exercise (N=40)		Control (N=40)	
	Mean	SD	Mean	SD
Pre-intervention	1.05	0.25	1.27	1.11
Post-intervention	1.09	0.28	1.09	0.52
Change within group	0.04	0.16	-0.18	1.04
p-value at 20 weeks	0.13* 0.28*		28*	
Difference at 20 weeks between exercise and control group	0.01 (95% CI -0.16 to 0.19, p=0.87)**			

- \* p for change within group
- \*\* adjusted for BMI, age, gender as well as pre-test values



When comparing high-density lipoprotein (HDL) between exercise and control group over the intervention period, a non-significant difference (p=0.87) was observed. A 0.01 mmol/L (95% CI -0.16 to 0.19) difference in HDL levels was seen between groups over the 20 week period. A non-significant difference was observed in the exercise group (p=0.13) with an increase of 0.04mmol/L (0.16), a non-significant (p=0.28) mean HDL reduction of 0.18 mmol/L (1.04) was observed in the control group.

	Exercise (N=40)		Control (N=40)	
LDL (mmol/L)	Mean	SD	Mean	SD
Pre-intervention	3.05	0.97	3.17	0.86
Post-intervention	2.89	0.74	3.11	0.93
Change within group	-0.16	0.78	-0.04	0.81
p-value at 20 weeks	0.22* 0.77*			*
Difference at 20 weeks between	-0.22 (95% CI -0.55 to 0.11, p=0.19)**			
exercise and control group				

#### Table 5: Low Density Lipoprotein Values in the Exercise and Control Groups

\* p for change within group

\*\* adjusted for BMI, age, gender and baseline value

When comparing low density lipoprotein (LDL) between the exercise and control group over the intervention period, a non-significant difference (p=0.19) was observed. A 0.22 mmol/L (95% CI -0.55 to 0.11) reduction in LDL levels was seen between groups over the 20 week period. A non-significant decrease, was observed in the exercise group (p=0.22) with a decrease of 0.16mmol/L (0.78), similar trends i.e. a non-significant (p=0.77) adjusted-for-baseline change with a mean LDL reduction of 0.04mmol/L (0.81) was observed in the control group.





Total Cholesterol (mmol/L)	Exercise (N=40)		Control (N=40)	
	Mean	SD	Mean	SD
Pre-intervention	4.92	1.10	5.08	0.84
Post-intervention	4.69	0.81	5.04	1.02
Change within group	-0.23	0.88	-0.03	0.88
p-value at 20 weeks	0.11* 0.81*		*	
Difference at 20 weeks between exercise and control group	-0.30 (95% CI -0.66 to 0.04, p=0.09)**			

#### Table 6: Total Cholesterol Values in the Exercise and Control Groups

- \* p for change within group
- \*\* adjusted BMI, age, gender and baseline value

When comparing total cholesterol (TC) between exercise and control group over the intervention period, a non-significant difference (p=0.09) was observed. A 0.30 mmol\L (95% CI -0.66 to 0.04) reduction in TC levels was seen between groups over the 20 week period. A non-significant (p=0.11) difference was yielded in the exercise group with a decrease of 0.23mmol/L (0.88) as well as in the control group (p=0.81) with a mean TC reduction of 0.03mmol/L (0.88).

# Table 7: Triglyceride Values in the Exercise and Control Groups

	Exerci	se (N=40)	Control (N=40)		
Triglycerides (mmol/L)	Median	Min-Max	Median	Min-Max	
Pre-intervention	1.06	0.84-1.74	1.29	1.1-1.9	
Post-intervetnion	1.04	0.79-1.52	1.2	0.95-2.03	
p-value at 20 weeks	0.16*		0.73*		
Difference at 20 week between exercise and control group	-0.05 (95% CI -0.25 to 0.14, p=0.57)**				

Median (25<sup>th</sup>/75<sup>th</sup>) minutes- max values.

- \* p for difference over time within groups
- \*\* Differences in log triglycerides adjusted for BMI, age, gender and baseline value



When comparing triglycerides (TG) between the exercise and control group over the intervention period, a non-significant difference (p=0.57) was observed. A 0.05 mmol/L (95% CI -0.25 to 0.14) reduction in TG levels was seen between groups over the 20 week period. A non-significant (p=0.16), was found in the exercise group. A similar trend was observed in the control group, with a non-significant (p=0.73) change.

#### 3.10 Discussion

The primary aim of this paper was to establish the effectiveness of a resistance exercise and dietary education intervention programme on baseline HbA<sub>1C</sub> and lipid profiles in a cohort of African participants with type 2 DM. This study failed to demonstrate a difference (statistically significant) of at least 1% in the HbA<sub>1c</sub> after the intervention. The secondary hypothesis was also rejected as the implementation of the PRT programme did not show a significant change in lipid profile comprising low-density lipoprotein, high-density lipoprotein, total cholesterol and triglycerides.

This study did not show that supervised progressive resistance exercise and dietary education decreases HbA<sub>1c</sub> and lipid profiles more than dietary education alone. Although the baseline energy expenditure (METS) of both groups were similar (table 2), interpretation of the results was complicated by the fact that participants having both poorly controlled (greater than 7 percent) and well-controlled HbA<sub>1c</sub> were included in the study at baseline. This may have modified the effect of the exercise modality. The main focus was to achieve a significant reduction in the HbA<sub>1c</sub> by 1%, given a standard deviation of 2.23%. Within the exercise group there was a significant reduction (p=0.04), but no significant difference in HbA<sub>1c</sub> was observed between groups, over time (p>0.05) when adjusted for age, gender, BMI and baseline values.

The present study is in accordance with the results reported by Keyserling *et al.* [53] and Dunstan *et al.* [45] they reported minimal changes in HbA<sub>1c</sub> in all groups for both studies. The improvement in the HbA<sub>1c</sub> levels of 0.54% in the exercise group



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is also in line with the results obtained by Dunstan *et al.* [46] who reported a reduction of 0.39% in their exercise group. The study done by Keyserling *et al.* [53] apportioned the minimal improvement in glycaemic control to the fact that the study did not address medication adherence, which to an extent is also a shortcoming in the current study. In contrast to the above studies research done by Goldhaber-Fiebert and Collegues [54] found a more substantial reduction of 1.8 + 2.3% in HbA<sub>1c</sub> in a 12-week lifestyle intervention. Their study was based on 11 weekly nutrition classes and supervised walking groups three times per week. The frequent contact hours and direct supervision of exercise may have contributed to the success of the study. Previous investigations conducted involving resistance exercise in adults with type 2 diabetes in a supervised setting, have shown a reduction in the HbA<sub>1c</sub> from baseline levels ranging between 0.5 to 1.2% [55].

While older persons may need a longer adaptation period to become accustomed to an exercise routine, the 20-week (5 month) study period was long enough to induce some positive, but statistically insignificant, changes in both the primary (HbA<sub>1c</sub>) and secondary (lipid profile) outcomes. The improvement in the in both groups may be attributed to the Hawthorne effect [56]. The subject's participation in the trial and interest portrayed by the field workers and health care workers and exercise trainers may have contributed to the improvement in both groups rather than the exercise per se. It is recommended, however, that the duration, intensity and, most importantly, frequency of the programme be taken into consideration in exercise prescription for type 2 diabetics to achieve optimal benefits.

Having type 2 DM increases the incidence of cardiovascular disease two to four-fold [57]. The beneficial effect of physical activity on cardiovascular risk is related to an increase in insulin sensitivity [58]. Insulin resistance is an important contributor to premature coronary disease, particularly when associated with hypertension, hyperinsulinaemia, central obesity and an overlap of metabolic abnormalities. The risk factors for coronary heart disease in type 2 DM are increased LDL cholesterol, decreased HDL cholesterol, hypertension, hyperglycaemia and smoking [13]. It is also noted that intra-abdominal obesity is associated with insulin resistance type 2 DM, hypertension, dyslipidaemia and cardiovascular disease. The metabolic



syndrome is a cluster of these abnormalities. Hypertriglyceridaemia, low HDL, altered LDL cholesterol and elevated free fatty acids are strong risk factors of cardiovascular disease [59]. A study undertaken by Dattilo and Kris-Etherton [60], has shown that weight-loss of 1 kg decreases serum cholesterol by 1%, triglycerides by 1.9% and fasting plasma glucose values by 3.6mg/dL (0.2mmol/L).

The beneficial effects of regular exercise on lipid and lipoprotein are well documented [61]. Many studies published demonstrated that regular exercise results in widespread beneficial effect on the lipoprotein profile, with the majority of the improvements being related to duration as opposed to intensity of exercise [62]. As stated in the STRIDDE study, whether the effects of exercise are only acute, lasting 1-3 days, as is a consistent finding with regards to insulin sensitivity, or whether the effects of regular exercise on lipids are more sustained [32]. As stated in the STRIDDE study investigators were, however, more interested in whether the early versus sustained nature of improved lipid profiles were related primarily to exercise training and/or exercise intensity.

The important findings of the study proved that the benefits and the improvements in HDL size and large HDL are sustained up to 2 weeks after exercise withdrawal. HDL cholesterol is thought to have significant clinical influence such as antiinflammatory antioxidative, antiaggregatory, anticoagulant and profibrinolytic activities [63], in addition to its role in reverse cholesterol transport. Tables 4 to 7 reflect the lipid profiles in the exercise and control groups over the 20-week trial period. A promising but non-significant trend of increased HDL and decreased LDL, TC and TG was observed within the groups, but no difference was seen between groups. The LDL levels also proved to be insignificant over the 20 week period. It is also noted that with the TC a small reduction was seen in both control and exercise group but this was not significant to cause a significant reduction over 20 weeks of intervention. Triglycerides also proved to be non-significant when comparing the results over the 20 week period with and between groups. Due to the insignificant changes of lipid profiles i.e. LDL, TC, HDL and TG these are indicators of sustained cardiovascular risks. In general there is an inverse correlation between HDL and TG levels. Studies suggest that decreasing TG plays



a major role in increasing HDL levels [64]. The STRIDDE study [32] showed that there is a marked discordance in the effects of the exercise training responses in VLDL-TGs and HDL metabolism, which suggests it, is likely that these responses have a different mechanism.

Acute changes in lipid metabolism is due to the changes in insulin signaling mediated by recent bouts of exercise [65]. The rapid reversal of insulin action in muscle following cessation of exercise may be secondary to the rapid change in VLDL metabolism in muscle with enforced inactivity. A reduction in VLDL metabolism in muscle with inactivity leads to diversion of fatty acid metabolism away from mitochondrial oxidation and toward increases in triglyceride stores, which has a suppressing effect on insulin action. Changes in HDL-C, however, are harder to achieve, are likely related to changes in body habitus and possibly increases in oxidative capacity in muscle, are likely longer lasting, and are harder to reverse, even with enforced inactivity [32].

Although the current study using moderate PRT failed to show an improvement in lipid profile, other studies using moderate-intensity exercise resulted in twice the magnitude of triglyceride lowering as compared to higher intensity training, and proved beneficial to men with low HDL cholesterol, elevated TG, and abdominal obesity [66]. Using moderate-intensity exercise relative to high-intensity exercise relies more on lipid as a fuel source. This may imply that moderate-intensity exercise has a longer-lasting effect on lipoprotein lipase in muscle and hepatic lipase in liver. This theoretically leads to increased lipid uptake and oxidation in skeletal muscle, with resultant improvements in insulin action and lower steadystate glucose, insulin, and triglyceride levels. High-intensity exercise may lead to a higher rate of triglyceride mobilization from fat stores as a response to the higher catecholamine levels with high-intensity exercise, thereby counteracting any stimuli to reduce VLDL-TG levels through increased utilization and oxidation in muscle. Combined, these effects might explain the relative magnitude of the training-induced lowering of serum VLDL and triglycerides with moderate-intensity exercise relative to vigorous-intensity exercise. Alternatively, vigorous exercise tends to increase mitochondrial capacity relative to lower intensity exercise and the imbalance



between supply and demand, created by training cessation and lipid storage, may have a detrimental effect on mitochondrial fatty acid oxidation, storage, and insulin action in the tissues (muscle, fat, and liver) of vigorous-intensity exercisers, thereby resulting in a "rebound" in serum VLDL and triglycerides in these groups [66]. Physical inactivity has numerous, significant, detrimental metabolic consequences. Exercise thus has the potential to impact positively on the lipid profile of an individual, thus also reducing the blood pressure. Numerous positive effects such as cardiovascular fitness and serum lipid profiles can be induced by performing a minimum of a 10 minutes of exercise on a daily basis [67].

Circuit-type resistance training seems to be a feasible and effective therapeutic modality in moderately obese sedentary patients with type 2 DM [42]. However frequency, duration and intensity are important aspects of an exercise regime. In this study the supervised exercise sessions were presented twice a week. The intensity was determined from a pilot study and adjusted throughout the study over the duration of five months. This was expected to be sufficient when compared with other exercise studies. There were, however, some limitations in the present study. The design adopted was a randomised control study investigating PRT on numerous variables, over a relatively long term (5 months), with multiple group While the researcher relied on block randomization to control for sessions. confounding variables e.g. age, gender and activity levels, randomization of a relatively small sample (n=80) failed to address the equality in groups regarding the different confounding variables. Subjects with good and poor HbA1c were pooled prior to group assignment, and it is possible that the effect was diluted by those subjects with good control from the start. Given that the experimental intervention programme in this study showed the correct trends, the disappointing outcomes may be due to the fact that the exercise programme was not challenging enough in intensity and frequency. The logical deduction is the need to increase the frequency to at least 3 to 5 days a week at a greater intensity to result in a favourable outcome. However, the logistical challenge of implementing and managing such a programme within a resource-poor community setting must also be taken into consideration.



Although the study did not yield any significant differences between groups with regard to the HbA<sub>1c</sub> and lipid profile, it did however create an awareness of the potential benefits of exercise to a diabetic patient in a resource-poor setting. There are a number of studies in the literature that have focused on the benefits of exercise in patients with type 2 DM. Although his study failed to demonstrate a statistically significant difference of at least 1% in the HbA<sub>1c</sub> it is important to note that the 0.5% difference achieved could be clinically significant. This Mamelodi community study is unique in that no study has evaluated the efficacy of a PRT programme in such a setting in South Africa. Further studies should investigate the efficacy of progressive resistance training on HbA<sub>1c</sub> and lipid profile, taking into account only poorly controlled type 2 DM patients.



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#### Chapter 4

# The Efficacy of a 20-Week Progressive Resistance Training Programme on Morphological, Musculoskeletal and Aerobic Fitness in Participants with Type 2 Diabetes Mellitus

#### Abstract

**Background:** Progressive resistance training (PRT) has been recognised as a useful therapeutic tool for the treatment of a number of chronic diseases, including type-2 DM. PRT has been reported to increase muscle strength, lean muscle mass, bone mineral density and to enhance insulin sensitivity, which consequently facilitates glycaemic control, functional status and mobility.

**Aims:** The purpose of the study was to determine the efficacy of a 20 week progressive resistance training (PRT) and a dietary education programme on body composition, musculoskeletal and aerobic fitness in a cohort of 80 male and female type 2 diabetics from ages 40-65 years. Participants were of African heritage and were recruited in a resource-poor setting from the outpatients' clinic at the Mamelodi hospital in Gauteng, South Africa.

**Methods**: A randomized controlled trial design was adopted for the study. Subjects were assigned to a PRT group (n=40) and control group (n=40). Participants in the PRT group were exposed to progressive resistance training and dietary education whilst the control group (CT) where only exposed to dietary education. The outcome measures entailed anthropometry, muscle strength, endurance, flexibility, aerobic performance and rates of perceived exertion.

