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±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, 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 improvement. This is typically accomplished by increasing repetitions or 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 (http://www.randomization.com) [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

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 5th 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

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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.

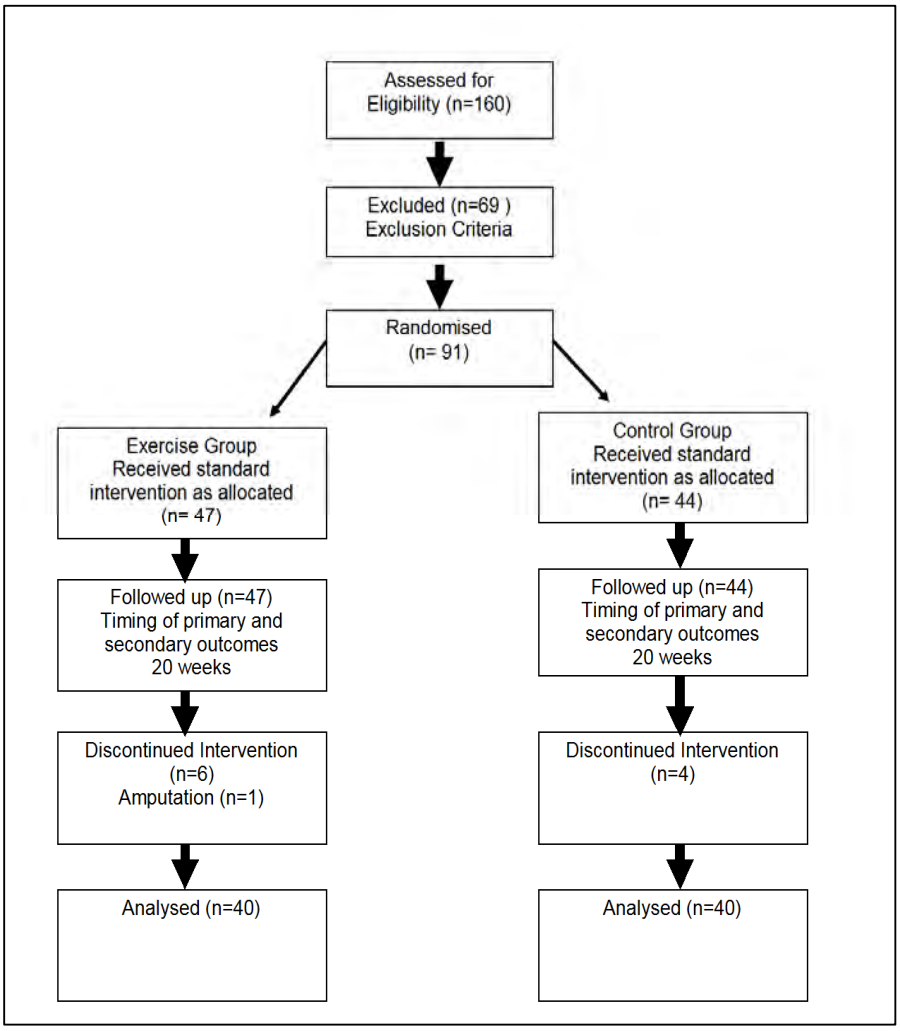


Figure 3: Diagram Showing the Flow of Participants through Each Stage of the Randomized Controlled Trial

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: $\%BF=0.31457\ (\text{abdominal C})^{b} - 0.10969\ (BW) + 10.8336$
Women: $\%BF=0.11077\ (\text{abdominal C})^{b} - 0.17666\ (HT) + 0.14354\ (BW) + 51.03301$

Index for the above formulae:

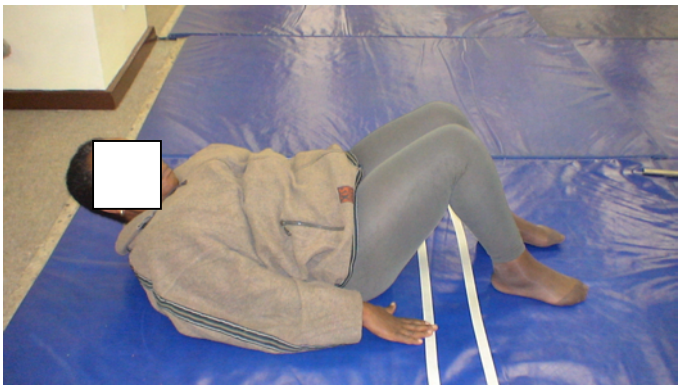
[b]: Abdominal C (cm) is the average of two circumferences measured (1) laterally between the lower end of the rib cage and the iliac crests and (2) at the umbilicus level.
HT: height
BW: body weight (kg)
C: circumference

