CHAPTER 5

EFFECT OF EXERCISE ON HAEMOGLOBIN A_{1C} IN BLACK FEMALES WITH TYPE 2 DM MELLITUS

INTRODUCTION

A small increase in physical activity has benefits on health outcomes including all-cause mortality. Evidence obtained from several recent randomized controlled trials have shown that increasing physical activity has beneficial effects on metabolic control over and above its effect on weight. [12,57,126,133]

The cornerstones of diabetes care in South Africa are education, medical nutritional therapy, hypoglycaemic agents and exercise. [8] However, the overall physical activity level (activities of both daily living and occupational physical activity) have been shown to be low in this population, as demonstrated in an earlier study in a similar population. [246]

A qualitative study in a subset of the population has shown that patients are keen to do exercise, but lacked knowledge about exercise as well as a venue in which to do exercises. [258]

The aim of this final phase of the study was therefore to establish the efficacy of an exercise intervention to decrease $HbA1_c$ over a period of 12 weeks, in Type 2 DM black female subjects, aged 40 to 65 years. Secondary outcomes to be assessed were body mass index, walking distance and the subjective experiences of the subjects.

METHOD

ETHICAL CLEARANCE

The Protocol and Ethics Committee of the University of Pretoria approved the study (Appendix 2).

The superintendent, the chief executive officer of the Mamelodi Hospital and physicians providing medical services at the diabetes out-patient clinic were informed about the study and their approval was obtained.

Each subject gave verbal consent prior to the baseline testing when she was recruited to take part in the study. When the participants reported for the baseline testing, they received information about the study in their own language and had the opportunity to ask questions. If the participants indicated that they were willing to take part in the study, they were requested to give written informed consent. Each participant received a signed copy of the consent form (Appendix 2).

STUDY DESIGN

A single blind, randomised controlled clinical trial design was used for the study. The two groups differed only with respect to exercise being prescribed for the one group. Subjects, who arrived for the baseline test, were randomised into either an exercise group or a control group by means of block randomisation by computer. (http://www.randomisation.com). [33]

HYPOTHESIS

An exercise / physical activity intervention will decrease the HbA_{1c} by 1% given a SD of 2.23% with α=0.05 and β=0.10 in a sample of 144 female Type 2 DM patients, aged 40 to 65 years.

SAMPLE SIZE

A total sample of at least 144 subjects, with 72 in the experimental and 72 in the control groups, was necessary to detect a difference of 1% in HbA_{1c} levels (assuming an SD of 2.23%) between the two groups at the end of the 12 weeks trial period. For an one-sided test, improvement would only be considered if α=0.05 and β=0.10 with a power of 80%. In anticipation of a possible dropout rate of 10% it was decided to recruit 80 participants for each group.

SUBJECTS

The study was conducted at the Mamelodi Day Hospital, east of Pretoria, in the Gauteng Province of South Africa. The study participants were black females between the ages of 40 and 65, with Type 2 DM and a known duration of the disease for at least one (1) year. All participants were residents of the suburb of Mamelodi and attended the diabetic out-patient clinic at the Mamelodi Hospital on a regular basis. Due to the relatively small number of men seen at the clinic, the study was restricted to women with Type 2 DM. Females were also chosen because it was thought that they would be more likely to keep research-related appointment visits than the men. This may have biased the sample.

The recruitment of subjects commenced on 26 February 2002 at the diabetic out patient clinic. The clinic was conducted on Tuesdays and Thursdays at the Mamelodi Hospital. Subjects were approached individually, while they were waiting to see the doctor. The researcher introduced herself to each subject, requested permission to look at the subject's file, as well as to ask the subject a few questions. All consecutive eligible subjects attending the clinic over a period of six months were approached and invited to take part in the study. Duration of diabetes was not recorded.

Subjects were screened for chest pain on effort, possible infarction and intermittent claudication, cerebro-vascular incidents, arthritis, macrovascular disease, general health and retinopathy by means of the London School of Hygiene Cardiovascular Questionnaire [259] (Appendix 3). Cases where there was uncertainty regarding the aforementioned conditions were referred to the attending specialist physician (PR), for clinical evaluation. Subjects were not tested for HIV infection.

Subjects were excluded from the study in the following instances:

- Mental incompetence
- Inability to walk
- Chest pain on effort
- Self-reported history of myocardial infarction
- Intermittent claudication grade 2
- Autonomic neuropathy
- Respiratory dyspnoea
- Heart failure
- Stroke
- Severe limiting osteoarthritis
- Wounds on or infections of the feet
- Presence of other major diseases
- Previous laser therapy for the eyes
- Pregnancy
- Full-time employment
- Plans to move from the area during the study period.

Subjects' files were marked with a small green sticker, with a note to inform the attending physician of the subjects' intended participation. The presence of a green sticker on a file also helped the researcher to identify subjects who were recruited but did not turn up for the baseline test.

If a subject was still interested in taking part in the study, a new appointment date for baseline testing was made.

After preliminary verbal consent was obtained, an appointment was made for the baseline test on the first Wednesday that was convenient for the recruited subject. This was done to ensure that the recruited persons did not forget about the project or lose interest. Appointments were made for 08h00, 09h00 and 10h00 to prevent unnecessarily long waiting periods. [258]

Recruited persons received a typed reminder with the date of the appointment on it. The subjects, who had telephones, were reminded telephonically two days prior to the appointment day. A new appointment was made if the previous set date no longer suited them. Subjects who were booked for the baseline test, but did arrive were telephoned, and if the subject still verbally consented, a new appointment date was set. The subjects, who did not have telephones, were again approached when they had a follow-up visit at the diabetes clinic. A new appointment date was set if the subject still consented to take part in the study.

THE RESEARCH TEAM

The principle researcher, who was not blinded to the randomisation of the subjects, did the administrative work, for instance phoning for randomisation, paying of the transport and the making of the next appointments.

The research assistant, a multilingual registered nurse, was employed and trained to capture the demographic and clinical data and to administer the translated questionnaire. She was not present during the randomisation of the subjects, nor did she receive a list with the names of the subjects or the randomisation.