**Results**: The following pre-post intervention changes were found for the PRT vs. CT. Umbilical abdominal circumference (PRT: pre 106.91 (16.16) vs. post 104 (15.26); p=0.09 vs. CT: pre 105.0 (14.38) vs. post 105.66 (14.07) cm: p=0.58); anterior abdominal circumference (PRT: pre 100.34 (12.88) vs. post 98.34 (10.44) cm; p=0.07 vs. CT: pre 99.74 (12.86) vs. post 96.63 (12.50) cm: p=0.08); body mass index (PRT: pre 33.53 (6.92) vs. post 33.37 (6.76); p=0.70 vs. CT: pre 30.85 (5.36) vs. post 31.36 (5.58): p=0.37), waist to hip ratio (PRT: pre 0.85 (0.08) vs. post 0.85 (0.09); p=0.60 vs. CT: pre 0.89 (0.14) vs. post 0.86 (0.09): p=0.13);



fat percentage (PRT: pre 45.09 (6.04) vs. post 44.55 (5.99); p=0.06 vs. CT: pre 42.30 (6.39) vs. post 42.12 (6.59) %: p=0.96). None of these morphological changes within the PRT group were significantly better (p>0.05) than that in the CT group. Muscular endurance (wall squat) scores were PRT pre 50.5 (29-109) vs. post 115 (58-172.5); p=0.0011 vs. CT: pre 33 (21.5-54.5) vs. post 51.5 (37-121) sec; p=0.0017), with a greater change in CT group (p=0.004); muscular strength (abdominal crunches) PRT pre 35.12 (10.8) vs. post 35.65 (9.30); p=0.81 vs. CT: pre 30.27 (9.62) vs. post 34.07 (11.91) reps: p=0.03), flexibility (sit and reach) PRT pre 37.32 (9.13) vs. post 38.81 (9.56); p=0.17 vs. CT: pre 39.28 (8.73) vs. post 39.35 (9.25) cm; p=0.92). Aside from the wall squat (p=0.004), none of these musculoskeletal changes between the groups differed significantly (p>0.05). Six minute walk distance was PRT: pre 324.18 (114.88) vs. post 445.78 (69.67); p=0. 00 vs. CT: pre 353.98 (128.90) vs. post 440.60 (104.41) m: p=0.00). Ratings of perceived exertion (RPE) in the PRT vs. CT for the 6 min walk showed lower indices of pre-exercise dyspnea ( $0.25\pm0.52$  vs.  $0.48\pm0.94$ ) and fatigue ( $0.21\pm0.42$ vs.  $0.63\pm0.87$ ; p≤0.01) and similar post-exercise dyspnea (1.95±1.28 vs.  $1.98\pm1.61$ ) and fatigue ( $2.03\pm0.97$  vs.  $2.3\pm1.8$ ) - despite the PRT subjects being able to cover a greater distance in the 6 min, although the latter was not statistically significant (p=0.29).

**Conclusion**: PRT and dietary education had no significant superior benefit than dietary education alone on body composition, musculoskeletal and cardio-respiratory fitness. An inadequate intensity and duration of the PRT intervention are possible reasons for not observing an effect.

**Keywords**: Strength training, physical fitness, muscle morphology, power, musculoskeletal fitness, aerobic function and rating of perceived exertion.



#### 4.1 Introduction

Diabetes Mellitus (DM) is a major global health problem reaching epidemic proportions worldwide with serious implications for mortality and morbidity [1, 2]. The growing global burden of DM has focused more attention on primary prevention. Both cross-sectional and longitudinal studies have identified a number of risk factors and co-morbidities of DM, some of which are potentially modifiable [3], these include overweight, obesity, low lean body mass and decreased cardiovascular and respiratory fitness. In most affluent populations, the prevalence of obesity as measured by the BMI (body mass index) among adults varies from 10 to 40%. Overweight affects an even larger proportion of the population than obesity [4]. Overweight also carries an increased risk of the same complications as obesity and the risk is particularly high when abdominal obesity is evident. It has also been established in cross-sectional studies that the measure of waist-to-hip ratio strongly associates with type-2 DM [5]. This association has usually been interpreted as the result of central fat distribution, central obesity, upper body obesity, or truncal fatness. However, waist circumference is more highly predictive of visceral intra-abdominal fat accumulation than waist to hip ratio [5], and studies have shown a stronger relationship between waist circumference and type-2 DM development [6]. The major complications are type-2 DM, hypertension, stroke, ischemic heart disease, certain cancers and physical disability, which collectively may account for 5-10% of all health costs [4]. Resistance training has recently been recognised as a useful therapeutic tool in the treatment of a number of chronic diseases [7, 8] and it has been demonstrated to be safe and efficacious for the elderly [9] and obese individuals [10].

#### Effect of Progressive Resistance Training on Physiological Variables

Progressive resistance training (PRT) is defined as exercise where the resistance against which a muscle generates force, is progressively increased [11]. PRT implies muscle movement against resistance, such as weights, rubber elastised therabands or ones own body weight against gravity. Resistance training is typically of higher intensity and shorter duration than aerobic activities. Intensities



are often measured as a percentage of an individual's one repetition maximum (1RM). Intensities of 60-90% of 1RM are typically utilised in PRT programs, although the initial resistance training used may be as low as 30% [12]. Patients can also be instructed to achieve a "comfortably hard level" of exertion (4-5) on the Borg Scale of Perceived Exertion [13] as an alternative method of quantifying intensity. As an individual's strength increases with proper training, a progression in the overload placed on the muscle needs to occur to sustain further This is typically accomplished by increasing repetitions or improvement. resistance. This type of exercise places unique stress on the musculoskeletal system, which in turn causes and anabolic adaptation response in both muscle and bone. Aerobic exercise does not elicit such a response [12]. Resistance training has been reported to enhance insulin sensitivity [14], daily energy expenditure [15, 16] and quality of life. Furthermore resistance training has the potential for increasing muscle strength [17, 18] lean muscle mass [19] and bone mineral density [20] which in turn enhances functional status and glycaemic control, leading to changes in neuroendocrine and cardiovascular function [21].

Physical activity for those patients without significant complications or limitations should include appropriate endurance and resistance exercise for developing and maintaining cardio-respiratory fitness, body composition, and muscular strength and endurance [22]. It is well-known that resistance training can improve muscular strength, local muscular endurance and power and stimulate positive effects on body composition such as a decrease in percentage body fat [23]. Flexibility is often neglected and considered to be unimportant when rating fitness. However flexibility is imperative to maintain the full range of motion of joints, particularly in individuals with type-2 DM [24]. A study undertaken by Herriott et al. [25], showed that flexibility and resistance training caused significant strength gains in older adults with and without type-2 DM with flexibility gains being most prevalent in the diabetic participants [25]. If strength, endurance and flexibility are not maintained, musculoskeletal fitness is compromised, which can significantly impact physical health and wellbeing. Unlike aerobic training, resistance training is dependent to an extent on equipment, knowledge of exercise techniques and some initial instruction. If resistance training is going to materialise as a realistic



form of exercise for individuals with type-2 DM, research is needed to develop practical, sustainable and economically viable ways to implement resistance training safely at a population level [26].

#### 4.2 Aim

The primary focus of this research was to establish the effectiveness of a PRT and dietary education intervention programme on morphological, musculoskeletal and aerobic fitness in patients with type-2 DM.

#### 4.3 Hypothesis

The implementation of a progressive resistance-training exercise and dietary education programme would improve the morphology, body composition as well as musculoskeletal and aerobic fitness of subjects more than dietary education only.

#### 4.4 Materials and Methods

#### 4.4.1 Participants

The study was undertaken in Mamelodi, a suburb in the City of Tshwane Metropolitan Municipality in the province of Gauteng, South Africa. The participants (n=80) included black male (6=control group and 11=exercise group) and female (34=control and 29=exercise group) participants from 40-65 years with type 2 DM without complications and a known duration of the disease for at least one year. Most participants were recruited from the outpatient clinic at the Mamelodi government hospital whilst they were waiting to be seen by a doctor. Participants were also recruited from local churches in the Mamelodi area. Participants were excluded according to the following criteria: Cardiovascular contraindications: Unstable angina, untreated severe left main coronary artery disease, angina, hypotension or arrhythmias provoked by resistance training, acute myocardial infarction, end-stage congestive heart failure, severe valvular



heart disease, malignant or unstable arrhythmias, large or expanding aortic aneurysm, known cerebral aneurysm, acute deep venous thrombosis, acute pulmonary embolism or infarction, and recent intracerebral or subdural hemorrhage; Musculoskeletal contra-indications: Significant exacerbation of musculoskeletal pain with resistance training as well as unstable or acutely injured joints, tendons or ligaments, fracture within the last 6 months (delayed union) and acute inflammatory joint disease; Other contra-indications: Rapidly progressive or unstable neurological disease, failure to thrive, terminal illness, uncontrolled systemic disease, symptomatic or large abdominal or inguinal hernia, hemorrhoids, severe dementia/behavioural disturbance, acute alcohol or drug intoxication, acute retinal bleeding, detachment/severe proliferative diabetic retinopathy, recent ophthalmic surgery, severe cognitive impairment, uncontrolled chronic obstructive pulmonary disease, prosthesis instability, severe (readings: systolic >160 mmHg and diastolic >100 mmHg) and malignant hypertension, as well as signs and symptoms suggestive of immuno-suppression.

#### 4.4.2 Design, Randomization and Procedures

The experimental design comprised a pre-test post-test randomised controlled trial. The study comprised of two groups, a control group (no PRT with dietary education only) and an experimental group (received supervised PRT and dietary education). Participants who volunteered for baseline testing were randomised by means of block randomization, using a computerised programme (<u>http://www.randomization.com</u>) [27]. However due to the relatively small sample size, important potential confounders such as age, gender and BMI were not matched or balanced and were adjusted for in the analysis.

The principal investigator was not blinded to the randomization of the participants, and trained university student assistants were recruited to assist in basic administrative work, however, the subjects were blinded to randomization. One hundred opaque sealed envelopes were used for the randomization process. Each envelope was numbered according to the randomization programme and a label was placed inside each one. The options were: (1=A=Exercise or



2=B=Control group). The letter A represented exercise and B represented control. On the appointed day, each of the participants who reported at the YMCA Hall at 08h30 was required to select an envelope indicating the group to which each had been assigned. At this session all participants were again briefed on the aim of the study. After being randomly assigned the participants were asked to fill out the consent forms.

#### 4.5 Ethical Clearance

The protocol was approved by the Research Ethics Committees of the Faculties of Humanities and Health Sciences at University of Pretoria (Number 66/2004). The chief executive officer, superintendent and physician providing medical services as well as the health-care workers at the DM out-patient clinic of the Mamelodi Hospital, also consented. On reporting for baseline-testing participants received information on the study in their own language as well as in English and had the opportunity to ask questions. If they were sufficiently interested in the study the prospective participants provided their signed, written, informed consent. Before commencing with the programme individuals had to undergo a thorough medical evaluation by a specialist physician, to be screened for the presence of any contra-indications to exercise.

#### 4.6 Intervention Programme

The duration of the study intervention programme was 20-weeks. Due to availability of subjects the study was staggered and therefore spanned over a period of 18 months in total (February 2004-June 2005), and was conducted in periods of 20 weeks until the targeted number of subjects were obtained. The YMCA hall in Mamelodi was used to perform the weekly intervention exercise and dietary educational sessions.



#### 4.6.1 Dietary Education

Research has suggested that both diet and exercise are cornerstones [28] which play pivotal roles in the control of type 2 DM. Participants who participated in this intervention programme were given dietary education, conducted in a community hall by the resident dietician at the Mamelodi Hospital with a view to educating participants on proper dietary habits. However no attempts were made to change their diet during the study. Before block randomization into exercise and control groups, all participants were given general information on lifestyle changes. The participants from the exercise and control groups had no contact or interaction with one another during the study. Dietary education for the control group was conducted twice a month for 20-weeks whilst the experimental group also received their dietary education twice a month following one of their exercise sessions. The PRT group and control group received their dietary education on different days of the week. Both groups received education in the form of dietary aids (food models), which the resident dieticians used to provide detailed information on portion sizes of food consumed. Educational aids such as pamphlets and diagrams were used to illustrate the preferred types of food selected and to explain the glycaemic indices of food groups. The instructions stressed the need for a reduction in the intake of total energy, total fat and cholesterol-rich foods. An ideal meal was served to all participants after the education sessions to enlighten them on the types of food to be consumed while stressing the preparation methods and portion sizes.

#### 4.6.2 Exercise Intervention

Exercise sessions took the form of progressive resistance training (PRT) using equipment such as dumbells, elasticized bands, exercise balls and own body weight. The exercise intensities increased on a monthly basis using 5 differently coloured elastised therabands of varying resistance. The colours of the elasticized therabands and the resistance respectively were: yellow (1.5 kg), red (2.0 kg), green (2.7 kg), blue (3.5 kg) and black (4.5 kg). A bench-press and leg press 1RM test was determined by trial using a sub-sample of 10 subjects (6



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females and 4 males) at the physiotherapy gymnasium in the Mamelodi hospital. This was done primarily to determine the initial repetitions per set of exercises than the resistance, as the elasticised tensile resistance (colour) of the theraband was constant for all subjects during each month of the study, with a different theraband (increased resistance) thus being used for each month (X5) of the 20 week program. Dumbells and ankle weights of 2 kg resistance were used, with the repetitions per exercise progressively increasing from 3 sets of 6 repetitions in month 1 to 3 sets of 12 repetitions in month 5. For the first 4 months there was an increase of 2 repetitions each month and in the 5<sup>th</sup> month the repetitions (12 reps) were the same as the fourth month. Between each station the subjects were given 30 seconds rest to move from one station to the other, and repetition of each exercise was done every 4 seconds. In certain instance chairs were substituted for the exercise gym balls. Tables were improvised for exercise benches and door knobs as well as railings in the hall were used to fasten the elastic bands. Participants performed supervised PRT on two non-consecutive days per week (Appendix 5: Exercises). The exercise programme commenced with 30 minute-sessions, progressing to 60 minute-sessions towards the end of the study. Before and after each exercise session blood pressure and glucose levels were measured to ensure that none of the participants was hypoglycaemic (<3.7 mmol/L) prior to exercising or had high blood pressure readings (increase in systolic blood pressure >170 mmHg) that would be contra-indicative to exercise. If any patients indicated that they did not consume prescribed medication they were not allowed to participate in the days activities. All exercise participants congregated in the community hall where they had to do a general warm up and stretching exercises for 20 minutes. The exercising participants which comprised of forty people were divided into four groups with ten participants in each group. The groups then did a circuit workout for the remaining 40 minutes, rotating at each station of the circuit. The groups were then given a further 10-15 minutes which was used as a cool-down period as well as to perform few basic stretching exercises. All the exercises were supervised by qualified exercise science students. An attendance register was kept for each exercise session.



Figure 1: Supervised Exercise Sessions Conducted on Participants using Therabands



Figure 2: Modified Wall Push-Ups Done by Diabetic Participants

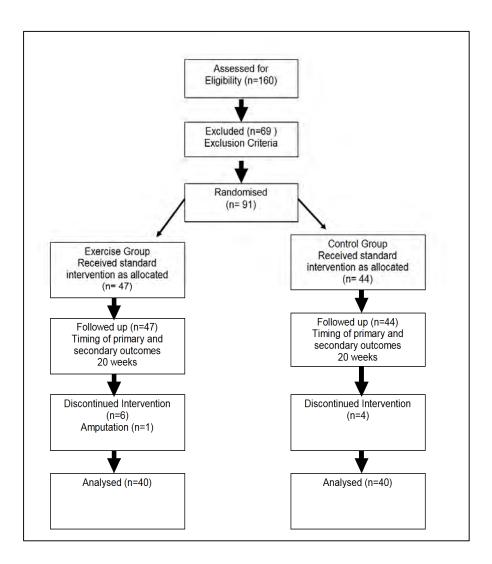


#### 4.7 Sample Size

The initial sample consisted of 91 participants, with a subsequent dropout of 11 participants, leaving forty participants in an experimental group (6 males and 34 females) and forty participants in a control group (11 males and 29 females). Progress through the various stages of this study is highlighted in figure 3. The discontinuation of participants as highlighted in figure 3 was due to personal problem experienced, non-compliance and amputation.



Follow–up was done by means of telephone calls and letters that were posted to participants homes or hand delivered while they waited at the diabetes outpatient clinic. Socio-economic problems, psychosocial problems, death in the family and illnesses were given reasons for not attending the exercise and dietary sessions. No adverse effects or side effects were reported in either group.



# Figure 3: Diagram Showing the Flow of Participants through Each Stage of the Randomized Controlled Trial



#### 4.8 Physical Parameters

The following outcomes were measured: morphology (body mass, stature, waist circumference, waist-to-hip ratio, body mass index), body composition (relative body fat), musculoskeletal fitness (muscular strength, muscular endurance and flexibility), and cardio-respiratory fitness (6-minute walk test- 6MWT).

#### 4.8.1 Morphology and Body Composition

A combined Detecto platform scale and stadiometer was used to measure both body mass and stature. Body mass was determined to the nearest 0.1 kg. The participants wore light clothing and were without shoes. Stature was determined to the nearest 0.1 cm. Subjects were barefooted and stood erect with the head positioned in Frankfort horizontal plane.

Circumferences that were measured with an anthropometric tape measure, were used to determine the derived measures of waist-to-hip ratio (WHR) i.e. ratio of the minimum circumference of the abdomen to the circumference of the buttock at the maximum protuberance. Body mass index (BMI) was calculated from body mass (kg) divided by height (m) squared. The estimated relative body fat was calculated using abdominal circumference and the regression equation of Weltman *et al.* [29] cited in Hayward & Wagner [30]. Abdominal circumference was measured anteriorly (midway between the xyhoid process of the sternum and the umbilicus) laterally (between the lower end of the ribcage and iliac crest) and lastly at the umbilicus level.