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

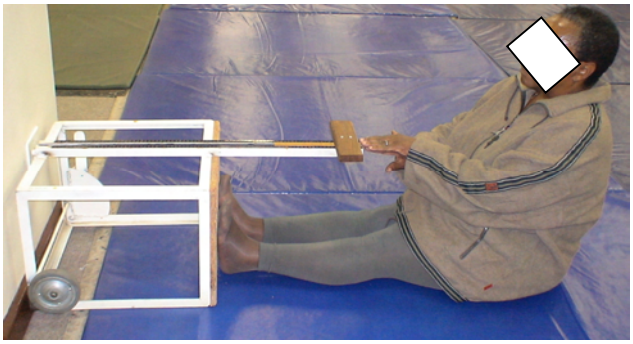
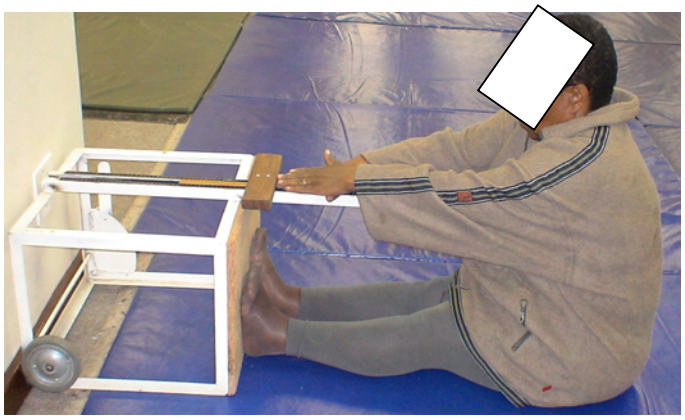


Figure 6b: In the Motion of Executing the Reach Movement

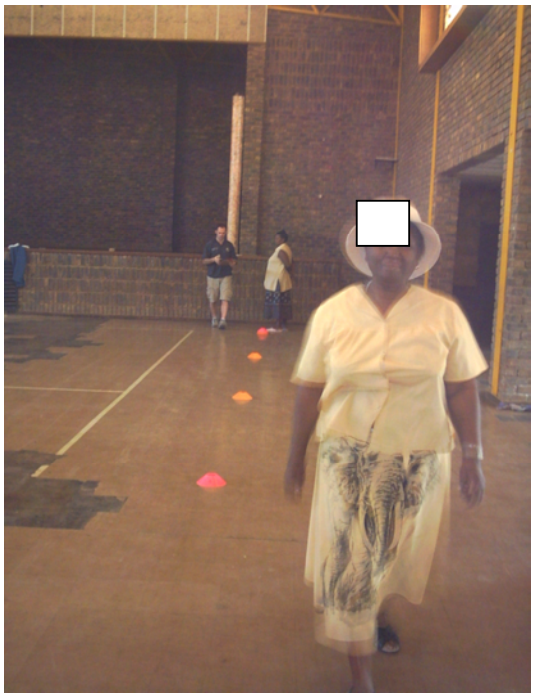


4.8.3 Cardio-respiratory Fitness

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.

Table 1: Frequency Distribution of Demographic Variables

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

Variable	Exercise (N=40)		Control (N=40)	
	Mean	SD	Mean	SD
Glycosylated Haemoglobin (%)	9.01	3.11	9.32	2.32
Body Mass Index (kg/m^2)	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.

Abdominal Circumference (cm)	Exercise (N=40)		Control (N=40)	
	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*		0.58*	
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 Circumference (cm)	Exercise (N=40)		Control (N=40)	
	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 exercise and control group	0.09 (se 1.74) (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

Body Mass Index (kg/m^2)	Exercise (N=40)		Control (N=40)	
	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 exercise and control group	-0.45 (se 0.71) (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)	Exercise (N=40)		Control (N=40)	
	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*	
Difference at 20 weeks between exercise and control group	-0.01 (se 0.02) (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.

Table 7: Fat Percentage in the Exercise and Control Groups

Fat Percentage	Exercise (N=40)		Control (N=40)	
	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*	
Difference at 20 weeks between exercise and control group	-0.009(se 0.21) (95% CI 0.09 to 0.91; p=0.96)**			

* 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

Table 8: Muscular Endurance in the Exercise and Control Groups

Muscular Endurance (sec) (Wall Squats)	Exercise (N=40)		Control (N=40)	
	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*	
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)**			

* 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) Abdominal Crunches	Exercise (N=40)		Control (N=40)	
	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 and control group	-0.43 (se 2.37) (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 Control Groups

Flexibility (cm)	Exercise (N=40)		Control (N=40)	
	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	0.17*		0.92*	
Difference at 20 weeks between exercise and control group	-0.73 (se 1.27) (95% CI -1.99 to 2.99; p=0.57)**			

* 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 20-week 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 the Exercise and Control Groups

Distance (m)	Exercise (N=40)		Control (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 Exercise and Control group	**19.22 (se 18.03)** (95% CI -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.

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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 and Control 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±0.52 vs. 0.48±0.94) and post-exercise dyspnea (1.95±1.28 vs. 1.98±1.61). 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 and Control Groups

Fatigue Index	Exercise (N=40)		Control (N=40)		P-Value
	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±0.42 vs. 0.63±0.87; p≤0.01) and similar post-exercise fatigue (2.03±0.97 vs. 2.3±1.8). 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^2 have a four-fold higher risk of type-2 DM than women with a BMI <22 kg/m^2. Women with a BMI of 24-25 kg/m^2 have a five-fold increased risk, and those with a BMI >35 kg/m^2 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 waist-to-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^2) 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 (≤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 caloric intake [48]. In this study, all participants that were recruited were 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^{th} (p25) and 75^{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 ($p\leq0.05$) 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; $p\leq0.01$) 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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