A nurse from the Institute of Pathology took all the blood samples for HbA_{1c} testing. Samples were marked with the subjects' research numbers and were collected by a courier from the Institute of Pathology.

The nurse who took the samples and the laboratory technician were both blinded to the randomisation of the subjects.

The dietician at the Mamelodi hospital who gave the lectures on diet was also blinded.

IDENTIFICATION OF SUBJECTS

A study number, consisting of the first two letters of the surname of each subject and a number was allocated to each subject prior to randomisation. If for instance, Constance Mothabeng (fictitious name) was the 50th patient who consented to take part in the study, she would be allocated the number "MO50". This number was then used on all assessment forms, the questionnaire and the blood samples of the patient. Therefore no person other than the author was aware of the randomisation of the patient.

RANDOMISATION

The principal researcher prepared 180 envelopes with either the letter A or B enclosed in each envelope. The letter A indicated the exercise group and B indicated the control group. The envelopes were then sealed and put in order according to the computer-generated randomisation list. Subjects were randomised into either an exercise group or a relaxation group in 17 blocks of 10 each. The envelopes were put in a holder and kept in an administrative office at the Department of Clinical Epidemiology, Faculty of Health Sciences at the Pretoria Academic Hospital. When a subject reported for the baseline test and consented to take part in the study, the principle researcher telephoned the administrative office and the next envelope was opened and the contents read to the researcher over the telephone. The name of the subject was then written on the opened envelope and it was returned to the holder. The list of subjects and their randomisation was kept in a safe place by the researcher.

To further ensure that the research assistant was blind to the randomisation of the participants, the only form of identification on the questionnaires, EDTA-tubes and the clinical data forms, were the study numbers of the subjects.

PILOT STUDY

On 13 March 2002 a pilot study was conducted on six subjects to test the research procedure. The data of these six subjects were included in the pre-test and post-test data with the rest of the sample.

INSTRUMENTS

The American Diabetes Association's Position statement on Diabetes and Exercise [25] was used as the basic reference for the planning of the clinical evaluation at baseline.

Demographic, clinical and quality of life data were captured. A structured questionnaire was used to obtain information on general health, well-being and treatment satisfaction. The questionnaire was available in English, Afrikaans, isiPedi/isiSotho/isiTswana and isiZulu (Appendix 3). The questionnaire had been standardised and validated by testing it on 85 black diabetic subjects attending the Kalafong and Pretoria Academic Hospitals during October/ November 2001. [260]

The questionnaire consisted of three sub-scales.

GENERAL HEALTH

The 5-item health perception sub-scale from the 36-item abbreviation of the Rand Medical Outcomes Scale (SF-36) was used to measure general health. [261] Each item is scored on a 1 to 5 basis, with the score reversed on the first, third and fourth items. Item 1 was re-scored to indicate the unequal intervals in the ordinal response scale: 1 = 5; 2 = 4.36; 3 = 3.43; 4 = 1.99 and 5 = 1 more accurately.

Scores were then transformed linearly from zero to 100, where zero and 100 are assigned to the lowest and highest scores, respectively. The cut-off points for poor general health is a score of 70 or less. Reliability coefficient for the scale was 0.98. [260]

THE DIABETES TREATMENT SATISFACTION QUESTIONNAIRE (DTSQ)

This questionnaire has been specifically designed to measure satisfaction with diabetes treatment regimens in people with diabetes. [262] The scale consists of six items that measure satisfaction and two items that are concerned with hypoglycaemia and hyperglycaemia. Subjects rate their treatment and experience over the past two weeks on a six-point scale ranging from six (very satisfied/convenient/flexible/definitely recommend) to zero (very dissatisfied/inconvenient/inflexible/definitely not recommended). Scores are totalled to give an overall treatment satisfaction score (range 0-36) with higher scores denoting greater treatment satisfaction.

The hypo/hyperglycaemia items are also rated on a 6-point scale, ranging between six (most of the time) and zero (none of the time). Scores are totalled to give an overall blood glucose control score (range 0-12), with lower scores indicating better blood glucose control. The reliability coefficient was 0.90 in the study by Westaway et al [260]

WELL-BEING

The Well-being scales, designed by Bradley and her associates [262] consist of six items to measure depression, six items to measure anxiety and six items to measure positive well-being (range 0-18). Respondents indicate how often they felt that each statement applied to them during the last two weeks on a 4-point scale from zero (not at all) to three (all the time).

Ratings for items on each sub-scale should be totalled after reversing scores where necessary (Depression items 1,3,4, 6 and Anxiety items 5 and 6).
Sub-scales are scored so that a higher score on each sub-scale indicates a higher level of the mood described by the sub-scale label.

A General Well-being total score is obtained by totalling the sub-scale scores after reversing the scores on the Depression and Anxiety sub-scales. Reliability coefficients ranged between 0.66 and 0.70 for the Depression scale and 0.76 and 0.88 for the Anxiety sub-scale. The value for the Positive Well-being ranged between 0.88 and 0.89. [260]

CLINICAL MEASUREMENTS

Body mass was determined to the nearest 0.1 kg standing barefoot in light clothing on a calibrated electronic scale (Soehnle Digital ®). Height was measured to the nearest 0.1cm using a 2m Panamedic stadiometer attached to the wall. Each subject's body mass index was calculated by dividing the body mass by the square of the subject's height. [223]

Blood pressure was measured according to published guidelines using a Mercury Baumanometer ®.[263] The subject was seated with right arm supported on a table and rested for five minutes. The mid-arm circumference was measured and a large cuff (15 cm-rubber bladder) was used for an arm circumference of 33 cm or greater. Two measurements were taken and if there was a difference of more than 5 mmHG between readings, a third measurement was taken. The mean of the nearest measurements was used to determine the mean blood pressure.