The following formulae were thus applied for males and females:

Men: %BF=0.31457 (abdominal C)<sup>b</sup> – 0.10969 (BW) + 10.8336 Women: %BF=0.11077 (abdominal C)<sup>b</sup> – 0.17666 (HT) + 0.14354 (BW) + 51.03301



#### Index for the above formulae:

<sup>b</sup>: Abdominal C (cm) is the average of two circumferences measured (1) laterally between the lower end of the rib cage and the iliac crests and (2) at the umbilicus level.

HT: height BW: body weight (kg) C: circumference

#### 4.8.2 Musculoskeletal Fitness

To access the subjects muscular strength/endurance, abdominal crunches was measured by the maximal number of correct abdominal crunches performed in one minute [31] . A gym mat, with masking tape and string across the gym mat in two parallel lines, 10 cm apart. The subject laid in a supine position, with the head resting on the mat, arms straight and fully extended at the sides and parallel to the trunk, palms of the hands in contact with the mat, and the middle fingertip of both hands at the 0 mark line. The knees were bent at a 90-degree angle. The heels remained in contact with the mat, and the test was performed with shoes on. The subjects performed as many consecutive curl-ups as possible, without pausing. The test was terminated after 1 minute. The test was terminated before 1 minute if subjects experienced undue discomfort, were unable to maintain the proper curl-up techniques (e.g. heels lifted off the floor) over two consecutive repetitions, despite cautions by the test supervisor.



#### Figure 4a: Abdominal Crunches Start Position



# Figure 4b: In the Motion of Executing the Movement



The wall squat was used to measure muscular endurance of the lower body particularly the quadriceps muscle group performed in 3 minutes. A smooth wall and a stopwatch were used. The procedure required the subject to stand comfortably with feet approximately shoulder width apart, with their back against a smooth vertical wall. Subjects slowly slid their back down the wall to assume a position with both subjects' knees and hips set at 90-degree angles. The timing started when both feet grounded firmly on the ground and was stopped when the subject could not maintain the position of if they were unable to squat for the entire 3 minutes.



# Figure 5a: Wall Squats Start Position



# Figure 5b: End position



Flexibility was used to measure the hip, hamstring and low back flexibility. Flexibility was assessed using the sit-and-reach test with the flexibility box [32] The subjects warmed-up by doing basic stretching prior to the test. The subject

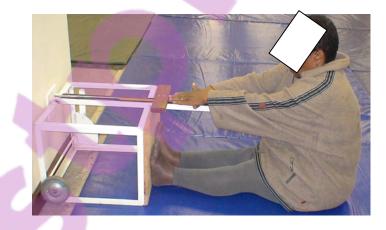


sat with the heels placed against the edge of the box (figure 3). The subject reached forward slowly with both hands, moving as far as possible and holding the terminal position. The fingers overlapped and remained in contact with the sit and reach box. The score was the most distant point reached. The best of three trials were taken. The test was executed without shoes. The knees remained extended throughout the test, but the tester did not press the subjects' legs down.

#### Figure 6a: Sit and Reach: Start position with a Sit and Reach Box



#### Figure 6b: In the Motion of Executing the Reach Movement



#### 4.8.3 Cardio-respiratory Fitness

The six-minute walk test (6 MWT) [33], a sub-maximal exercise test which provides an accurate reflection of a participant's aerobic fitness in diseased



populations was employed to measure cardio-respiratory fitness. The participant was instructed to walk from end to end over a 33m course, covering as much ground as she/he could during the specified six minutes. The participant was instructed to stop if discomfort was experienced during the test. The researcher was allowed to encourage the participants during the walk by calling out one of the pre-test-determined phrases, such as "You're doing well" or "Keep up the good work", after each completed lap. At the end of the test the researcher shouted "Stop", and the distance covered was recorded. A calibrated Sport Timer® was used to time the six minutes for all participants [33] . Exclusion criteria for the test were factors such as arthritis, swelling of the legs and angina as recommended for walk test ratings [32].

#### Figure 7: In the Motion of Walking the 6 Minute Walk Test



Rates of Perceived Exertion were simultaneously measured using Borg's Perceived Exertion Category-Ratio Scale, which rates exercise intensity on a



scale of 0 to 11 [13]. The RPE is associated with the relative metabolic rate and the relative heart rate in most individuals [13]. This scale is a valuable and reliable indicator in monitoring an individual's exercise tolerance [34]. Lactate threshold (LT) is an important anchor point for perception of effort during exercise and is not affected by the state of training or gender. An exercise intensity equal to LT can be prescribed by having people exercise at an intensity that is perceived as "somewhat hard" or equivalent to a Borg scale rating of 13 to 14 [13]. Borg's RPE was developed to allow subjective rating of feelings during exercise taking into account personal fitness level, environmental conditions and general fatigue levels [35]. The participants were required to rate their feelings before and after the 6-minute walk taking into account fatigue and dyspnea. The heart rate was taken using an automated arm wrist monitor (Wristech: Model No: JB3649) attached to the left arm. The monitor type uses automatic inflation, with oscillometry as a measurement method. The value of such a scale is that it provides exercisers with a guideline that is easily understood. A cardio-respiratory training effect and the threshold for blood lactate are achieved at a rating of "somewhat hard" to "hard" which approximates a rating of 4 to 5 (hard) on the category scale.

The current study utilized the 6MWT to assess the sub-maximal level of functional aerobic capacity. While a maximal test offers increased sensitivity in the diagnosis of asymptomatic ischaemia, but it is not feasible to assess such cardio-respiratory endurance in a community setting. In a recent review of functional walking tests it was concluded that the 6MWT was easy to administer, better tolerated, and more reflective of activities of daily living than other walk tests [36]. The 6MWT evaluates the global and integrated responses of all the systems involved during exercise. Because most activities of daily living are performed at sub-maximal levels of exertion, the 6MWT reflects the functional exercise level for daily physical activities optimally. According to the American thoracic Society sub-maximal test provided a reasonably accurate reflection of the participants' fitness, it could be conducted at a lower cost and reduced risk and it required less time and effort on the part of the participant [33]. Accordingly, the 6MWT was selected





as an appropriate mode of testing in the field setting within the Mamelodi Community where this study was conducted.

During the study, somatic RPE and specific symptomatic complaints such as degree of chest pain, burning, discomfort, dyspnea, fatigue and leg discomfort/pain were assessed routinely during the exercise tests. Participants were asked to provide subjective estimates every 2 minutes of the protocol (verbally or manually).

## 4.9 Statistical Analysis

The analysis of data was done using Stata 10 [37]. Descriptive statistics (mean and standard deviation) were used to describe outcome assessments of morphology (body mass, stature, waist circumference, waist-to-hip ratio, body mass index), body composition (relative body fat), musculoskeletal fitness (muscular strength, flexibility), and cardio-respiratory fitness (6 minute walk test) of both the exercise and control group at baseline and at the end of the study. Paired t-tests were used when comparing values within groups over time. However when comparing values between groups over time, a repeated measures analysis of co-variance (ANCOVA) was used adjusting for baseline values, age, gender and BMI. The variable muscle endurance (wall-squat) was skewed to the left, therefore it was log transformed. A p-value ≤0.05 was regarded as statistically significant.

## 4.10 Results

The demographics of the sample by gender, age, educational level and employment status are given in table 1. The sample size consisted of 17 males and 63 females.

The ages of the participants ranged from 40-65 years. The majority (52.50%) of the exercise group had passed standard 7 (grade 9) whilst the majority (40%) of the control group had passed standard 10 (grade 12). The employment status indicated that majority (52.5%) in the exercise group were unemployed, whilst the



majority (40%) in the control group were pensioners. Formal statistical testing and matching of groups at baseline was not done and such post randomization differences observed were thus due to chance. However, age and gender appear not to have been balanced between the two groups and were thus adjusted for in subsequent analyses.

#### Exercise (N=40) Control (N=40) **DEMOGRAPHIC VARIABLES** Ν % Ν % 15.00 27.50 Males 6 11 GENDER Females 34 85.00 29 72.50 40-50 11 27.50 6 15.00 AGE (Years) 51-60 16 40.00 17 42.50 61-70 13 32.50 17 42.50 St 1-4 7 17.50 8 20.00 **EDUCATIONAL** 21 52.50 12 30.00 St 5-7 LEVEL 27.50 40.00 St 8-10 11 16 NONE 1 2.50 4 10.00

Part-time

Full time

Pensioner

Unemployed

**EMPLOYMENT** 

**STATUS** 

## Table 1: Frequency Distribution of Demographic Variables

Table 2 highlights the relevant baseline characteristics of participants in the exercise and control groups. The mean values reflect the control and exercise group to be more or less homogeneous which can be attributed to randomization.

1

1

17

21

2.50

2.50

42.50

52.50

4

5

16

15

10.00

12.50

40.00

37.50



## Table 2: Baseline Clinical Data

	Exercise (N=40)		Contro	ol (N=40)
Variable	Mean	SD	Mean	SD
Glycosylated Haemoglobin (%)	9.01	3.11	9.32	2.32
Body Mass Index (kg/m <sup>2</sup> )	33.53	6.93	30.84	5.36
Waist to Hip Ratio	0.86	0.08	0.88	0.11
Energy Expenditure (METS)*	1662	343-3525	1347	714-2578.5

N= Number of patients

SD= Standard deviation

BMI adjusted at baseline

\*Median (min-max)

## EFFECT OF EXERCISE ON MORPHOLOGY AND BODY COMPOSITION

## Table 3: Umbilical Abdominal Circumference in the Exercise and Control Groups.

	Exercise (	N=40)	Control (N=40)	
Abdominal Circumference (cm)	Mean	SD	Mean	SD
Pre-intervention	106.91	16.16	105.00	14.38
Post-intervention	104.84	15.26	105.66	14.07
Change within group	-2.06	7.64	0.66	7.50
p- value	0.09	0.09* 0.58*		
Difference at 20 weeks between exercise and control group	-3.25 (se 1.67) (95% CI -2.77 to 3.77, p=0.056)**			

Table 3 compares the difference in abdominal circumference in the exercise and control group over the 20-week trail period. There was no statistically significant difference observed between the exercise and control group (p=0.056) when compared over the 20-week intervention period. A larger but non-significant



difference over time was observed within the exercise group (p=0.09) than the control (p=0.58) groups.

Table 4: Anterior	Abdominal	Circumference	in	the	Exercise	and	Control
Groups							

Anterior Abdominal	Exercise	(N=40)	Control (N=40)		
Circumference (cm)	Mean	SD	Mean	SD	
Pre-intervention	100.34	12.88	99.74	12.86	
Post-intervention	98.34	10.44	96.63	12.5	
Change within group	-2.00	6.82	-3.11	10.91	
p- value	0.07* 0.08*				
Difference at 20 weeks between	0.09 (se 1.74)				
exercise and control group	(95)	% CI -2.9 to	3.9; p=0.96)	**	

- \* p for change within group
- \*\* p comparing exercise with control waist circumference over time adjusted for age, gender, BMI and baseline value.

Table 4 compares the anterior abdominal circumference in the exercise and control groups over the 20-week trail period. There was no statistically significant difference observed between the exercise and the control (p=0.96) when compared over the 20-week intervention period. A statistically non-significant decrease was observed within the exercise (p=0.07) and the control (p=0.08) groups.



## Table 5: Body Mass Index in the Exercise and Control Groups

	Exercise (	Control (N=40)			
Body Mass Index (kg/m²)	Mean	SD	Mean	SD	
Pre-intervention	33.53	6.92	30.85	5.36	
Post-intervention	33.37	6.76	31.36	5.58	
Mean difference	-0.15	2.47	0.51	3.60	
p- value	0.70* 0.37*				
Difference at 20 weeks between	-0.45 (se 0.71)				
exercise and control group	(95% CI –0.89 to 1.89; p=0.53)**				

- \* p for change within group
- \*\* p comparing exercise with control BMI over time adjusted for age, gender, BMI and baseline value.

Table 5 compares the differences in BMI in the exercise and control groups over the 20-week trial period. There was no significant difference when comparing changes in BMI values between the exercise and control group over the 20-week intervention period (p=0.53). A non-significant decrease was observed in the exercise (p=0.70) and a non-significant increase in the control (p=0.37) groups.

## Table 6: Waist to Hip Ratio in the Exercise and Control Groups

Waist to Hip Ratio (WHR)	Exercis	se (N=40)	Control (N=40)	
waist to hip hato (whit)	Mean	SD	Mean	SD
Pre-intervention	0.85	0.08	0.89	0.14
Post-intervention	0.85	0.09	0.86	0.09
Mean difference	-0.01	0.08	-0.03	0.13
p- value	0.60* 0.13*			3*
Difference at 20 weeks between exercise	-0.01 (se 0.02)			
and control group	(95% CI 0.46 to 0.54 ; p=0.47)**			

- \* p for change within group
- \*\* p comparing exercise with control WHR over time adjusted for age, gender,BMI and baseline value.



Table 6 compares the differences in WHR in the exercise and control groups over the 20-week trial period. There was no-significant difference when comparing changes in WHR values between the exercise and control groups over the 20 week intervention period (p=0.47). As seen a non-significant decrease was observed in the exercise (p=0.60) as well as the control (p=0.13) groups.

Fat Percentage	Exercise	Exercise (N=40)			
r at reicemaye	Mean	SD	Mean	SD	
Pre-intervention	45.09	6.04	42.30	6.39	
Post-intervention	44.55	5.99	42.12	6.59	
Mean difference	0.54	1.78	0.17	1.41	
p- value	0.06* 0.43*			3*	
Difference at 20 weeks between	-0.009(se 0.21)				
exercise and control group	(95% (	(95% CI 0.09 to 0.91; p=0.96)**			

## Table 7: Fat Percentage in the Exercise and Control Groups

- \* p for change within group
- \*\* p comparing exercise with control fat % over time adjusted for age, gender,
   BMI and baseline value (p=0.64 if adjusted without BMI in model)

Table 7 compares the difference in fat percentage in the exercise and control groups over the 20-week trial period. There was no significant difference when comparing fat percentages between exercise and control group over the 20 week intervention period (p=0.96). A non-significant decrease was also observed in the exercise group (p=0.06) as well as in the control group (p=0.43).



## EFFECT OF EXERCISE ON MUSCULAR FITNESS

	Exe	rcise (N=40)	Control (N=40)		
Muscular Endurance (sec) (Wall Squats)	Medians (p=50)	(25th percentile- 75th percentile)	Medians (p=50)	(25th percentile- 75th percentile)	
Pre-intervention	50.5	29-109	33	21.5-54.5	
Post-intervention	115	58-172.5	51.5	37-121	
p- value	0.0011* 0.0017*			0.0017*	
Difference at 20 weeks between exercise and control group on a log scale	-0.50 (se 0.17) (95% CI 0.17 to 0.83; p=0.004)**				

## Table 8: Muscular Endurance in the Exercise and Control Groups

## \* p for change within group

\*\* p comparing exercise with control endurance over time adjusted for age, gender, BMI and baseline value(outcome and baseline value were log transformed).

The above table compares the difference in muscular endurance in the exercise and control groups over the 20-week trial period. There was a significant improvement in endurance in the exercise group (p=0.0011) as well as in the control group (p=0.0017). However most importantly there was a significant difference (p=0.004) when comparing muscular endurance values of exercise and control groups over the 20-week intervention period. This indicates that there was a significantly greater improvement at 20 weeks in the PRT group compared to the control group. The log transformation makes the interpretation of the observed difference difficult, however, calculation of the log difference observed shows that the increase over time in the control group was 60% of that in the exercise group (95% CI 44-84%).



## Table 9: Muscular Strength in the Exercise and Control Groups

Muscular Strength (reps)	Exercise	(N=40)	Control (N=40)		
Abdominal Crunches	Mean	SD	Mean	SD	
Pre-intervention	35.12	10.88	30.27	9.62	
Post-intervention	35.65	9.30	34.07	11.91	
Mean difference	0.53	13.56	3.80	10.70	
p- value	0.81* 0.03*				
Difference at 20 weeks between exercise	-0.43 (se 2.37)				
and control group	(95% CI 0.36 to 5.14; p=0.86)**				

- \* p for change within group
- \*\* p comparing exercise with control strength over time adjusted for age, gender,
   BMI and baseline value.

Table 9 compares the difference in muscular strength in the exercise and control groups over the 20 week trail. A significant increase (3.8 crunches, p=0.03) was observed in the control group. When comparing the 2 groups as seen above, the anomalous improvement in the control group with regard to strength was not significantly better when compared to the exercise group over the 20-week intervention period (p=0.86). A non-significant increase (p=0.81) was observed in the exercise group.