The Six-minute walk test was conducted in an enclosed area on a course 33 metre long course. A Webco Steel Measuring tape was used to measure out the 33 metre course. The subject was instructed to walk from end to end, covering as much ground as she could during the allotted time of six minutes. The subject was also instructed to stop the test and to report any chest pain, light-headedness, severe tiredness or any other adverse effect experienced during the test. The research assistant faced the subject and called out one of a predetermined set of encouraging phrases, such as "You're doing well!" or "Keep going", after each completed lap. At the end of the test she called out "Stop", and the distance covered was recorded. A calibrated Avant Sport timer ® was used to time the six minutes for all the subjects. [162]

Rating of perceived exertion was assessed using the Borg Perceived Exertion Scale [264] (Appendix 3). Although significantly less specific, it is possible to perform a reasonably accurate exercise prescription without a maximal exercise test. The Rating of Perceived Exertion (RPE) is closely associated with the relative metabolic rate and the relative heart rate in most individuals. [264] Lactate threshold (LT) appears to be 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.

The Haemoglobin A1c (HbA1c) Reagent Kit in conjunction with SYNCHRON® Systems HbA1c Calibrators and SYNCHRON Systems Hemolyzing Reagent, were used for the quantitative determination of haemoglobin A1c concentration as a percentage of total haemoglobin in whole blood. [265] Freshly drawn blood samples were collected in EDTA-tubes as routinely done in any laboratory test. The samples were then transported in ice to the Institute of Pathology, University of Pretoria within six hours of being drawn by a courier. Subjects did not fast before the blood samples were taken.

A physical activity diary with illustrations of some of the most common physical activities at home was compiled. The illustrations were used to enable those subjects who were illiterate, to keep a diary. An example of the physical activity diary is presented in Appendix 4. The subjects in the exercise group were instructed to keep a daily record of the time they spent on each of the activities in the diary. Subjects received a new diary form each time they reported for an exercise class. The metabolic equivalent intensity levels (MET) for these activities were known and could be calculated. [266] The body mass of the subject in kilograms was multiplied by the MET value of the activity and the duration of the activity to estimate the kilocalorie energy cost of each activity at home. The type of activities included in the physical activity form, as well as the MET values are presented in Table 5.1.

TABLE 5.1

PHYSICAL ACTIVITIES AT HOME AND MET-VALUES [266]

Physical activity	MET-value
Cleaning windows	3.0
Ironing	2.3
Scrubbing floors on hands and knees	3.8
Sweeping floors / carpets	3.3
Multiple household tasks at once (light effort)	2.5
Walking slow pace, firm surface	2.5
Vacuuming	3.5
Gardening in general	4.0
Raking yard	4.0
Sitting, knitting	1.5
Tailoring, hand sewing	2.0
Tailoring, machine sewing	2.5
Child care, standing-dressing, bathing, grooming, occasional lifting	3.0
Doing laundry by hand	3.5
Cooking and food preparation	2.5
Washing dishes, clearing from table	2.5

GENERAL INFORMATION QUESTIONNAIRE

The questionnaire consists of questions to evaluate the subjective experience of the subjects after the 12-week intervention. Questions about the logistical aspects of the programme and interest in the continuation of the programme were asked. Subjects' interest in becoming group leaders for future interest groups was established. Subjects were also asked for any other suggestions they may have for future planning purposes.

RESEARCH PROCESS

Data capturing commenced on Wednesday 13 March 2002. Six to 16 subjects reported every Wednesday to the Physiotherapy department at the Mamelodi Hospital for baseline testing and again after completing the 12 weeks programme.

The order for the pre- and post-intervention assessments was the same for both the exercise and relaxation groups and is presented in Table 5.2.

TABLE 5.2

THE ORDER OF THE BASELINE AND POST-INTERVENTION ASSESSMENTS OF PATIENTS IN BOTH THE EXERCISE AND RELAXATION GROUPS

Welcome, introductions and expression of appreciation

↓

Name labels

↓

Information in isiSotho/isiTswana/isiPedi/isiZulu and English

↓

Answering of questions

↓

Written and witnessed informed consent (copy to patient)

↓

Allocation of study number

↓

HbA_{1c} sample

↓

Demographic data

↓

Health, Well-being and Treatment Satisfaction questionnaire

↓

Measurement of blood pressure

↓

Measurement of heart rate

↓

Measurement of height

↓

Measurement of body mass

↓

Calculation of body mass index

↓

Six-minute walk test

↓

RPE

↓

Heart rate

↓

Refreshments

↓

Information and payment of transport

↓

Next appointment

After the baseline test, appointments were made with the subjects in the exercise group for the following Monday. Appointments for the subjects in the relaxation group were made for the following Friday. Subjects were instructed to wear suitable clothes and shoes.

A typed note with the date and time of the new appointment was given to each subject. The subject was then paid R20-00 for transport and thanked for her attendance.

THE INTERVENTION

The exercise- and relaxation groups differed only with regard to the exercise intervention.

Since a clinical trial is an experiment on human beings, the ethical aspects of the study are indisputable. The findings of the studies described in Chapters 3 and 4 with similar sample groups have shown that the subjects had knowledge about the benefits of exercise and they expressed the need for a structured exercise programme. [258] Therefore expectation of some form of exercise was created through the kinds of questions that were asked in both of the previous studies. To solve the problem of what treatment to give the relaxation group, it was decided to do self-relaxation training with them in order to control for the non-specific social and psychological aspects of exercise.

It was also clear during the recruitment of subjects at the Diabetic out-patient clinic at the Mamelodi Hospital, that the subjects did not understand the concept of randomisation. They often requested to be in the exercise group when the research process was explained to them. For ethical reasons, care was taken to have beneficial interventions for both groups, that the intervention would be interesting for the subjects, to ensure the subjects' adherence to the programme.

The exercise and relaxation group interventions were held on Monday and Friday mornings respectively. These two days were also chosen to keep contamination of the groups to the minimum. Care was taken to strictly keep participants in their specific groups by means of an list of attendance and appointments for specific dates. Care was taken to point out the subject's self-responsibility for her health care and that the programme was structured to empower her with knowledge and exercise skills.

Table 5.3 gives an overview of the course followed during the 12 – week intervention period.

TABLE 5.3

INTERVENTIONS FOR THE EXERCISE AND RELAXATION GROUPS RESPECTIVELY

Exercise group Monday mornings 08:00-11:00	Relaxation group Friday mornings 08:00-11:00
Welcome ↓ List of attendance ↓ Name label ↓ Introduction of subjects coming for the first time ↓ Discuss exercise book Addressing problems ↓ Physical activity record ↓ Aerobic exercise (< 60% of maximal heart rate) for 45 minutes ↓ Stress importance of home exercise and walking ↓ Education ↓ Refreshments ↓ Payment of transport ↓ Next appointment	Welcome ↓ List of attendance ↓ Name label ↓ Introduction of subjects coming for the first time ↓ Relaxation class 30 minutes ↓ Education ↓ Refreshments ↓ Payment of transport ↓ Next appointment

THE EXERCISE GROUP

The overall physical activity level (of both daily living and occupational physical activity) was low in this population as demonstrated in an earlier study in the same population (described in Chapter 3). [246] The aim of the exercise intervention was to promote regular participation in moderate intensity physical activity on most days of the week in a community with limited resources.

The choice of the intervention was influenced by the fact that the subjects were not used to exercise and by the fact that most of them were overweight. Furthermore, the participants were only clinically screened and no ischaemic response to exercise was done.

The intervention consisted of an incremental daily home exercise programme, the use daily of physical activity records and six fortnightly aerobic exercise classes. [27] This form of intervention was chosen because the Department of Health of South Africa supports management of diabetes at primary level.

Care was therefore taken to choose a mode of exercise, which could be practised safely in a community setting, but also with the aim of empowering the participants in exercise skills. It has been shown that a programme of lifestyle activity may offer similar health benefits and may be a suitable alternative to vigorous exercise for overweight women. [267]

THE EXERCISE INTERVENTION

The aim of the exercise intervention was to promote regular participation in moderate intensity physical activity on most days of the week in a community with limited resources. The intervention consisted of an incremental daily home exercise programme, the use of daily of physical activity records and six fortnightly aerobic exercise classes.

The Mamelodi Hospital was chosen as a venue because the patients all knew the venue and could use public transport to reach it. It would have been better to have exercise venues closer to the patients' homes, but since the patients were randomised after they consented to take part in the study, no prior arrangements for venues in the different neighbourhoods in Mamelodi could be made. Also the negotiations regarding the use of community centres would be a lengthy process. The author was also unknown to the community leaders. Furthermore, the community centres are used for a wide variety of community activities and exercise classes would also be subordinate to other regular community activities. It would also be difficult for the researcher to control the circumstances under which the patients received education and exercise, since some venues were unsuitable for exercise and educational purposes.

HOME EXERCISE PROGRAMME

A home-based exercise programme was chosen due to the participants' home responsibilities, such as taking care of children, older people and community activities. It has been shown that lifestyle physical activity is as effective as structured exercise for improving fitness in adults. [120,267] The fact that the participants were women, who needed to exercise in a safe environment, also contributed to this decision.

A further aim of the programme as mentioned earlier was to empower the participants to take responsibility for their own health and to exercise on their own. [172] Participants were encouraged to form small groups of women living near each other to join in the exercises, and to increase the social support, which was one of the outcome expectations expressed as described in Chapter 4.

While it would have been preferable to have the support of a spouse, the majority of patients were single (54.3%).[257] This limitation was addressed by offering fortnightly exercise sessions at the Mamelodi Hospital. It was hoped that these session would provide social and group support.

Patients were instructed to increase walking at home from 10 to 45 minute bouts over the 12 weeks of training. Subjects were instructed to walk twice a day starting with 5 minutes per session and to increase their total daily walking time with 10 minutes every two weeks up to 45 minutes per day. It was decided to use short bouts of exercise in order to incorporate exercise into the lifestyle of the mainly sedentary population. [150] Instructions were to walk fast and swing the arms. [268,150] Subjects were encouraged to work up a slight sweat and a quicker respiratory rate, thus working at a moderate RPE of 12-14 or somewhat hard. [269]

This method was used, because the traditional method of monitoring heart rate by palpation could not be followed due to the fact that most of the subjects do not wear watches. Walking was indicated by the subjects of the previous study (Chapter 4) as a suitable form of exercise.

Each subject also received a notebook with instructions and graphic demonstrations of the gentle flexibility exercises to improve and maintain range of motion and to stretch the major muscle groups. (Appendix 5). This was done to educate the patients about exercise and to address the other outcome expectations, namely better health and flexibility.

Subjects were urged to do their home exercises at least five times per week, but if possible every day of the week. [27]

PHYSICAL ACTIVITY DAIRY

The aim of the physical activity diary (Appendix 4) was to provide a detailed account of habitual daily activities and their associated duration. [266] Subjects were continuously reminded that physical work at home was also a form of exercise, but that they had to increase the speed, duration and intensity of doing these activities. [25]

A physical activity diary with illustrations of some of the most common physical activities at home was compiled. The illustrations were used to enable the subjects who were illiterate, to keep a diary. Subjects were instructed to keep a daily record of the time they spent on each of the activities in the diary. Multi-coloured stickers were used to remind the subject at which week in the programme she was and when to return the physical activity log.

The metabolic equivalent intensity levels (MET) for these activities were known and could be calculated. [266] The physical activity logs were checked; problems discussed and new logs were handed out for the next fortnight. In this way problems experienced could be addressed and the patient could be motivated to keep on trying. [180]

HOSPITAL EXERCISE PROGRAMME

The fortnightly exercise sessions at the Mamelodi hospital were used to educate the subjects about exercise, to demonstrate the home exercises and to address problems experienced with their home programmes.

Exercises consisted of low-impact aerobic large range movements performed to rhythmic music in the gymnasium that had suitable lighting and ceiling fans.

The duration of the aerobic exercise class presented at the Mamelodi Hospital was 45 minutes and was divided as listed below:

- 10 minute warm-up period.
- 25 minutes of aerobic exercise.
- 10-minute cool-down period.

During the warm-up session aerobic walking at low intensity level was done to prepare the skeletal muscles, heart and lungs for the progressive increase in exercise intensity. This was followed by gentle stretch exercises of all the muscle groups that would be used during the active exercise session.