## Table 10: Flexibility (Sit and Reach Test) in the Exercise and ControlGroups

	Exercise	(N=40)	Contr	ol (N=40)
Flexibility (cm)	Mean	SD	Mean	SD
Pre-intervention	37.32	9.13	39.28	8.73
Post-intervention	38.81	9.56	39.35	9.25
Mean difference	1.49	6.76	0.07	4.39
p- value	0.1	7*	0.92*	
Difference at 20 weeks between exercise	-0.73 (se 1.27)			
and control group	(95% CI -1.99 to 2.99; p=0.57)**			).57)**

- \* p for change within group
- \*\* p comparing exercise with control flexibility over time adjusted for age, gender, BMI and baseline value.

Above is a comparison of flexibility in the exercise and control groups over the 20week trial period. There was no significant difference when comparing flexibility values between exercise and control group over the 20-week intervention period (p=0.57). No significant changes were seen in the exercise (p=0.17) or the control (p=0.92) groups.

## EFFECT OF EXERCISE ON CARDIOVASCULAR FITNESS

Table 11:	Six-Minute Walk	Distance in	n the Exercise	and Control Groups
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Distance (m)	Exercise	(N=40)	Contr	ol (N=40)	
	Mean	SD	Mean	SD	
Pre-intervention	324.18	114.88	353.98	128.90	
Post-intervention	445.78	69.67	440.60	104.41	
Mean difference (distance)	121.7	140.77	86.63	98.90	
p- value	*0.00 *0.00				
Difference at 20 weeks between	19.22 (se 18.03)**				
Exercise and Control group	(95% Cl -34.83 to 35.83; p=0.29)**				



- \* p for change within group
- \*\* p comparing exercise with control flexibility over time adjusted for age, gender,
   BMI and baseline value.

Table 11 compares the difference in distance walked at baseline with distance walked after the 20-week exercise intervention programme. An increase in the mean walking distance in the exercise group of 121.7m was significant (p<0.001) as was the smaller increase in mean walking distance of 86.6m in the control group (p<0.001). These changes were not significantly different, however, when comparing lap differences of exercise and control groups over the 20-week intervention period (p=0.29).

## Table 12: Perceived Exertion (Dyspnea) at 20 weeks in the Exercise andControl Groups

Dyspnea Index	Exercise (N=40)		Control (N=40)		P-Value
	Mean	SD	Mean	SD	
Pre 6 Min Walk	0.25	0.52	0.48	0.94	p= 0.54
Post 6 Min Walk	1.95	1.28	1.98	1.61	

Table 12 compares the RPE (dyspnea) index at 20 weeks between the exercise and control groups. Ratings of perceived exertion (RPE) in the PRT vs. CT for the 6 min walk showed lower indices of pre-exercise dyspnea ( $0.25\pm0.52$  vs.  $0.48\pm0.94$ ) and post-exercise dyspnea ( $1.95\pm1.28$  vs.  $1.98\pm1.61$ ). When comparing the pre and post dyspnea index at the 20 week 6 MWT, a non significance was observed (p=0.54) between groups.





# Table 13: Perceived Exertion (Fatigue) at 20 weeks in the Exercise andControl Groups

	Exercise (N=40)		Control (N=40)		P-Value
Fatigue Index	Mean	SD	Mean	SD	
Pre 6 Min Walk	0.21	0.42	0.63	0.87	p= 0.66
Post 6 Min Walk	2.03	0.97	2.3	1.8	

Table 13 compares the RPE (fatigue) index at 20 weeks between the exercise and control groups. After 20 weeks, ratings of perceived exertion (RPE) in the PRT vs. CT for the 6 min walk showed lower indices of pre-exercise fatigue  $(0.21\pm0.42 \text{ vs. } 0.63\pm0.87; p\leq0.01)$  and similar post-exercise fatigue  $(2.03\pm0.97 \text{ vs.} 2.3\pm1.8)$ . When comparing the pre and post dyspnea index at the 20 week 6 MWT, a non-significant difference was observed (p=0.66) between groups, despite the PRT subjects being able to cover a greater distance in the 6 min (table 11).

## 4.11 Discussion

Increased physical activity and participation in a comprehensive exercise programme incorporating resistance training, flexibility and aerobic endurance activities has shown to reduce the risk of several chronic diseases such as coronary heart disease, obesity, diabetes and lower back pain. Observational epidemiologic evidence supports increased physical activity as a means to prevent age-associated weight and fat gains which are common in patients with type-2 DM [38]. Attempts to normalise blood glucose levels are generally made through the implementation of long-term aerobic exercise training such as walking, running or cycling. Since the early 1950s and 1960s, resistance training has been a topic of interest in the scientific, medical and athletic communities. Resistance training has shown to be the most effective method for developing musculoskeletal strength, and it is currently prescribed by many major health organizations for improving health and fitness [39]. However resistance



programmes have also been associated with improving fitness and some aspects of cardiovascular functioning and recently resistance training has been put forward as an appropriate type of exercise in the exercise regime of persons with type-2 DM [40].

Overweight or obesity with abdominal fat distribution co-exists for 80-95% of cases with type 2 DM and remains a major obstacle in the successful long-term management of the disease [4]. Women with a BMI of 23-24 kg/m<sup>2</sup> have a fourfold higher risk of type-2 DM than women with a BMI <22 kg/m<sup>2</sup>. Women with a BMI of 24-25 kg/m<sup>2</sup> have a five-fold increased risk, and those with a BMI >35 kg/m<sup>2</sup> have a 9-fold increased risk, of type-2 DM [41]. In a study of twenty four healthy men Seidell et al. [42] have shown that those with increased waist-to-hip ratios had relatively less thigh muscle, raised insulin and decreased muscle endurance. The waist to hip ratio became a popular instrument and was shown to be a powerful predictor of the incidence of DM in adult men and women. The present study supports previous findings regarding the association of high waistto-hip ratio, high body mass index and large waist circumference with type-2 DM. In keeping with the norms for BMI of the world Health Organisation both the exercise and control groups (table 5) fell into the obesity class I (30.0-34.9 kg/m<sup>2</sup>) and the waist circumference also reflected a disease risk (men ≤102cm and women ≤88cm) [43]. As seen in table 6, the waist to hip ratio of both the exercise and control group falls within the low to moderate waist to hip ratio norms as depicted by Bray and Gray [44]. In keeping with the norms categorized by the age range (40-65 years), the exercise groups had a waist to hip baseline mean of 0.85 and twenty weeks mean of 0.85 which fall within the low category ratio for men  $(\leq 0.88)$  and in the high category ratio for women (0.80-0.90). When looking at the control group baseline and twenty week the waist to hip ratio also fell within the low to moderate category ratio for men (low ≤0.88 or ≤90) depending on the age range, and in the high category ratio for women (0.80-0.90) [44]. As seen in table 7, the subjects in the exercise group the mean fat percentage is 44.55 and in the control group 42.12 which clearly falls within the norms categorising one as being obese [45]. Aside from the positive association with increased obesity, blood pressure, risk of DM and poorer blood lipid profile, increased fat mass is also



linked to reduced musculoskeletal strength and flexibility [40]. Recent data in literature has shown that modest increments of physical fitness in diabetic patients reduce by two fold the risk of overall mortality [42, 46]. Obesity often coexists with diabetes therefore it is presumed to multiplicatively increase the risk of mortal events in diabetic [47]. Men with percent body fat values of less than 20% and women less than 30% are considered "within standards".

Changes in body composition have been an important training feature in many physical fitness programmes [23]. Unfortunately, while positive trends were shown, none of the body composition variables namely abdominal circumference, waist circumference, BMI, WHR and fat percentage changed significantly when compared to controls in this study. Changes in body composition are often determined by a combination of factors such as genetics, physical activity and In this study, all participants that were recruited were caloric intake [48]. sedentary and genetics was not considered when screening participants. Subjects were classified as being previously sedentary based on participation in a structured physical activity program. Subjects recruited were from a poor resource community and in most instances did walk long distances to get to their desired destination. An important variable that possibly caused insignificant differences in body composition is the caloric intake. The dietary variable was difficult to control during the study as the community studied was poor and funding was not available to monitor dietary habits. However, dietary education was offered to both the exercise and control groups twice monthly for the 20-week period.

The implementation of resistance training programmes is associated with increased musculoskeletal fitness, as indicated by increased muscular strength and endurance [40]. A study undertaken by Willey and Singh [21], reported on the feasibility of progressive resistance training compared to aerobic exercise in DM. They compared the two types of training because of concomitant cardiovascular, arthritic and other diseases patients with type-2 DM may have. According to Willey and Singh [21] muscle wasting due to ageing and physical inactivity, exacerbated problems of peripheral glucose uptake. As PRT increased



muscle mass, strength and endurance, it had positive effects on bone density, osteoarthritic symptoms and mobility impairment.

Regarding the muscle strength, initially the exercise group was stronger than the control group possibly due to it comprising of a larger proportion of younger subjects. The exercise group increased minimally with regard to strength when compared to the control group. The control groups' increase in strength was slightly better over the 20-week intervention than that of the exercise group. The increase in leg strength reflects adaptations to the exercise regime which could have a positive impact on insulin sensitivity. However, there was no significant difference between the exercise and control groups over time when adjusting for baseline, age and gender. The common dictum of most resistance training studies is that the training programme must be "progressive" in order to produce substantial and continued increases in muscle strength and size [23]. The exercise sessions in this study were well organized, commencing with exercise sessions of 30 minutes, progressing to 60 minutes towards the end of the study. Intensities ranged from 50%-80% of their one-repetition maximum (1RM), ending with 3 sets of 6-12 repetitions. The repetitions increased as the months progressed in order to intensify the exercise sessions. The non-effectiveness of the PRT could be attributed to insufficient resistance, although various resistance bands of increasing tensile resistance were used during the exercise sessions with each colour depicting an increase in resistance over the 20 week duration.

The data regarding muscular endurance measurements were skewed therefore the medians and the  $25^{\text{th}}$  (p25) and  $75^{\text{th}}$  (p75) percentiles were reported and not the medians and standard deviations as with other exercise variables. Results showed that there was a significant improvement in the endurance values within the exercise group (p=0.0011) as well as the control groups (p=0.0017). An important finding was a significant difference (p=0.004) being observed in the improved endurance values in favour of exercise versus control group over the 20 week period. This positive finding could be attributed to the resistance training done on the leg muscles as well as the frequent walking during the 20 weeks to and from the exercise venue.



A study done by Herriott *et al.* [25], showed a limited but small increase in flexibility in type-2 DM patients. The study also stated that flexibility was imperative in order to maintain the full range of motion of joints particularly in individuals with type-2 DM who may experience limited joint mobility due to glycation of joint structure [24]. This study showed no significant increase in flexibility in either the control or exercise group over the 20-week intervention trial period. As research suggests, flexibility decreases with 20-30% between 30 and 70 years of age [49]. Factors associated with an increased rate of decline in ROM are immobilization and inactivity. Individual measures of flexibility were similar in the exercise and control groups both before and after the 20-week PRT programme with no significant changes in their flexibility levels.

The result of a cross-sectional activity participation study by Irwin *et al.* [50], showed that 30 minutes of moderate physical activity such as brisk walking was associated with a 6.6% reduction in fasting insulin levels. This finding was important since it was done on women who were not used to, or did not regularly perform, vigorous physical activity. Research done Tanasescu *et al.* [51], reported that walking was associated with reduced risk of mortality and morbidity. They reported that walking pace was inversely associated with cardiovascular disease and total mortality, independent of the duration.

Because the six-minute walk test (6MWT) attempts to test the sub-maximal level of functional capacity, most patients do not achieve maximal exercise capacity during the 6MWT. They choose their own intensity of exercise and are allowed to stop and rest during the test. Although no significant between group differences were observed (p>0.05), the difference in the increased mean walking distance in the exercise group of 121.7m (p≤0.05) substantially greater than the change for the control group of 86.63m which also proved to be significant improvement (p<0.05). After 20 weeks, ratings of perceived exertion (RPE) in the PRT vs. CT for the 6 min walk showed lower indices of pre-exercise dyspnea (0.25±0.52 vs. 0.48±0.94) and fatigue (0.21±0.42 vs. 0.63±0.87; p≤0.01) and similar post-exercise dyspnea (1.95±1.28 vs. 1.98±1.61) and fatigue (2.03±0.97 vs. 2.3±1.8) - despite the PRT subjects being able to cover a greater distance in the 6 min.



As stated that the subjects that were recruited were not participating in a structured physical activity. The participants in the exercise group and control group received general health and dietary advice twice monthly at the community hall and hospital respectively. In a resource-poor setting, many individuals walk to their destinations. Getting to and from the hospital typically required these patients to walk as transport fees for them were expensive thus necessitating going by foot to educational sessions, and thus daily walking activity could not be controlled. This could have explained the increase in walking distance in the six minute walk test. Although the control group was not given formal education on exercise, general health advice was given patients, waiting to see the physician for medical assistance or on collection of their medication at the pharmacist. Therefore, it is possible that they increased their physical activity on the basis of their new knowledge about the benefits of exercise.

In conclusion, the intervention period was long enough to observe changes in the primary and secondary outcomes, but too short to have sustainable results regarding changes in morphology, body composition, musculoskeletal and cardio-respiratory fitness. Middle aged sedentary and older participants should tolerate higher exercise intensities and may need a longer adaptation period to enjoy optimal benefits from PRT programs [52]. The limited effect of the exercise intervention may have been attributed to the exercise sessions not being intensive enough or the relatively small size of the sample. There is a need for more research into different combinations of intensity-specific types and volumes of progressive resistance training, as a form of physical activity, required for greater efficacy in managing type-2 DM.



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## Chapter 5

## Influence of a Dietary Education Programme on Diabetes Care, Knowledge and Activities among Persons with Type 2 Diabetes Mellitus

## Abstract

**Background**: Diabetes mellitus (DM) self-care management is of importance because of the assumption that adoption of a healthy lifestyle will produce better metabolic control of DM, and that this will help to avoid subsequent acute and long-term complications of the disease. Many studies have investigated the link between DM self-care and level of DM control as well as psychosocial factors which may be predictive of self-care.

**Aims:** The purpose of the study was to describe the knowledge and practices with respect to dietary habits and medication usage among a cohort of 80 male and female type 2 diabetics from ages 40-65 years. Participants were of African heritage and were recruited in a resource-poor setting from the outpatients' clinic at the Mamelodi hospital in Gauteng, South Africa.

**Methods**: An evaluation was done on a group of patients selected for a randomized controlled clinical trial involving a progressive resistance training (PRT) and a dietary education programme. The self-report Diabetes Self-Care Activity questionnaire was used to assess three categories of DM care over 7 days i.e. knowledge and practices of dietary intake (basic food groups), glucose monitoring and use of medication. The questionnaire was administered at baseline and again at 20-weeks.

**Results**: With regards to dietary adherence at 20 weeks, the overall data suggests that a large proportion of subjects always (66.25%) adhered to a recommended diet as opposed to usually (20.00%) or sometimes (11.25%). Although the CT group adherence improved significantly (p=0.01) the change was not significantly better (p=0.61) than that of the PRT group. The majority of the cohort indicated good practice in high-fibre food intake making up either a quarter (36.25%) or half (42.50%) of their diet but there was no change (p<0.05) during this study. The majority of the cohort indicated that high-fat foods make either



none (35.00%) or a quarter (43.75%) of their weekly meals and the CT group improved significantly (p=0.009) more in reducing the high fat content of their weekly meals than the PRT group after the study. The majority of the subjects indicated good practice with food high in complex sugars making up make either none (58.75%) or a quarter (37.50%) of their weekly meals and there was no change (p>0.05) in this during the study. The majority of the subjects did not adhere to weekly urine testing with (73.75%) "never" doing so and (16.25%) "rarely" tested their urine over the previous 7 days, but the PRT group adhered significantly (p=0.001) more to this practice than the CT group, after the study. The majority (95.00%) of the cohort indicated good adherence in ingesting all of their prescribed medication and there was no change (p>0.05) in this during the study.

**Conclusion:** It was evident that adherence to recommended weekly dietary practices could be improved, but generally, the intake of high fibre foods, high fat foods and complex sugars was acceptable. While adherence to urine testing was poor, intake of prescribed medication was good. The dietary education group did reduce their high fat content in foods more than the PRT group, while the PRT group improved their urinary testing more than the CT, which indicates an improved awareness of these aspects brought about by the intervention. However, exercise interventions and dietary education has to be a continuous process in order to impact positively on diabetes care, knowledge and activities among persons with type 2 diabetes mellitus.

Keywords: Dietary education, Type-2 DM mellitus, community setting. DM care questionnaire, dietary knowledge, dietary practices



## 5.1 Introduction

In as much as the human genetic constitution has remained unchanged over the past 50,000 years or so, it is likely that an evolutionary mismatch between the patterns of nutrient intake and physical activity of our hunter-gatherer ancestors and that of modern industrialised societies underlies the global epidemic of chronic diseases such as diabetes mellitus (DM) [1, 2]. The value of tight blood glucose control in type-2 DM has been convincingly demonstrated in the United Kingdom Prospective DM Study, among other studies [3]. Improvement in glycaemic control is the critical factor in reducing the risks of chronic diabetic complications [4,5] and type-2 DM is more prevalent in those that are overweight and sedentary [6].

According to Social Cognitive Theory [7] adherence to a treatment regimen is influenced by knowledge, beliefs about one's ability to perform certain behaviours and the value of doing so, the skill to do so and incentives for engaging in a particular behaviour. In view of this statement it has been suggested that lifestyle intervention may lead to the primary prevention of Type-2 DM [8], possibly in as many as 50% of cases. In 1995, 135 million adults had DM worldwide, and this number is projected to be 300 million by 2025 [9]. DM is one of the chronic diseases in which self management plays a role in the treatment. Therefore, health care workers and doctors should educate the patient on the disease and its management. It is well understood that a better educated patient will have higher levels of compliance in DM self-care and also lower levels of glycosylated haemoglobin, suggesting better glycaemic control. The theory of reasoned action [10] states that an individuals intention to adhere to the self care regimen is determined by his/her attitude. Attitudes are determined by the individual's beliefs about the outcome of performing certain behaviours. Knowledge of the patients' attitudes towards the disease and DM care is therefore necessary to understand their behaviour and in order to educate them.

The purpose of the present paper was to obtain baseline and 20 week intervention data regarding the attitudes, knowledge and practices with respect to dietary



habits and medication usage among an African cohort of type-2 diabetics in a resource-poor community setting. This analysis formed part of a clinical trial evaluating the efficacy of a physical activity (progressive resistance training) and lifestyle intervention (dietary education) on health outcomes in persons with type 2 diabetes.

## 5.2 Materials and Methods

## 5.2.1 Participants

The study was undertaken in Mamelodi, a suburb in the city of Tshwane in the province of Gauteng, South Africa. The study participants (n=80) included black male and female participants between the ages 40-65 years with type-2 DM without complications and a known duration of the disease for at least one year. Most participants were recruited from the outpatient clinic at the Mamelodi government hospital as well as from local churches in the Mamelodi area. The following exclusion criteria were used: Cardiovascular contraindications Unstable angina, untreated severe left main coronary artery disease, angina, hypotension, or arrhythmias provoked by resistance training, acute myocardial infarction, endstage congestive heart failure, severe valvular heart disease, malignant or unstable arrhythmias, large or expanding aortic aneurysm, known cerebral aneurysm, acute deep venous thrombosis, acute pulmonary embolism or infarction, and recent intracerebral or subdural hemorrhage; Musculoskeletal contraindications: Significant exacerbation of musculoskeletal pain with resistance training, unstable or acutely injured joints, tendons or ligaments, fracture within the last 6 months (delayed union), acute inflammatory joint disease; Other contraindications: Rapidly progressive or unstable neurological disease, failure to thrive, terminal illness, uncontrolled systemic disease, symptomatic or large abdominal or inguinal hernia, hemorrhoids, severe dementia/behavioral disturbance, acute alcohol or drug intoxication, acute retinal bleeding, detachment/severe proliferative diabetic retinopathy, recent ophthalmic surgery, severe cognitive impairment, uncontrolled chronic obstructive pulmonary disease, prosthesis instability, severe (systolic >160mmHg and diastolic >100mmHg) and



malignant hypertension, and signs and symptoms suggestive of immunosuppression.

## 5.3 Ethical Clearance

The protocol was approved by the Research Ethics Committees of the Faculties of Humanities and Health Sciences at University of Pretoria (Number 66/2004). The chief executive officer, superintendent and physician providing medical services as well as the health-care workers at the diabetes mellitus (DM) out-patient clinic of the Mamelodi Hospital also consented to the diabetes mellitus study being conducted.

## 5.4 Study Design and Sampling

A baseline descriptive survey and post intervention analysis was used with quantitative data captured by means of a questionnaire. The initial sample consisted of 91 participants, with a subsequent dropout of 11 participants, leaving forty participants in an experimental group (6 males and 34 females) and forty participants in a control group (11 males and 29 females). Progress through the various stages of this study is highlighted in figure 1. The discontinuation of participants as highlighted in figure 1 was due to personal problem experienced, non-compliance and amputation. Follow–up was done by means of telephone calls and letters that were posted to participants homes or hand delivered while they waited at the diabetes outpatient clinic. Socio-economic problems, psychosocial problems, death in the family and illnesses were given reasons for not attending the exercise and dietary sessions. No adverse effects or side effects were reported in either group.



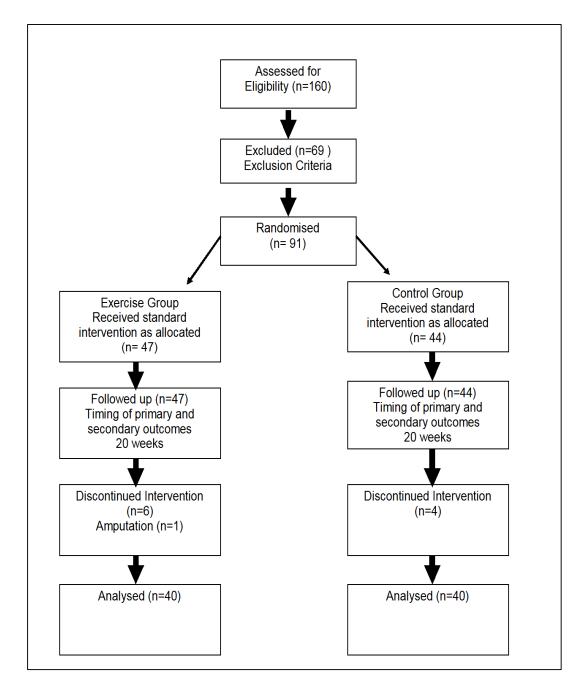


Figure 1: Diagram Showing the Flow of Participants through Each Stage of the Randomized Controlled Trial.



### 5.4 Intervention Programme

The duration of the study intervention programme was 20-weeks. Due to availability of subjects the study was staggered and therefore spanned over a period of 18 months in total (February 2004-June 2005), and was conducted in periods of 20 weeks until the targeted number of subjects were obtained. The YMCA hall in Mamelodi was used to perform the weekly interventions of dietary educational sessions (control group) and progressive resistance training plus dietary education (exercise group).

## 5.5.1 Dietary Education

Research has suggested that both diet and exercise are cornerstones [11] which play pivotal roles in the control of type 2 DM. Participants who participated in this intervention programme were given dietary education, conducted in a community hall by the resident dietician at the Mamelodi Hospital with a view to educating participants on proper dietary habits. However, no attempts were made to change their diet during the study. Before block randomization into exercise and control groups, all participants were given general information on lifestyle changes. The participants from the exercise and control groups had no contact or interaction with one another during the study. Dietary education for the control group was conducted twice a month for 20-weeks whilst the experimental group also received their dietary education twice a month following one of their exercise sessions. The PRT group and control group received their dietary education on different days of the week. Both groups received education in the form of dietary aids (food models), which the resident dieticians used to provide detailed information on portion sizes of food consumed. Educational aids such as pamphlets and diagrams were used to illustrate the preferred types of food selected and to explain the glycaemic indices of food groups. The instructions stressed the need for a reduction in the intake of total energy, total fat and cholesterol-rich foods. An ideal meal was served to all participants after the education sessions to enlighten them on the types of food to be consumed while stressing the preparation methods and portion sizes.



## 5.5.2 Exercise Intervention

Exercise sessions took the form of progressive resistance training (PRT) using equipment such as dumbells, elasticized bands, exercise balls and own body weight. The exercise intensities increased on a monthly basis using 5 differently coloured elastised therabands of varying resistance. The colours of the elasticized therabands and the resistance respectively were: yellow (1.5 kg), red (2.0 kg), green (2.7 kg), blue (3.5 kg) and black (4.5 kg). A bench-press and leg press 1RM test was determined by trial using a sub-sample of 10 subjects (6 females and 4 males) at the physiotherapy gymnasium in the Mamelodi hospital. This was done primarily to determine the initial repetitions per set of exercises than the resistance, as the elasticised tensile resistance (colour) of the theraband was constant for all subjects during each month of the study, with a different theraband (increased resistance) thus being used for each month (X5) of the 20 week program. Dumbells and ankle weights of 2 kg resistance were used, with the repetitions per exercise progressively increasing from 3 sets of 6 repetitions in month 1 to 3 sets of 12 repetitions in month 5. For the first 4 months there was an increase of 2 repetitions each month and in the 5<sup>th</sup> month the repetitions (12 reps) were the same as the fourth month. Between each station the subjects were given 30 seconds rest to move from one station to the other, and repetition of each exercise was done every 4 seconds. In certain instance chairs were substituted for the exercise gym balls. Tables were improvised for exercise benches and door knobs as well as railings in the hall were used to fasten the elastic bands. Participants performed supervised PRT on two non-consecutive days per week (Appendix 5: Exercises). The exercise programme commenced with 30 minute-sessions, progressing to 60 minute-sessions towards the end of the study. Before and after each exercise session blood pressure and glucose levels were measured to ensure that none of the participants was hypoglycaemic (<3.7 mmol/L) prior to exercising or had high blood pressure readings (increase in systolic blood pressure >170 mmHg) that would be contra-indicative to exercise. If any patients indicated that they did not consume prescribed medication they were not allowed to participate in the days activities. All exercise participants congregated in the community hall where they had to do a general warm up and



stretching exercises for 20 minutes. The exercising participants which comprised of forty people were divided into four groups with ten participants in each group. The groups then did a circuit workout for the remaining 40 minutes, rotating at each station of the circuit. The groups were then given a further 10-15 minutes which was used as a cool-down period as well as to perform few basic stretching exercises. All the exercises were supervised by qualified exercise science students. An attendance register was kept for each exercise session.

## 5.6 Instrumentation

The Diabetes Self-Care Activity Questionnaire (DSCAQ) [12] was administered to all subjects at baseline and at the end of the 20-week intervention period. The questionnaire (Appendix 2) assessed three categories of DM care over the previous 7-days i.e. knowledge and practices of dietary intake (basic food groups), glucose monitoring and medication usage. A pilot study was conducted to pretest the Diabetes Self-Care Activity Questionnaire. The questionnaire was administered by the primary researcher. While most subjects indicated their preference to have the questionnaire administered in English, where necessary the resident dietician, who had proven practical experience and the ability to communicate in the local languages (Sotho and Zulu), explained terminologies in the simplest form.

## 5.6.1 Assessment of the Diabetes Self-Care Activities Questionnaire

The Diabetes Self-Care Activity Questionnaire (DSCAQ) is a self-report measure to monitor the frequency of different regimen activities over a seven day period. The purpose of developing such an instrument was to provide a measure of selfcare for several different regimen areas that would be feasible for use in most clinical research settings. Areas of regimen assessed in the questionnaire are diet, glucose testing and medication usage. Many of the items included in this instrument were based on a large-scale project conducted by the Rand Corporation [13] to identify and develop psychometrically acceptable measures of performance of DM regimen activities considered to be most important by a panel





of experts. The latest version of the DSCA scale consists of 12 questions. For each regimen area, items were constructed to measure both absolute levels of self-care behaviour and adherence to individual prescriptions (involving a comparison of self-care behaviour and the perceived prescription).

The adherence levels of dietary self-care are measured using only three items in the questionnaire (Appendix 2). The first category of the questionnaire deals with "adherence to dietary practices based on dietary knowledge" over the previous seven days and three dietary questions which are concerned with the "percentage of meals which included high-fibre foods, high-fat foods, sweets and desserts". The second category deals with the question of "frequency of glucose monitoring", and the last category deals with the questions on "adherence to medication usage". The rationale for employing a 7-day recall period is that self-reported behaviour is expected to vary over time, and one wants to obtain a stable estimate. Asking subjects to remember details over a longer interval may result in increased inaccuracies.

## 5.7 Statistical Analysis

Data was analyzed using the Stata 10 software programme [14]. Data was summarised using standard descriptive techniques such as mean, SD, median, frequency, percentage and range. A non-parametric inferential technique, the Wilcoxon signed-rank test, was used to calculate differences within groups at baseline and at the end of the study. The two-sample Wilcoxon ranksum (Mann-Whitney) was used to calculate differences between groups at baseline and at the end of the study.

## 5.8 Results

The demographics of the sample by gender, age, educational level and employment status are given in table 1. The sample size consisted of 17 males and 63 females. The ages of the participants ranged from 40-65 years. The majority (52.50%) of the exercise group had passed standard 7 (grade 9) whilst



the majority (40%) of the control group had passed standard 10 (grade 12). The employment status indicated that majority (52.5%) in the exercise group were unemployed, whilst the majority (40%) in the control group were pensioners. Age and gender (table 1) as well as BMI (table 2) appear not to have been balanced between the two groups and were adjusted for in subsequent analyses (formal statistical testing was not done because, due to randomization, any differences observed were due to chance).

DEMOGRAPHIC VARIABLES		Exercise	(N=40)	Control (N=40)	
		Ν	%	Ν	%
OFNDED	Males	6	15.00	11	27.50
GENDER	Females	34	85.00	29	72.50
	40-50	11	27.50	6	15.00
AGE (Years)	51-60	16	40.00	17	42.50
	61-70	13	32.50	17	42.50
	St 1-4	7	17.50	8	20.00
EDUCATIONAL	St 5-7	21	52.50	12	30.00
LEVEL	St 8-10	11	27.50	16	40.00
	NONE	1	2.50	4	10.00
	Part-time	1	2.50	4	10.00
EMPLOYMENT	Full time	1	2.50	5	12.50
STATUS	Pensioner	17	42.50	16	40.00
	Unemployed	21	52.50	15	37.50

## Table 1: Frequency Distribution of Demographic Variables

Table 2 highlights the relevant baseline characteristics of participants in the exercise and control groups. The mean values reflect the control and exercise group to be more or less homogeneous which can be attributed to randomization.



## Table 2: Baseline Clinical Data

	Exerci	se (N=40)	Control (N=40)		
Variable	Mean	SD	Mean	SD	
Glycosylated Haemoglobin (%)	9.01	3.11	9.32	2.32	
Body Mass Index (kg/m²)	33.53	6.93	30.84	5.36	
Waist to Hip Ratio	0.86	0.08	0.88	0.11	
Energy Expenditure (METS)*	1662	343-3525	1347	714-2578.5	

N= Number of patients SD= Standard deviation BMI adjusted at baseline \*Median (min-max)

The distribution of the scores in the dietary and medication categories of the Diabetes Self-Care Activity Questionnaire are reported in tables 3-8 and are represented by the absolute and relative (percentages) frequency of responses to items probed. Results are presented under the following sub-sections:

- 1. Dietary habits; and
- 2. Medication routine (including urine glucose monitoring)

## 5.8.1 Dietary Habits

The results pertaining to the dietary habits of the respondents are presented in tables 3 to 6. There were four dietary questions posed to the subjects, these were:

- How often was a recommended diet followed over the past week?
- What percentage of their meals included high fibre foods?
- What percentage of their meals included high fat foods?
- What percentage of their meals included complex sugars?