The intensity of the training was set at moderate, obtaining a maximal heart rate percentage of 55-69% and a RPE of 12-13. [25]

The cool-down consisted of 10 minutes of gentle stretching of the muscle groups used during the active exercise session.

PRECAUTIONARY MEASURES

The aerobic exercise class was done in the gymnasium. Participants were urged to drink 200 to 800 ml of water per hour during the exercise session to ensure adequate hydration. [270] Although the subjects were clinically screened for the various signs and symptoms of disease affecting the heart and blood vessels, eyes, kidneys and nervous system, the precautionary measures taken into consideration are described in Table 5.4.

TABLE 5.4

PRECAUTIONARY MEASURES DURING EXERCISE CLASSES FOR THE EXERCISE GROUP

Take medication as prescribed by the physician.
Have a small snack before coming for exercise.
Do not to exercise if the diabetes is out of control.
Drink ± 200 ml water two hours before exercise.
Wear suitable clothing and shoes for the exercise session.
Drink 200-800 ml water during the exercise session.
Report any of the following during the exercise session:
- Excessive sweating
- Palpitations
- Chest pain
- Dizziness
- Any other discomfort not usually experienced
- Rest when tired

Subjects were also observed and instructed to look out for any adverse signs and symptoms during the exercise. Anaerobic exercise and exercise involving straining, jarring or Valsalva –like manoeuvres were avoided.

High-intensity and strenuous exercises were avoided and participants were never forced to go on if they felt tired. Repetitive weight-bearing exercises were avoided to prevent any injury to the feet. Subjects did weight-bearing exercise on the gymnasium mats if they did not have suitable shoes and always wore socks. Care was taken to remove any apparatus that could injure a subject during the exercise class. Subjects were constantly reminded of these precautions to avoid any injuries while exercising at home.

EDUCATION

The education was the same for both the exercise and the relaxation groups and consisted of inter-active group sessions on the same day as the intervention at the hospital (Appendix 6). The subjects received education on the management of Type 2 DM and the role of exercise in the management of the disease. The prevention of hypoglycaemia during exercise was included in the education on the role of exercise.

Food sample examples were used to show subjects the different products and also to teach them to look at the labels on the products. They could also taste products for salt and fat content. This was done since not all subjects could read the fine print on the labels due to poor eyesight and lack of glasses in this sample.

Sessions on food portion size and use of fat, fibre and the use of salt in the diet were given. The first two lectures were given by the researcher in English, but with handouts in isiPedi/isiSotho/isiTswana and isiZulu. Ms Monique Roux, a qualified dietician and a staff member of the Mamelodi Hospital, gave the lectures on diet.

THE RELAXATION GROUP

Subjects in the relaxation group attended fortnightly education and relaxation classes at the hospital (Appendix 7). All questions about exercise were answered, since it would be unethical to withhold information from patients. During the relaxation classes, subjects were instructed to progressively tense, then relax alternative muscle groups. They were also told to what to think, for instance "Notice your body relaxing, feel how relaxed and warm your body is becoming and how it spreads to other parts of the body". [214]

RECORD OF ATTENDANCE

An attendance list was kept for both groups and subjects were not allowed to attend on days other than those allocated to them to prevent contamination between the exercise and relaxation groups.

FOLLOW-UP OF SUBJECTS IN BOTH GROUPS

When a subject, from either the exercise or the relaxation group did not come for her next session, one of the following steps were taken:

If the subject had a telephone number, she was telephoned. The problem was discussed and a new appointment was made for the following exercise class.

In the case where the subject did not have a telephone number, and the researcher saw her again at the Diabetes Clinic, she was approached and the problem was discussed and a new appointment was made. If the subject did not have a telephone number and also did not come for two appointments in a row, a letter was send to the subject's physical address, requesting the subject to come on the following relevant date. The problem was then discussed and solved if possible.

When a subject did not react to any of the above mentioned steps, it was accepted that the subject was no longer willing to take part in the project and exercised her choice to withdraw from the study, as was stipulated in the informed consent document.

In cases where a subject in the exercise group accidentally left her physical activity diary at home, she was instructed to bring it with her the next time. When a subject did not complete the diary, she was questioned about it and the problem was addressed.

POST-TRIAL TEST PROCEDURE

The post-trial test was conducted after 12 weeks and the procedure is described in Table 5.2. Each subject received a written report of the research results within one month after completion of the trial. A copy of this report was also sent to the attending physicians for their information and record keeping.

All patients who completed the programme, received a certificate of attendance as a token of appreciation (Appendix 8).

STATISTICAL ANALYSES

Data were analysed using Statistix ® and Stata ® software. Data are presented as means ± SD, frequencies and percentages. The paired *t*-test was used to calculate p values for the comparison of means within the experimental and control groups respectively.

An analysis of co-variance (ANCOVA) was used to compare the experimental and control groups with respect to change in $HbA1_c$ and change in BMI and the six-minute walking distance, using baseline values as cofactor respectively. [33] A p-value < 0.05 was regarded as statistically significant for a one-sided test.

RESULTS

Data capturing commenced on Wednesday 13 March 2002 and ended on 12 November 2002.

The progress through the various stages of the study, including the flow of participants, withdrawals and the timing of primary and secondary outcomes are presented in Figure 5.1.