Contro	l n=40 <sup>▲</sup>	Exercice n=40 <sup>▲</sup>		Overall n=80		
n (%)		n (%)		n (%)		
Pre*	Post**	Pre	Post	Pre	Post	
14 (35.00)	27 (67.50)	22 (55.0)	26 (65.0)	36 (45.00)	53 (66.25)	
9 (22.50)	9 (22.50)	4 (10.0)	7 (17.50)	13 (16.25)	16 (20.00)	
13 (32.50)	3 (7.50)	7 (17.50)	6 (15.00)	19 (20.00)	9 (11.25)	
2 (5.00)	0	5 (12.50)	1 (2.50)	7 (8.75)	1 (1.25)	
2 (5.00)	1 (2.50)	2 (5.00)	0 (0)	4 (5.00)	1 (1.25)	
* E vs C pre : p=0.14			▲ pre vs post in control group: p=0.01			
** E vs C post : p=0.61			▲▲ pre vs post in exercise group: p=0.59			
	n Pre* 14 (35.00) 9 (22.50) 13 (32.50) 2 (5.00) 2 (5.00) 2 (5.00)	n (%)         Pre*       Post**         14 (35.00)       27 (67.50)         9 (22.50)       9 (22.50)         13 (32.50)       3 (7.50)         2 (5.00)       0         2 (5.00)       1 (2.50)         peo.14       0	n (%)       n (%)         Pre*       Post**       Pre         14 (35.00)       27 (67.50)       22 (55.0)         9 (22.50)       9 (22.50)       4 (10.0)         13 (32.50)       3 (7.50)       7 (17.50)         2 (5.00)       0       5 (12.50)         2 (5.00)       1 (2.50)       2 (5.00)         action       1 (2.50)       2 (5.00)	n (%)       n (%)         Pre*       Post**       Pre       Post         14 (35.00)       27 (67.50)       22 (55.0)       26 (65.0)         9 (22.50)       9 (22.50)       4 (10.0)       7 (17.50)         13 (32.50)       3 (7.50)       7 (17.50)       6 (15.00)         2 (5.00)       0       5 (12.50)       1 (2.50)         2 (5.00)       1 (2.50)       2 (5.00)       0 (0)	n (%)n (%)n (%)Pre*Post**PrePostPre14 (35.00) $27 (67.50)$ $22 (55.0)$ $26 (65.0)$ $36 (45.00)$ 9 (22.50)9 (22.50)4 (10.0)7 (17.50) $13 (16.25)$ 13 (32.50)3 (7.50)7 (17.50) $6 (15.00)$ $19 (20.00)$ 2 (5.00)05 (12.50)1 (2.50)7 (8.75)2 (5.00)1 (2.50)2 (5.00)0 (0)4 (5.00)* pre vs post in control group:	

### Table 3: Adherence to Recommended Dietary Practices

The distribution of the scores in the 5 categories of "adherence to recommended dietary guidelines" occurring in the previous week is reported in table 3. The subjects were requested to indicate how often they did adhere to the dietician's guidelines when preparing or eating their meals. There was no significant differences when comparing the exercise to the control groups at baseline (p=0.14) and when comparing the groups at the end of the study (p=0.61). When comparing changes in the exercise group changes over the 20 week period there was no significant differences observed (p=0.59), however when comparing changes in the control group (dietary education) over the 20 week period significant (p=0.01) improvement was reflected. The major shift in the results of the control group when questioned after the 20 week intervention was seen in the increased number of subjects who indicated that "always" followed a recommended diet. The overall cohort of subjects (66%) indicated at the end of the study that they "always" follow a recommended diet as compared to the baseline data which constituted of (45%) the subjects.



Percentage of	Contro	Control n=40 <sup>▲</sup>		e n=40 <sup>▲</sup> ▲	Overall n=80	
High-Fibre Foods	n (%)		n (%)		n (%)	
in a Meal	Pre*	Post**	Pre	Post	Pre	Post
0%	0	(5.00)	0	1 (2.50)	0	(3.75)
25%	15 (37.50)	14 (35.00)	14 (35.00)	15 (37.50)	29 (36.25)	29 (36.25)
50%	12 (30.00)	15 (37.50)	13 (32.50)	19 (47.50)	25 (31.25)	34 (42.50)
75%	8 (20.00)	8 (20.00)	9 (22.50)	4 (10.00)	17 (21.25)	12 (15.00)
100%	5 (12.50)	1 (2.50)	4 (10.00)	1 (2.50)	9 (11.25)	2 (2.50)
* E vs C pre : p=1.00		▲ pre vs post in control group: p= 0.38				
** E vs C post : p= 0.72		▲▲ pre vs post in exercise group: p= 0.47				

## Tables 4: Consumption of High Fibre Foods

The distribution of the total scores regarding the "consumption of high fibre food" among subjects is reflected in table 4. The subjects had to indicate what percentage of their weekly meal consisted of high fibre foods. The term high fibre was explained to the subjects in layman terms and examples where given. As reflected in table 4 there was no significant differences at baseline when comparing exercise and control groups (p=1.00) as well as the end of the study (p=0.72). When comparing the both groups over the 20 week period it was also found that there was no significant differences within the control (p=0.38) and exercise groups (p=0.47). From the table one can see that overall, the majority of the subjects are distributed either 25% or 50% category i.e. at baseline and at end of the which is in accordance to the norms stipulated by Frost, Dornshorst and Moses [15].



Percentage of	Contro	l n=40 <sup>▲</sup>	Exercice	e n=40 <sup>▲</sup> ▲	Overa	ll n=80
High-fat Foods	n (	(%)	n (%)		n (%)	
in a Meal	Pre*	Post**	Pre	Post	Pre	Post
0%	16 (40.00)	13 (32.50)	11(27.50)	15 (37.50)	27 (33.75)	28 (35.00)
25%	17(2.50)	25 (62.50)	17 (42.50)	18 (45.00)	34 (42.50)	43 (53.75)
50%	4 (10.00)	0	10 (25.00)	7 (17.50)	14 (17.50)	7 (8.75)
75%	2 (5.00)	2 (5.00)	1 (2.50)	0	3 (3.75)	2 (2.50)
100%	1 (2.50)	0	1 (2.50)	0	2 (2.50)	0
* E vs C pre	* E vs C pre : p= 0.41		▲ pre v	s post in co	ntrol group:	p= 0.053
** E vs C post	:p= 0.009		<b>▲</b> ▲ pr	e vs post in o	exercise gro	up: p 0.57

#### Table 5: Consumption of High-Fat Foods

Table 5 represents the distribution of the subjects consuming high-fat foods under the sub-scales ranging form 0%-100%. In questioning how often the participants consumed high-fat foods over the previous seven day period, a good trend was observed because of an overall reduction in the undesirable, high-fat categories (75% and 100% category) and an increase in the low-fat consumption (25%) category. More participants in the control group moved to low-fat categories post intervention, which is indicative that, in this respect, diet education alone was more effective than diet education and exercise which showed no-significant When comparing between-group data there was a highly change (p=0.5). significant difference between groups (p=0.009) at the end of the study which can largely be ascribed to significant (p=0.05) pre and post differences in the control group. As in the case of analysis dealing with "adherence to dietary recommendations", the exercise group could be viewed as being too reliant on the exercise intervention as a treatment modality as opposed to the dietary adherence. In viewing the overall data the majority of the subjects post intervention (n=43; 53.75%) indicated that 25% of their diet consisted of high fat food as compared to the baseline data where only 34 (42.50%) had indicated this to be the case. This reflects a reduction in the 100%, 75% and 50% category and a shift to the lower (25% to 0%) fat consumption categories.



Percentage of	Contro	l n=40 <sup>▲</sup>	Exercic	e n=40 <sup>▲ ▲</sup>	Overa	ll n=80
Complex Sugars	n (%)		n (%)		n (%)	
Eaten in a Meal	Pre*	Post**	Pre	Post	Pre	Post
0%	20 (50.00)	23 (57.50)	20 (50.00)	24 (60.00)	40 (50.00)	47 (58.75)
25%	15 (37.50)	16 (40.00)	16 (40.00)	14 (35.00)	31 (38.75)	30 (37.50)
50%	4 (10.00)	1 (2.50)	3 (7.50)	1 (2.50)	7 (8.75)	2 (2.50)
75%	1(2.50)	0	1 (2.50)	1 (2.50)	2 (2.50)	1 (1.25)
100%	0	0	0	0	0	0
* E vs C pre : p=	* E vs C pre : p= 1.000			control grou	p: p= 0.50	
** E vs C post : p=	0.91	<b>▲</b> ▲ b	ore vs post ir	n exercise gro	oup: p= 0.38	

#### Table 6: Consumption of Complex Sugars

In questioning how often the participants consumed foods high in complex sugars over the previous seven-day period, there was no significant difference (p=0.91) in post test scores between the groups. This could reflect good dietary adherence at base-line, thus leaving the groups with little room for improvement (less that 10 % of total energy being derived form complex sugars) [15]. With regard to food high in complex sugars majority of the subjects indicated that their weekly meals consisted of 0% pre: 40 (50.00) vs. post 47 (58.75) or 25% pre: 31 (38.75) vs. 30 (37.50) of their weekly meals. Although better distribution trends were observed in the exercise group, the changes were non significant (p=0.38). This could be attributed to the potential realisation in the exercise group regarding the value of low glycaemic index and simple carbohydrate for sustained energy-release during exercise. When viewing the overall data it is clearly seen that majority of the individual consumed no complex sugars at baseline 40 (50%) and a slight improvement has been seen at 20 week whereby 47 (58.8%) indicated they consumed no complex sugars.



#### 5.8.2 Glucose Monitoring

Subjects who were receiving oral medication (tablets only) were expected to use urine dip-stick tests to monitor their glucose levels. The use of glucose testing strips for capillary finger-prick monitoring levels was reserved for patients on insulin therapy.

A dhawaraa ta	Control (n=40) <sup>▲</sup>		Exercise (n=40)		Overall (n=40)	
Adherence to	n (%)		n (%)		n (%)	
Urine testing	Pre*	Post**	Pre	Post	Pre	Post
0% Never	37 (92.50)	35 (87.50)	34 (85.00)	24 (60.00)	71(88.75)	59(73.75)
25% (1/4) Rarely	1 (2.50)	1 (2.50)	3 (7.50)	12 (30.00)	4 (5.00)	13 (16.25)
50%(1/2) Sometimes	0.00	3 (7.50)	0.00	1 (2.50)	0.00	4 (5.00)
75% (3/4) Usually	1 (2.50)	1 (2.50)	2 (5.00)	1 (2.50)	3 (3.75)	2 (2.50)
100% (All) Always	1 (2.50)	0.00	1 (2.50)	1 (2.50)	2 (2.50)	2 (2.50)
* E vs C pre : p= 0.7	pre vs post in control group: p= 0.22					
** E vs C post : p= 0.001			pre vs post i	in exercise g	roup: p= 0.1	4

#### Table 7: Adherence/Frequency of Urine Tests

Table 7 reports on the participants' response regarding the percentage of the urine testing adhered to by the recommendation of a doctor. The overall majority of the subjects fell within the 0% (never) category at baseline, as well as after 20 weeks as availability to consumables to test urine was unavailable to subjects on a weekly basis. There was a slight improvement in the exercise group at 20 weeks where 30% of the people appearing in the "rarely" as compared to 60% who "never" used to test their urine at baseline, but the within-group changes were non-significant (p>0.05) in both the groups. When comparing values between groups at the 20 week, there was a significant difference (p=0.001). It was also observed that subjects in the exercise group indicated testing their urine more frequently, i.e. in the category "rarely" (30%) at twenty weeks as compared to



baseline where only (7.5%) tested. It was indicated during the education sessions in both groups that some of the subjects did purchase a dip-stick to have a more stringent control over their glucose.

#### 5.8.3 Medication Usage

The distribution of the scores in the 5 categories of "adherence to medication" is reported in table 8. The subjects were requested to indicate how much (volume) of the recommended diabetes medication (tablets) did the subjects consume. They could indicate in any one of the following categories: all, most, some none of them or no pills taken to control diabetes mellitus.

#### Table 8: Adherence to Medication Usage

Adherence to	Contro	l n=40 <sup>▲</sup>	Exercice	e n=40 <sup>▲</sup> ▲	Overa	ll n=80
Medication	n (%)		n (%)		n (%)	
Usage (volume)	Pre*	Post**	Pre	Post	Pre	Post
All of Them	39 (97.50)	37 (92.50)	38 (95.00)	39 (97.50)	77 (96.25)	76 (95.00)
Most of Them	1 (2.50)	3 (7.50)	0.00	1 (2.50)	1 (1.25)	4 (5.00)
Some of Them	0.00	0.00	1 (2.50)	00.00	1 (1.25)	0.00
None of Them	0.00	0.00	1 (2.50)	0.00	1 (1.25)	0.00
Don't take Pills	0.00	0.00	0.00	0.00	0.00	0.00
* E vs C pre= 1.000						
** E vs C post= 0.62			▲▲ pre vs post= 0.39			

The majority (96.25%) of the cohort indicated good adherence in ingesting all of their prescribed medication. Comparison of the exercise and control groups at baseline showed no significant difference (p=1.000) in the adherence to medication usage. Similar results were observed when comparing the post-test data results, with a non-significant difference (p=0.62) emerging between the exercise and control group. When comparing within group data a non-significant



difference was evident in the control group (p=0.32). The same results of nonsignificance were observed in the exercise group (p=0.39). In essence, subjects were compliant and did adhere to medication usage and there was no change (p>0.05) in this during the study.

#### 5.9 Discussion

Self-care management in DM is of importance, because the assumption is that adoption of a healthy lifestyle will produce better metabolic control and that this will help to avoid subsequent, acute and long-term complications of the disease. Many studies have investigated the link between DM self-care and level of DM control as well as psychosocial factors which may be predictive of self-care [16, 17]. Prospective cohort studies show that "low-risk lifestyle behaviour" can slow onset of type-2 DM in both males and females [18, 19].

The main dietary component for a diabetic individual should be carbohydrate containing foods with a low glycaemic index and cis-monounsaturated fat. A combination of carbohydrate and cis-monounsaturated fatty acids should provide 60-70% total daily energy intake. Total fats should be restricted to 35% total energy. Cis-monounsaturated fatty acids should provide between 10-20% total energy. Saturated fatty acids should provide fewer than 10% of total energy. Protein intake should range between 10-20% of total energy. Protein intake should not go below 0.6 g/kg normal body weight/day but should be at the lower end of the range (0.8 g/kg body weight/day) in cases of nephropathy or where abnormal microalbuminuria has been identified [15].

This study used a quantitative method in order to gain a better understanding of the attitudes, knowledge and practices of black type-2 diabetic patients in a resource-poor setting with respect to dietary habits and medication usage. When examining their diet from a nutritional point of view, good practices were observed in certain categories after the 20 week of intervention. With regards to dietary adherence the baseline response indicated no significant difference (p=0.14) between the exercise and control groups, with the majority (45%) of the complete



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cohort of participants at baseline indicating that they "always" followed a recommended diet. This was encouraging, but could be improved. With regards to the question on consumption of high-fibre foods, the majority of the subjects did indicate that high-fibre foods made up either a quarter or half of their weekly diet. This can be viewed as a good practice, but could be improved with proper education on dietary habits. The participants in the exercise and control groups consumed low-fat diets as suggested by the data where the majority of the subjects indicated that high fat food constituted between 0 - 25 % of their weekly diets. Diets high in carbohydrate (maize, sorgum and brown bread) and low in saturated fat are typical of traditional African diets [20, 21]. With regard to food high in complex sugars the baseline response indicated that the majority of the total cohort fell in the low categories i.e. either 0% or 25% of their total weekly meal, these categories of synthetic sugars indicated in general good practice. The low energy intake is very similar to that found in two other studies in the Northern Province in South Africa in black adults and although portion sizes were demonstrated to individuals, it was difficult for the subjects to establish appropriate portion sizes [20, 21]. The major barrier to dietary compliance was educating these individuals on food portion sizes and foods allowed. Prior to the study, there was no practice of regular scheduled appointments to visit the outpatient dietician for dietary education and very limited knowledge of portion sizes. Patients received basic information on dietary education during a routine visit to the hospital once every six months. Visits to the dietician were not compulsory and patients received conflicting information from nurses and other hospital staff on diet. It became evident that nurses and other health care workers are not qualified to counsel these patients on dietary education. These above-mentioned health workers have poor/limited knowledge on dietary education and advice on recommended traditional diets. The information given was inconsistent, incorrect or confusing to patients.

In South Africa the test to measure blood glucose and HbA<sub>1c</sub> is expensive whilst home glucose testing requires considerable educational input to be of any benefit [5]. In general what is offered to diabetics accessing public health facilities in resource-poor South African settings is random blood or urine glucose testing at



the local clinic. The accuracy of monitoring of glycaemic control and the usefulness of these tests in diabetic management has been questioned. Although there is strong evidence emphasizing health benefits of lifestyle modification for people with type-2 DM, less is known about the efficacy of primary care-based strategies for achieving the physical activity and dietary changes necessary to acquire these benefits [22]. This suggestion has been validated by recent systematic reviews addressing behavioural counselling (routine counselling with follow up) by primary health care workers to promote the values of healthy eating [23] and physical activity [24, 25] to the general population. The reviews acknowledge the difficulty of drawing conclusions for primary care-based studies completed to date, because of the lack of rigor and variation in population and study designs.

Most recently the Diabetes Prevention Programme (DPP) [26], in the United States examined strategies to evaluate the safety and efficacy of lifestyle and pharmacological interventions to delay or prevent development of type-2 DM in a diverse, high-risk population with impaired glucose tolerance. The DPP study reported that participants could reduce their chance of developing DM by 58% through physical activity and diet. The DPP's major goal was to achieve a minimum of 150 minutes of physical activity, similar in intensity to brisk walking and a minimum of 7% weight loss and maintenance per week.

There is good evidence that nurses and dieticians have a role to play in counselling and managing patients diagnosed with type-2 DM [27-30]. However, their role in promoting healthy lifestyle choices for people with pre-DM is less evident. Referral to specialized diabetic centres such as the Centre for Diabetes Endocrinology (CDE) or specialized regional focus groups in support of DM, can provide patients with important information regarding outcomes but evaluation of such data is limited and was not reported in this study. Furthermore centres such as CDE are private medical centres which may not be accessible to patients from a resource-poor setting.



In this study all the participants were type-2 diabetics and mostly overweight and had poor glycaemic control. Although the results of the majority of the participants showed favorable practices, it is difficult to determine the compliance with good dietary practices. The question may arise as to whether poor dietary knowledge and education contributed to the poor management of the factors stated above. A shortcoming of the dietary intervention program was that we were unable to control their dietary intake for the period of 20 weeks, due to cost implications. Although it was observed that the intake for dietary fibre was reasonable, this was not sufficient to bring about a reduction in the LDL cholesterol, which is one of the benefits associated with high dietary fibre intake [31].

The recommendation based on this study would be that proper dietary education be given to the patients attending the hospital on a regular basis, and that the dietician should always be available for consultations. Education should include a diet plan starting from the traditional staple diets, but emphasising a portion size in layman's terms, probably using "cup" sizes for easy comprehension. Patients should be advised on what the glycaemic index represents and the importance of this in simple terms, as well as what impact it may have on the glucose levels. Nurses and other health care workers who assist diabetic patients should be trained in optimal dietary education which will be beneficial to diabetic patients.

Pertinent to patient education and part of lifestyle modification is glycaemic control which encompasses self-monitoring or home blood glucose monitoring and administration of medication. It was observed in this study that patients attending the out-patient clinics in Mamelodi Hospital were required to visit the hospital every month to collect their oral medication. Due to the lack of resources and budget allocated by the Department of Health, blood glucose and blood pressure monitoring and urine tests are limited to once a month and once every six months respectively, with HbA<sub>1c</sub> done once a year. Therefore diabetes monitoring (HbA<sub>1c</sub>), urine dip-stick test and finger prick tests are not done on a regular basis to advise the subjects on how good or poor their diabetes management is.



In conclusion, it was evident that adherence to recommended weekly dietary practices in this cohort could be improved, but generally, the intake of high fibre foods, high fat foods and complex sugars was acceptable. While adherence to urine testing was poor, intake of prescribed medication was good. The dietary education group did reduce their high fat content in foods more than the exercise and dietary education group, while the latter group improved their urinary testing more than the group receiving dietary education only. This indicates an improved awareness of these aspects brought about by the intervention. However, exercise interventions and dietary education have to be a continuous process in order to impact positively on diabetes care, knowledge and activities among persons with type 2 diabetes mellitus, particularly in a resource poor setting.



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#### **Chapter 6**

#### Summary, General Conclusions and Recommendations

Type-2 DM is the most common chronic disease worldwide which requires continuing medical care. The number of people with type-2 DM is increasing rapidly. Six percent of the world population suffers from this disease, but only half of them have been diagnosed [1]. Strict metabolic control for micro-vascular related outcomes and blood pressure control for micro- and macro-vascular-related outcomes seem to be important in the prevention of vascular complications. In diabetics, micro and macro-vascular disease is the major cause of morbidity and mortality [2, 3, 5]. In order to reduce DM complications blood glucose, blood pressure and blood lipid control as well as foot care are imperative. Once DM has been diagnosed treatment with oral medication is often avoidable but DM patients are confronted with the need for life-style adaptations that entail, weight reduction, adapted nutrition requirements and more exercise.

The primary aim of this research was to study the effect of a community-based exercise (Progressive Resistance Training) and lifestyle (Dietary Education) intervention on health outcomes among African patients with type-2 DM in a resource-poor setting, with respect to the variables stated below.

- Part 1: Levels of physical activity (Chapter 2)
- Part 2: Glycosylated haemoglobin and lipid profiles (Chapter 3);
- Part 3: Morphological, musculoskeletal and cardio-respiratory fitness (Chapter 4); and
- Part 4: Activities of diabetes care (Chapter 5)

#### 6.1 Brief Description of the Study

The study was undertaken in Mamelodi, a suburb in the City of Tshwane Metropolitan Municipality in the province of Gauteng, South Africa. The participants (n=80) included black male (6=control group and 11=exercise group)



and female (34=control and 29=exercise group) participants from 40-65 years with type 2 DM without complications and a known duration of the disease for at least one year. Most participants were recruited from the outpatient clinic at the Mamelodi government hospital whilst they were waiting to be seen by a doctor. Participants were also recruited from local churches in the Mamelodi area.

The duration of the study intervention programme was 20-weeks. Due to availability of subjects the study was staggered and therefore spanned over a period of 18 months in total (February 2004-June 2005), and was conducted in periods of 20 weeks until the targeted number of subjects were obtained. The YMCA hall in Mamelodi was used to perform the weekly intervention of progressive resistance exercise and dietary educational sessions.

#### 6.2 Main Findings

# Part 1: Habitual Physical Activity among an African Cohort of Persons with Type 2 Diabetes Mellitus in a South African Resource-Poor Community Setting

**Results:** Using the short version of the International Physical Activity Questionnaire (IPAQ) the cohort showed a distribution of 16 (20.0%) subjects in the low activity category, 49 (61.25%) in the moderate activity category and 15 (18.75%) in the vigorous activity category, respectively. The median baseline weekly energy expenditure (METS) was 2052.5 (p25 - p75; 677 - 2793). Gender had a differentiating effect on physical inactivity (sitting time) with males (median 180 minutes) spending significantly (p=0.02) more time sitting than females (median 120 minutes). However gender, age, and BMI had no significant differentiating effect on categories of physical activity or energy expenditure. Similarly age and BMI did not influence levels of physical inactivity (sitting time).

**Conclusion:** The prevalence of physical inactivity at baseline among the cohort of patients studied was moderately high. Most subjects reported doing physical activity of a moderate nature, with low energy expenditure. Males were more



inactive than females. Efforts are needed to encourage active living and discourage sedentary habits, among patients with type-2 DM.

# Part 2: Effects of Progressive Resistance Training (PRT) on Glycosylated Haemoglobin (HbA<sub>1c</sub>) and Lipid Profiles in Participants with Type 2 Diabetes Mellitus.

**Results:** On measuring blood glucose and lipid profiles, the following pre-post intervention changes (mean (SD) were found for the PRT vs. CT for HbA<sub>1c</sub> (PRT: pre 9.01 (3.1) vs. post 8.47 (2.4); p=0.04 vs. CT: pre 9.32 (2.3) vs. post 9.17 (2.5)%: p=0.72), TC (PRT: pre 4.92 (1.10) vs. post 4.69 (0.81); p=0.11 vs. CT: pre 5.08 (0.84) vs. post 5.04 (1.02) mmol/L: p=0.09), LDL (PRT: pre 3.05 (0.97) vs. post 2.89 (0.74); p=0.19 vs. CT: pre 3.17 (0.86) vs. post 3.11 (0.93) mmol/L: p=0.19), HDL (PRT: pre 1.05 (0.25) vs. post 1.09 (0.28); p=0.13 vs. CT: pre 1.27 (1.11) vs. post 1.09 (0.52) mmol/L: p=0.87), TG (PRT: pre 1.06 (0.84-1.74) vs. post 1.04 (0.79-1.52); p=0.16 vs. CT: pre 1.29 (1.1-1.9) vs. post 1.2 (0.95-2.03) mmol/L: p=0.73). However, none of these changes within the PRT group were significantly better (p>0.05) than that in the control (dietary intervention only) group.

**Conclusion:** The PRT and dietary education program combined failed to show a better improvement in metabolic parameters, than a dietary education program alone. Although this study failed to demonstrate a statistically significant change of at least 1% in the HbA<sub>1c</sub> it is important to note that even the 0.5% difference achieved, can be considered as clinically significant. PRT needs to be of sufficient frequency and intensity to be effective as a treatment modality in persons with type 2 diabetes.





# Part 3: The Efficacy of a 20-Week Progressive Resistance Training Programme on Morphological, Musculoskeletal and Aerobic Fitness in Participants with Type 2 Diabetes Mellitus.

**Results:** On measuring morphological, musculoskeletal and cardio-respiratory fitness, the following pre-post intervention changes were found for the PRT vs. CT. Umbilical abdominal circumference (PRT: pre 106.91 (16.16) vs. post 104 (15.26); p=0.09 vs. CT: pre 105.0 (14.38) vs. post 105.66 (14.07) cm: p=0.58); anterior abdominal circumference (PRT: pre 100.34 (12.88) vs. post 98.34 (10.44) cm; p=0.07 vs. CT: pre 99.74 (12.86) vs. post 96.63 (12.50) cm: p=0.08); body mass index (PRT: pre 33.53 (6.92) vs. post 33.37 (6.76); p=0.70 vs. CT: pre 30.85 (5.36) vs. post 31.36 (5.58): p=0.37), waist to hip ratio (PRT: pre 0.85 (0.08) vs. post 0.85 (0.09); p=0.60 vs. CT: pre 0.89 (0.14) vs. post 0.86 (0.09); p=0.13); fat percentage (PRT: pre 45.09 (6.04) vs. post 44.55 (5.99); p=0.06 vs. CT: pre 42.30 (6.39) vs. post 42.12 (6.59) %: p=0.96). None of these morphological changes within the PRT group were significantly better (p>0.05) than that in the CT group. Muscular endurance (wall squat) scores were PRT pre 50.5 (29-109) vs. post 115 (58-172.5); p=0.0011 vs. CT: pre 33 (21.5-54.5) vs. post 51.5 (37-121) sec; p=0.0017), with a greater change in CT group (p=0.004); muscular strength (abdominal crunches) PRT pre 35.12 (10.8) vs. post 35.65 (9.30); p=0.81 vs. CT: pre 30.27 (9.62) vs. post 34.07 (11.91) reps: p=0.03), flexibility (sit and reach) PRT pre 37.32 (9.13) vs. post 38.81 (9.56); p=0.17 vs. CT: pre 39.28 (8.73) vs. post 39.35 (9.25) cm; p=0.92). Aside from the wall squat (p=0.004), none of these musculoskeletal changes between the groups differed significantly (p>0.05). Six minute walk distance was PRT: pre 324.18 (114.88) vs. post 445.78 (69.67); p=0. 00 vs. CT: pre 353.98 (128.90) vs. post 440.60 (104.41) m: p=0.00). Ratings of perceived exertion (RPE) in the PRT vs. CT for the 6 min walk showed lower indices of pre-exercise dyspnea  $(0.25\pm0.52 \text{ vs. } 0.48\pm0.94)$  and fatigue  $(0.21\pm0.42)$ vs.  $0.63\pm0.87$ ; p≤0.01) and similar post-exercise dyspnea (1.95±1.28 vs.  $1.98\pm1.61$ ) and fatigue ( $2.03\pm0.97$  vs.  $2.3\pm1.8$ ) - despite the PRT subjects being able to cover a greater distance in the 6 min, although the latter was not statistically significant (p=0.29).



**Conclusion**: PRT and dietary education had no significant superior benefit than dietary education alone on body composition, musculoskeletal and cardio-respiratory fitness. An inadequate intensity and duration of the PRT intervention are possible reasons for not observing an effect.

### Part 4: Influence of a Dietary Education Programme on Diabetes Care Knowledge and Activities among Person with Type 2 Diabetes Mellitus

Results: With regards to dietary adherence at 20 weeks, the overall data suggests that a large proportion of subjects always (66.25%) adhered to a recommended diet as opposed to usually (20.00%) or sometimes (11.25%). Although the CT group adherence improved significantly (p=0.01) the change was not significantly better (p=0.61) than that of the PRT group. The majority of the cohort indicated good practice in high-fibre food intake making up either a quarter (36.25%) or half (42.50%) of their diet but there was no change (p<0.05) during this study. The majority of the cohort indicated that high-fat foods make either none (35.00%) or a quarter (43.75%) of their weekly meals and the CT group improved significantly (p=0.009) more in reducing the high fat content of their weekly meals than the PRT group after the study. The majority of the subjects indicated good practice with food high in complex sugars making up make either none (58.75%) or a quarter (37.50%) of their weekly meals and there was no change (p>0.05) in this during the study. The majority of the subjects did not adhere to weekly urine testing with (73.75%) "never" doing so and (16.25%) "rarely" tested their urine over the previous 7 days, but the PRT group adhered significantly (p=0.001) more to this practice than the CT group, after the study. The majority (95.00%) of the cohort indicated good adherence in ingesting all of their prescribed medication and there was no change (p>0.05) in this during the study.

**Conclusion:** It was evident that adherence to recommended weekly dietary practices could be improved, but generally, the intake of high fibre foods, high fat foods and complex sugars was acceptable. While adherence to urine testing was poor, intake of prescribed medication was good. The dietary education group did reduce their high fat content in foods more than the PRT group, while the PRT



group improved their urinary testing more than the CT, which indicates an improved awareness of these aspects brought about by the intervention. However, exercise interventions and dietary education has to be a continuous process in order to impact positively on the diabetes care, knowledge and activities among persons with type 2 diabetes mellitus.

#### 6.3 General Conclusion

- Although the current PRT intervention study did not prove to be more effective than dietary education alone, and may raise a question with respect to clinical benefit, the introduction and implementation of exercise in the subjects' lives created an awareness of the importance of exercise in managing DM.
- Although his study failed to demonstrate a statistically significant improvement of at least 1% in the HbA<sub>1c</sub> it is important to note that even the 0.5% difference achieved is of clinical significance but would need a larger sample to prove statistical significance.

2. The limited effect of the exercise intervention may have been attributed to the exercise session not being intensive enough or the relatively small sample size. As stated the subjects that were recruited were not participating in structured physical activity, but in a resource poor setting, many individuals walk to their destinations and thus daily walking activity could not be controlled, in either of the groups, thus diluting the effect of the PRT in the exercise group.

#### 6.4 Recommendations for Future Research

On the basis of this study, the following recommendations are made for further research on exercise and type 2 DM patients:

 There is a need for more research into different combinations of intensityspecific types and volumes of progressive resistance training, as a form of physical activity, required for greater efficacy in managing type-2 DM.



- Post randomisation matching of groups with respect to confounding variables such as age, gender and exercise status, and HbA<sub>1c</sub> status (poor versus well controlled), should be addressed in future study design.
- Supervised exercise interventions should be sustained for at least one year duration with clinical and exercise variables being re-tested in follow-up after a one year period.
- A controlled diet should be implemented together with a structured exercise program to observe if there would be major changes in the clinical variables such as lipid profiles, BMI, and HbA<sub>1c</sub>.
- 6. The effects of well structured aerobic-type exercise, resistance-type and a combination of these should be investigated in this population.

#### 6.5 Recommendations for Practice

On completion of this research the following recommendations for practice are made:

- 1. All DM patients should visit dieticians for structured dietary education, specifically on proper dietary intake;
- Continuous service of a biokineticist/exercise scientist should be available at all public hospitals to evaluate the physical activity status of individuals, educate patients on the value of physical activity in managing DM and its comorbidities; and to provide home-based exercise programmes.
- Accordingly, continued supervised exercise sessions of suitable frequency, duration and intensity using basic equipment should be provided at community centres.



#### 6.6 References

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Appendix 1

International Physical Activity Questionnaire



#### INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

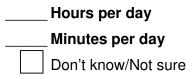
Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?



Days per week

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?



Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

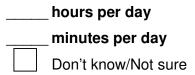


3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

#### Days per week

Skip to question 5

4. How much time did you usually spend doing **moderate** physical activities on one of those days?



Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?



How much time did you usually spend walking on one of those days?
 \_\_\_\_hours per day

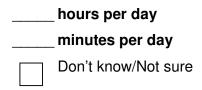
minutes per day

Don't know/Not sure



The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?



This is the end of the questionnaire, thank you for participating.



Appendix 2

**Diabetes Self Care Activity Questionnaire** 





# Summary Of Diabetes Self Care Activities

#### <u>Diet</u>

1. How often did you follow your recommended diet over last 7 days?

1	Always	
2	Usually	
3	Sometimes	
4	Rarely	
5	Never	

2. During the past week, what percentage of your meals included high fibre food, such as fruits, fresh vegetables, whole grain bread, dried beans, peas and bran?

1	0% [16]	
2	25% (1/4)	
3	50% (1/2)	
4	75% (3/4)	
5	100% (all)	

3. During the past week, what percentage of your meals included high fat food such as butter, ice-cream, oil, nuts and seeds, mayonnaise, avocado, deep fried food, salad dressing, and bacon, other meat with fat or skin?

1	0% [16]	
2	25% (1/4)	
3	50% (1/2)	
4	75% (3/4)	
5	100% (all)	



4. During the week what percentage of your meals Included sweets and desserts such as pie, cake, jelly, soft drinks (regular not diet drinks), cookies).

1	0% [16]	
2	25% (1/4)	
3	50% (1/2)	
4	75% (3/4)	
5	100% (all)	

#### Glucose testing

5. On how many of the last 7 days (that you were not sick) did you test your glucose (blood sugar) levels?

1	Everyday	
2	Most days	
3	Some days	
4	None of the days	

6. Over the last 7 days, what percentage of the glucose (blood sugar or urine) test recommended by your doctor did you actually perform?