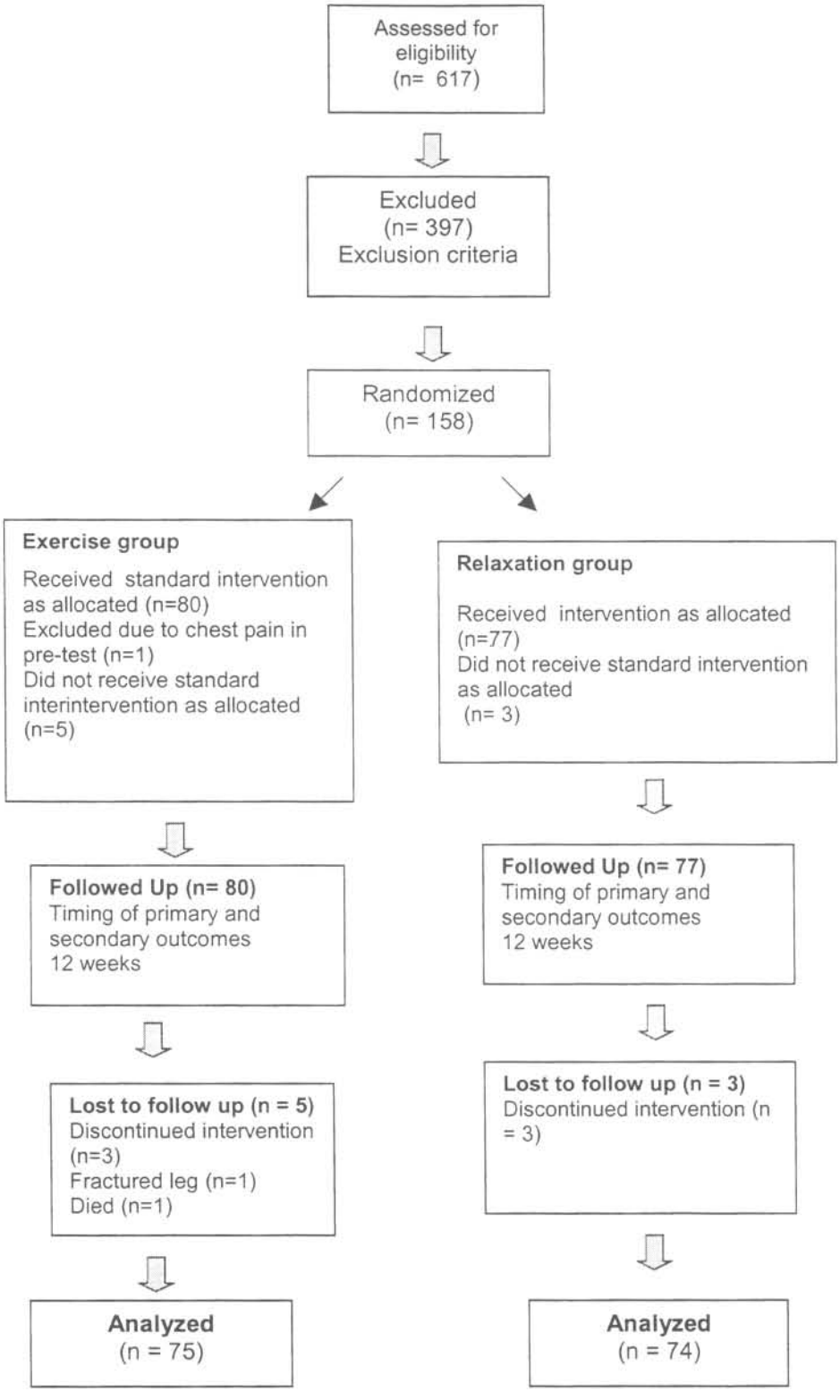

Figure 5.1 FLOW DIAGRAM OF PROCESS THROUGH THE PHASES OF THE TRIAL.

The baseline characteristics of the eight (8) subjects who did not complete the program (five (5) exercise and three (3) relaxation subjects) did not differ from the baseline characteristics of those subjects who completed the program. Subjects were followed up by means of telephone calls, letters and at the diabetes outpatient clinic. Psychosocial problems, death in the family and illness were reasons for not attending sessions at the hospital. No adverse events were reported in the exercise or the relaxation group during the trial.

DEMOGRAPHIC DATA

TABLE 5.5

The frequency distribution of the demographic variables is presented in Table 5.5.

Demographics		Frequency (%)	
		Exp (n= 80)	Contr (n=77)
Schooling (Years)	Unknown	26(32.5)	30(39)
	2-4 years	3(3.8)	2(2.6)
	5-7 years	41(51.3)	31(40.3)
	8-10 years	10(12.5)	12(15.6)
	Post St 10	0	2(2.6)
Language	IsiPedi	34(42.5)	33(42.9)
	Zulu	16(20)	15(19.5)
	IsiTswana	9(11.3)	7(9.1)
	Venda/ Ndebele	9(11.3)	7(9.1)
	Tsonga	4(5)	9(11.7)
	IsiSotho	4(5)	4(5.2)
	Afrikaans	4(5)	2(2.6)
Marital status	Married	36(45)	44(57.1)
	Widowed	20(25)	14(18.2)
	Single	15(18)	12(15.6)
	Separated	9(11.3)	7(9.1)
Income	Pension	30(37.5)	27(35.1)
	No answer	17(21.3)	21(27.3)
	Piece job	15(18.8)	12(15.6)
	Partner	10(12.5)	12(15.6)
	Relatives	7(8.8)	4(5.2)
	Friends	1(1.3)	1(1.3)
Other longstanding illnesses	None	14(17.5)	15(19.5)
	Hypertension	53(66.3)	45(58.4)
	Arthritis	1(1.3)	2(2.6)
	Combination	8(10)	9(11.7)
Type of treatment	Injections	23(28.8)	20(26)
	OHAs[1]	51(63.8)	50(64.9)
	Inject and OHA's	5(6.3)	7(9.1)
	Diet alone	1(1.3)	0

[1] Oral hypoglycaemic agents

The mean ages of the exercise and relaxation groups were respectively 54 and 55 years.

Percentages in parenthesis are as found in the exercise and relaxation groups respectively. The majority of the sample in both the experimental (64%) and control (56%) groups had schooling of between five and 10 years. Only two subjects had post-school qualifications. The subjects in both groups spoke mainly Isipedi (both groups = 43%), were married (45; 57%) and were pensioners (38; 35%). Most subjects in both groups indicated hypertension as their other long-standing illness (66; 58 %). Subjects were mainly treated with oral hypoglycaemic agents (64; 65%).