1	0% [16]
2	25% (1/4)
3	50% (1/2)
4	75% (3/4)
5	100% (all)



#### **Diabetes medication**

7. How many of your recommended number of pills to control diabetes did you take that you were supposed to?

1	All of them	
2	Most of them	
3	Some of them	
4	None of them	
-8	Don't take pills	

The End

Thank You



Appendix 3

**Participation Information Letter** 



### Participation Information Letter University of Pretoria

Department of Biokinetics, Sport and Leisure Sciences & Department of Clinical Epidemiology

TITLE: Effect of a Community-Based Exercise and Lifestyle Intervention on Health Outcomes in Persons with Type 2 Diabetes Mellitus

#### INTRODUCTION

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved. In the best interests of your health, it is strongly recommended that you discuss with or inform your personal doctor of your possible participation in this study, wherever possible.

#### WHAT IS THE PURPOSE OF THIS TRIAL?

You have been diagnosed as suffering from <u>Type 2 diabetes mellitus</u> and the investigator would like you to consider taking part in the research. The study will use male and female type 2 diabetic patients from the Mamelodi outpatient diabetic clinic. The participants are required to be between the ages of 40- 60 years without major complications.

#### WHAT IS THE DURATION OF THIS TRIAL?

If you decide to take part you will be one of approximately <u>160</u> patients. The study will last for up to **5 months**. You will be asked to visit the investigator **2** times per week for 5 months. At each visit you will undergo the following:

Twice weekly for 5 months you will be given an exercise session, the intensities will vary as we progress with the exercise. Twice a month after the exercise session you will receive education on dietary aspects for 1/2 an hour to an hour,



this will be in total 10 lectures for the experimental group and 10 lectures for the control group which will be conducted at different times. Various topics will be discussed on diabetes and diet.

2 tubes of blood (one for HbA1C and the 2nd tube for lipid profile).

Anthropometric tests (weight, height, body girths) will be used to determine weight loss before and after the exercise sessions.

Capillary Glucose test (pre- and post exercise) to observe the acute effects of an exercise session on blood glucose.

It is important that you let the investigator know of any medicines (either prescriptions or over-the-counter medicines), alcohol or other substances that you are currently taking.

#### HAS THE TRIAL RECEIVED ETHICAL APPROVAL?

This clinical trial Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2000), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of which may be obtained from the investigator should you wish to review it.

#### WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS TRIAL?

Your participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to other medical care. The investigator retains the right to withdraw you from the study if it is considered to be in your best interest. If it is detected that you did not give an accurate history or did nor follow the guidelines of the trial and the regulations of the trial facility, you may be withdrawn from the trial at any time.

#### IS ALTERNATIVE TREATMENT AVAILABLE?

This study does not aim to replace any treatment for diabetes. It is advised however that people with diabetes do exercise. If you do not want to participate in the exercises you will receive your standard medicines like always.



# MAY ANY OF THESE TRIAL PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?

Drawing blood is normally done as part of routine medical care and presents a slight risk of pain/ discomfort. Your protection is that experienced personnel perform the procedures under sterile conditions. A total of 2 tubes of blood will be collected over the course of the entire study. The strenuous exercise sessions will also result in you perspiring, which can cause temporary discomfort.

#### WHAT ARE THE RISKS INVOLVED IN THIS TRIAL?

The exercises may cause temporary muscle soreness but with continuous exercise the pain will disappear. The risk of low blood sugar may occur; if the situation arises a carbohydrate snack will be available to correct the condition.

# ARE THERE ANY WARNINGS OR RESTRICTIONS CONCERNING MY PARTICIPATION IN THIS TRIAL?

During the exercise sessions it is likely for a participant to feel faint, dizzy or weak if this occurs the participant must stop exercising immediately and the investigator has to be alerted so that the participant can be attended too.

#### **DISCONTINUATION OF TRIAL**

My participation in this research may be terminated without my consent if the investigators (s) believe that any portion of the study will put me at undue risk. My participation may also be terminated if I do not adhere to the study protocol.

#### **INSURANCE AND FINANCIAL ARRANGEMENTS**

University of Pretoria will provide payment for all trial procedures and reasonable medical expenses, which you may incur as a direct result of this trial as determined by the department of Biokinetics, Sport, and Leisure Sciences and the investigator. Neither you nor your medical scheme will be expected to pay for any study medication or trial procedures. You will be given R10 per visit to cover your transport costs.



#### SOURCE OF ADDITIONAL INFORMATION

For the duration of the trial, you will be under the care of <u>Yvonne Paul</u>. If at any time between your visits, you feel that any of your symptoms are causing you any problems, or you have any questions during the trial, please do not hesitate to contact him/her. The telephone number is <u>0834457111/(012) 3185806/5216</u> (<u>W)/(012) 3202470 (H)</u>, through which you can reach him/her or another authorized person.

#### CONFIDENTIALITY

All information obtained during the course of this trial is strictly confidential. Data that may be reported in scientific journals will not include any information, which identifies you as a patient in this trial. Should you wish, you may also contact the Ethics Committee, University of Pretoria on any issues related to the study.

Any information uncovered regarding your test results or state of health as a result of your participation in this trial will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this trial but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission. The only exception to this rule will be cases in which a law exists compelling us to report individuals infected with communicable diseases. In this case, you will be informed of our intent to disclose such information to the authorized state agency.



#### **INFORMED CONSENT**

I hereby confirm that I have been informed by the investigator, **Yvonne Paul** about the nature, conduct, benefits and risks of the clinical trial. I have also received, read and understood the above written information (Patient Information Leaflet and Informed Consent) regarding the clinical trial.

I am aware that the results of the trial, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a trial report.

I may, at any stage, without prejudice, withdraw my consent and participation in the trial. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the trial.

Patient's name		
	(Please print)	
Patient's signature		Date
Investigator's name	Yvonne Paul	
	(Please print)	
Investigator's signature		Date
I, <u>Yvonne Paul</u> herewit	h confirm that the above	patient has been informed

I, <u>Yvonne Paul</u> herewith confirm that the above patient has been informed fully about the nature, conduct and risks of the above trial.

Witness's name\* \_\_\_\_\_ Witness's signature \_\_\_\_\_ Date \_\_\_\_\_ (Please print)



#### **VERBAL PATIENT INFORMED CONSENT**

I, the undersigned, <u>Yvonne Paul</u>, have read and have explained fully to the patient, named ...... And/or his/her relative, the patient information leaflet, which has indicated the nature and purpose of the trial in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the trial and the alternative treatments available for his/her illness. The patient indicated that he/she understands that he/she will be free to withdraw from the trial at any time for any reason and without jeopardizing his/her subsequent injury attributable to the drug(s) used in the clinical trial, to which he/she agrees.

I hereby certify that the patient has agreed to participate in this trial.

Patient's Name			
	(Please print)		
Investigator's Name	Yvonne Paul		
	(Please print)		
Investigator's Signatur	e	Date	
Witness's Name	Witness's Signa	ature	Date

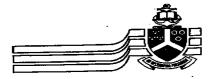




# Appendix 4

**Ethical Approval and Protocol Number** 





Soutpansberg Road MRC-Building Room 2 - 19		Private Bag x 385 Pretoria 0001 -	University of Preforia Faculty of Health Sciences Research Ethics Committee University of Preforia Date: 411/2004
Number	:	66/2004 ·	
New Title	:	The efficacy of a 20 week resistance training program in patients with type 2 diabetes mellitus.	
<b>Investigator</b>	: 、	Y Paul; Department of Bickinetics, sport and leisure sciences; Pretoria Academic Hospital; University of Pretoria.	
Sponsor	:	None - Supervisors: HJ van Heerden / P Rheeder	

This Protocol and Informed Consent have been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 18/08/2004 and found to be acceptable

Vescaren Fruies Annuaree	, children of the case of the
Prof P Carstens	BLC LLB LLD (Pret) Faculty of Law
Prof S.V. Grey	(female) BSc (Hons); MSc; DSc: Deputy Dean
*Prof V.O.L. Karusseit	MBChB; MFGP (SA); M.Med (Chir); FCS (SA): Surgeon
Dr M E Kenoshi	MB,CHB; DTM & H (Wits); C.E.O. of the Pretoria Academic Hospital
Prof M Kruger	(female) MB.ChB.(Pret); Mmed.Paed.(Pret); PhDd. (Leuven)
Dr N K Likibi	MB.BCh.; Med.Adviser (Gauteng Dept.of Health)
Dr F M Mulaudzi	(female) Department of Nursing,
Miss 8 Mullins	(female) BscHons; Teachers Diploma;
*Snr Sr J. Phatoli	(female) BCur (Et.Al) Senior Nursing-Sister
*Prof H.W. Pretorius	MBChB; M.Med (Psych) MD: Psychiatrist
*Reverent P Richards	B.Th. (UNISA), M.Sc. (Applied Biology) (Knights), M.Sc (Med) (Wits), TechRMS, DipRMS
*Dr L Schoeman	(female) Bpharm, BA Hons (Psy), PhD
Dr C F Slabber	BSc (Med) MB BCh, FCP (SA) Acting Head; Dept Medical Oncology
Prof J.R. Snyman	MBChB, M.Pharm.Med: MD: Pharmacologist
*Dr R Sommers	(female) MBChB; M.Med (Int); MPhar.Med;
*Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path) Senior Specialist; Oral Pathology
Prof C W van Staden	MBChB; Mmed (Psych); MD; FTCL; UPLM; Dept of Psychiatry

FWA Nr. 0000 2567 IRB Nr. 0000 2235

DR R SOMMERS; MBChB; M.Med (Int); MPhar.Med. SECRETARIAT of the Faculty of Health Sciences Research Ethics Committee - University of Pretoria

\* = Members attended the meeting on 18/08/2004.



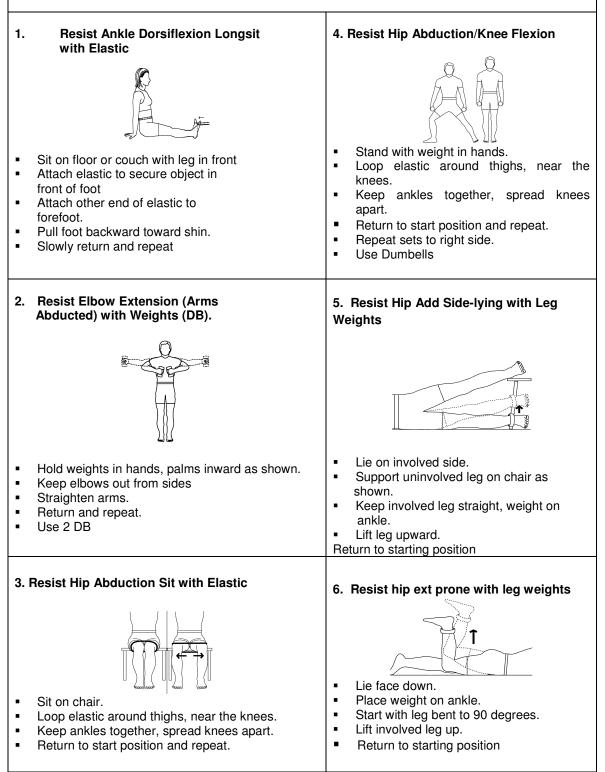
# Appendix 5

**Exercise Sheet** 

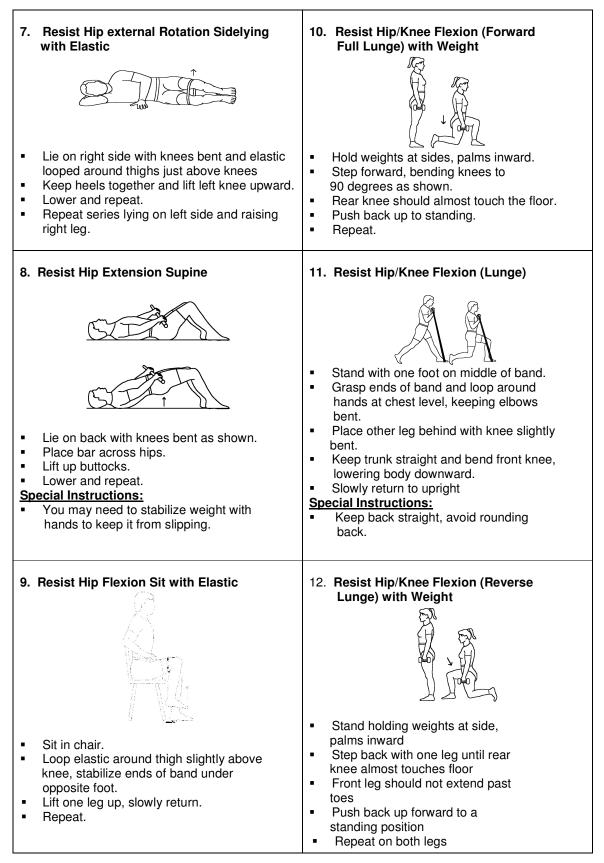




- 1. 3 sets of 10-12 reps , reps are increased as months progressed
- 2. Hold exercise for 4 Seconds
- 3. Rest 30 Seconds between sets
- 4. Perform 1 repetition every 4 sec









13. Resist Knee Flexion with Elastic Standing at Chair	16. Resist Lumbar Sidebend with Weights
<ul> <li>Stand in back of chair, holding chair for support.</li> <li>Attach elastic to chair leg.</li> <li>Loop elastic around ankle</li> <li>Bend knee backward</li> <li>Lower and repeat</li> </ul>	<ul> <li>Stand, holding weight in left hand.</li> <li>Bend to right.</li> <li>Return to start position and repeat.</li> <li>Repeat sets with weight in right hand and bending to left.</li> </ul>
14. Resist Knee Forward Squat with Weight	17. Resist Shoulder Abduction (Vertebral Emphasis) Unilateral with Elastic
<ul> <li>Stand with feet about hip distance apart</li> <li>Toes should be slightly pointed outward and aligned with knees</li> <li>Hold weights (dumbbells) in hands, resting on shoulders</li> <li>Squat down until thighs are almost parallel with floor while moving buttocks backward, similar to beginning to sit in a chair</li> <li>Return to start and repeat <u>Special Instructions</u></li> <li>Start with a partial squat and increase as you become familiar with the movement</li> </ul>	<ul> <li>Stand on elastic</li> <li>Begin with arm at side, elbow straight, holding elastic, palm forward</li> <li>Raise arm upward, out to side and over head</li> <li>Slowly return to starting position</li> </ul>
15. Resist Knee Press with Elastic	18. Resist Shoulder Bent Row
<ul> <li>Sit in chair.</li> <li>Loop elastic around bottom of foot as shown.</li> <li>Hold elastic in both hands.</li> <li>Push leg down straightening at knee Slowly return to start position and repeat.</li> </ul>	<ul> <li>Secure elastic under opposite foot.</li> <li>Hold elastic in involved arm.</li> <li>Slightly bend hips and knees and support upper body with other arm as shown</li> <li>Pull up on elastic, raising elbow to shoulder height.</li> <li>Slowly return to start</li> <li>Special Instructions</li> <li>Contract abdominal muscles and maintain a neutral spine, not allowing trunk to twist.</li> </ul>



19. Resist Shoulder Flexion Unilateral with	22. Stretch Cervical/Thoracic/Arm Neural
<ul> <li>Weights</li> <li>Image: Provide the straight of the s</li></ul>	<ul> <li>Stand with left arm on wall, hand backward as shown.</li> <li>Slowly turn body outward until as stretch is felt across chest.</li> <li>Slowly turn neck to right until a stretch is felt down the front of arm.</li> <li>Hold stretch for20 seconds and repeat on the alternative side</li> </ul>
20. Stretch Cervical Extension Sit	23. Stretch Groin Sit
<ul> <li>Sit in chair with good back support.</li> <li>Sit with proper posture.</li> <li>Slowly bend neck backward stretching the muscles on the front part of neck</li> <li>Hold stretch for 20 seconds and return to start position.</li> </ul>	<ul> <li>Sit with knees bent, soles of feet together</li> <li>Slowly let your knees drop to floor.</li> <li>Grasp ankles with hands and lean forward from the hips</li> <li>Special Instructions</li> <li>Try to keep elbows on inside of knees.</li> </ul>
21. Stretch Cervical Sidebend with Pressure Opposite Side	24. Stretch Hamstring Supine Wall
<ul> <li>Sit or stand.</li> <li>Place right hand on top of head</li> <li>Keep head facing forward and gently pull head sideways to right</li> <li>Repeat with left arm</li> <li>Hold stretch for 20 Seconds</li> </ul>	<ul> <li>Lie on back, leg elevated and positioned at doorway as shown.</li> <li>Buttocks should be about 5 inches from wall, low back flat on floor.</li> <li>Gently slide buttocks toward wall, keeping knee straight, until stretch is felt.</li> <li>Relax and repeat.</li> </ul>