TABLE 5.6

The difference in clinical outcomes between the exercise and relaxation groups is presented in Table 5.6.[2]

Variable	Timing	N		Mean(sd)		Comparison of groups with respect to change from baseline	
		Exp	Contr	Exp	Contr	95% CI	p-value
$HbA1_c$ %	Pre-test	80	77	9.36(2.42)	9.25(2.28)	(-1.16;-0.01)	0.05
	Post-test	75	74	8.99(2.59)	8.26(1.97)		
BMI (kg / m^2)	Pre-test	80	77	31.73(6.01)	33.72(6.64)	(-0.14;0.47)	0.28
	Post-test	75	74	31.82(6.10)	33.36(6.62)		
Systolic BP (mmHg)	Pre-test	80	77	131.81(18.07)	132.95(16.75)	(-3.42;5.58)	0.64
	Post-test	75	74	128.11(16.27)	129.81(14.46)		
Diastolic BP (mmHg)	Pre-test	80	77	80.14(10.63)	81.23(10.90)	(-2.62;2.99)	0.90
	Post-test	75	74	79.01(9.44)	79.58(8.40)		
Six minute (Meters)	Pre-test	80	77	452.83(88.17)	449.02(72.69)	(9.07; 39.04)	0.00
	Post-test	75	74	501.40(80.62)	476.8(65.52)		
RPE	Pre-test	80	77	12.33(3.88)	11.94(3.94)	(-1.47;0.97)	0.69
	Post-test	75	74	12.09(4.14)	11.80(3.98)		

The adjusted baseline mean $HbA1_c$ change in the exercise group after 12 weeks was -0.39% (95% CI -0.8 to 0.02) and was barely not significantly different (p=0.05) from the mean for the relaxation group -0.97% (95% CI -1.38 to 0.55). However, the relaxation group improved more than the experimental group.

[2] An analysis of co-variance (ANCOVA) was used to compare the exercise and relaxation groups using the baseline values as covariate.

The adjusted baseline mean BMI change in the exercise group was -0.07kg.m^2 (95% CI -0.28 to 0.14) and was not significantly different (p=0.28) from the mean for the control group -0.23kg.m^2 (95% CI-0.44 to 0.02).

The difference in adjusted baseline adjusted mean walking distance change in the exercise group of 46.76m (95% CI 36.20 to 57.32) was significantly better (p<0.01) than the change for the relaxation group of 22.7m (95% CI 12.07 to 33.33).

Systolic blood pressure improved in both groups, but the change was not significant (p=0.64) between groups (95% CI 3.42 to 5.58). This was also the case with the diastolic blood pressure (p=0.90) (95%CI –2.62;2.99).

The difference in the baseline adjusted mean rate of perceived exertion change from baseline in the exercise group after the six minute walking test was not significantly different (p=0.69) from the baseline value in the control group (95% CI-1.47;0.97).

Significant within-group improvements in both the exercise and the relaxation groups were demonstrated in the means of HbA_{1c} and walking distance as can be seen in Table 5.7.

TABLE 5.7

The difference in means within the exercise and relaxation groups respectively is presented in Table 5.7. [3]

Variable	Group	N	Mean(sd)	Comparison of means within the exercise and relaxation groups from baseline	
				95%CI	p-value
$HbA1_c$ %	Exercise	75	-0.63(0.31)	(-1.25;-0.02)	0.04
	Relaxation	74	-0.91(0.23)	(-1.38;-0.45)	<0.01
BMI (kg/m^2)	Exercise	75	-0.05(0.13)	(-0.31;0.21)	0.70
	Relaxation	74	-0.25(0.08)	(-0.41;-0.10)	0<.01
Six minute walk test (meters)	Exercise	75	46,36(6.5)	(33.43;59.28)	<0.01
	Relaxation	74	22.46(4.7)	(13.09;31.82)	<0.01

[3] The paired t-test was used to calculate a p value for the comparison of means within the exercise and relaxation groups respectively.

The comparison of the change in mean HbA_{1c} and mean walking distance over the period of 12 weeks between the exercise and relaxation groups are demonstrated in Figures 5.2 and 5.3 respectively.

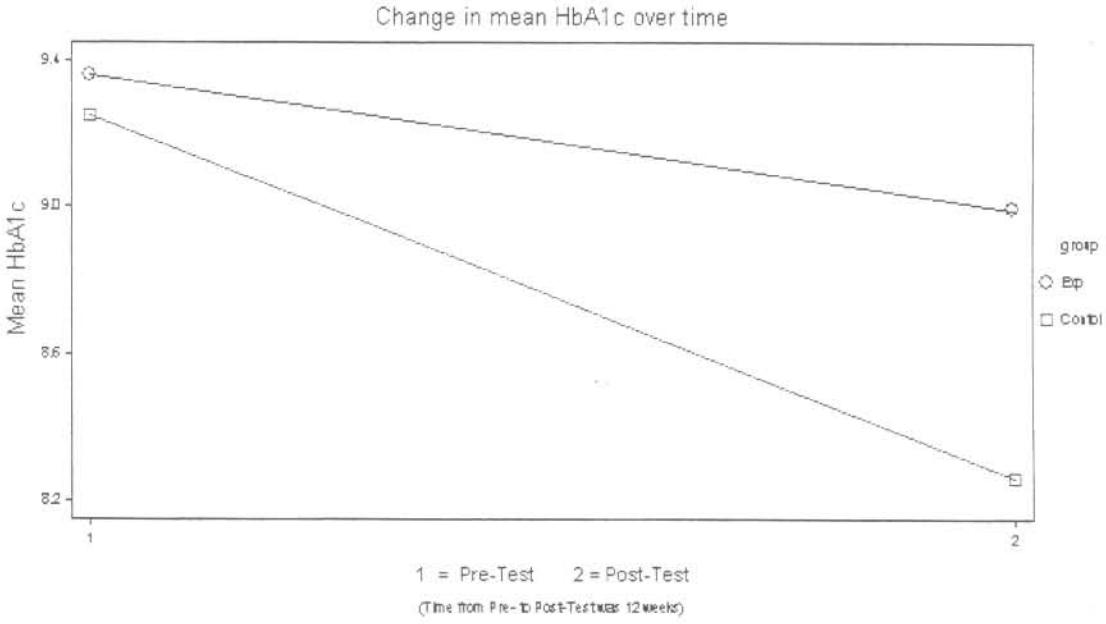

Figure 5.2. COMPARISON OF THE MEAN HbA_{1c} OVER 12 WEEKS BETWEEN THE TWO GROUPS

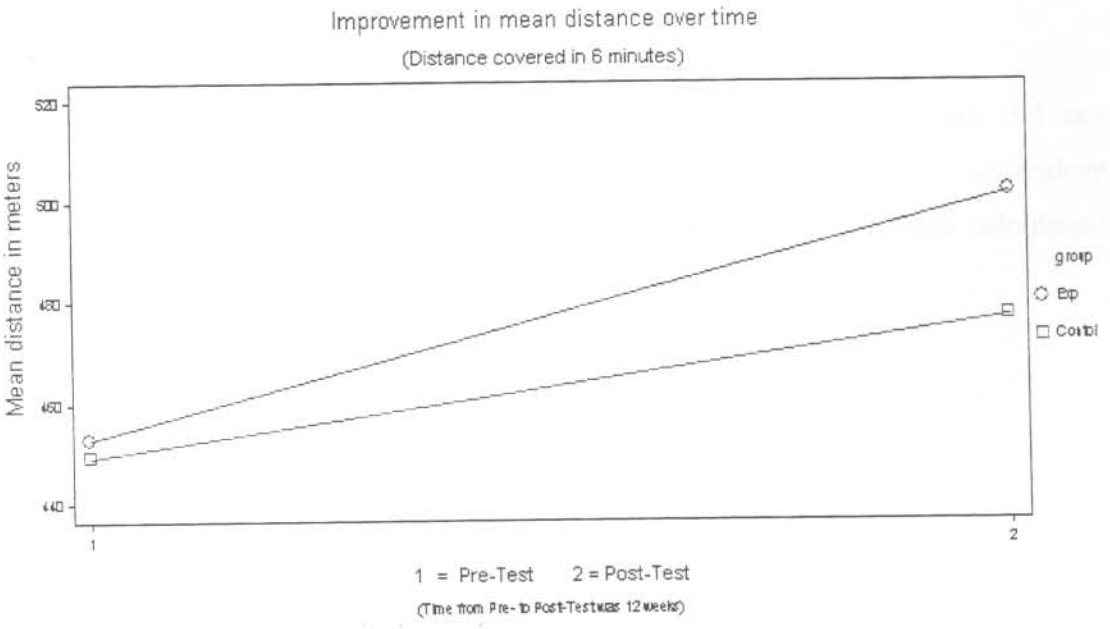

Figure 5.3 COMPARISON OF THE IMPROVEMENT IN MEAN WALKING DISTANCE OVER 12 WEEKS BETWEEN THE TWO GROUPS

PHYSICAL ACTIVITY AT HOME

In spite of repeated instructions subjects in the exercise group did not complete the physical activity records correctly. The metabolic equivalent intensity levels for these activities could therefore not be accurately calculated and were not included in the analysis of the data.

TABLE 5.8

HEALTH PERCEPTION

The quality of life questionnaire results are presented in Table 5.8.[4]

Variable	Timing	N		Mean(sd)		Comparison of groups with respect to change: baseline Baseline	
		Exer	Relax	Exer	Relax	95% CI	p-value
Perception of health	Pre-test	80	77	67.9(22.3)	69.16(22.87)		
	Post-test	75	74	85.19(12.33)	85.37(12.10)	(-8.44;7.03)	0.86
Satisf With Rx	Pre-test	80	77	30.61(2.38)	30.82(3.38)		
	Post-test	75	74	35.71(1.21)	35.96(0.26)	(-1.08;1.03)	0.96
Hyper-Hypo-Glycaemia	Pre-test	80	77	3.21(3.13)	3.57(3.48)		
	Post-test	75	74	0.31(1.05)	0.04(0.20)	(-1.82;0.44)	0.23
Depression	Pre-test	80	77	4.96(2.47)	4.53(2.23)		
	Post-test	75	74	4.57(2.11)	4.26(2.15)	(-1.01;0.95)	0.95
Anxiety	Pre-test	80	77	4.1(3.24)	3.60(2.66)		
	Post-test	75	74	0.59(1.18)	0.72(1.15)	(-0.30;1.80)	0.16
Positive Well-being	Pre-test	80	77	17.11(1.94)	17.18(1.46)		
	Post-test	75	74	17.96(0.35)	18(0)	(-0.61;0.47)	0.80
General Well-being	Pre-test	80	77	8.05(5.33)	9.05(4.04)	(-2.52;0.95)	0.37
	Post-test	75	74	12.8(2.68)	13.03(2.43)		

Both the exercise and relaxation groups' average scores placed them in the poor health perception category (≤ 70) before the intervention. The difference in the change from baseline health perception in the exercise group was not significantly different (p=0.86) from baseline in the relaxation group (95%CI-8.44;7.03).

[4] An analysis of co-variance (ANCOVA) was used to compare the exercise and relaxation groups using the baseline values as covariate.

However, the change from baseline within the experimental and the control groups, both with $p<0.01$, respectively, was significant. (Table 5.9) Cronbach's alpha coefficient (0.74) indicates a good internal consistency.

TREATMENT SATISFACTION

The difference in change from baseline treatment satisfaction in the exercise group was not significantly different ($p=0.96$) from the baseline in the relaxation group (95%CI –1.08; 1.03). The change within the two groups was once again significant ($p<0.01$). Item 4 did not contribute to the reliability of the construct as measured by Cronbach's alpha and was therefore excluded. Cronbach's alpha coefficient (0.60) indicates a satisfactory internal consistency for a 5-item scale.

The difference in change from baseline perceived frequency of hyper- and hypoglycaemia was not significant ($p=0.23$) (95%CI –1.82;0.44), but within the groups it was highly significant ($p<0.01$) as can be seen in Table 5.9.

DEPRESSION

The average scores for the depression scale were 4.96 in the exercise and 4.53 in the relaxation group. Neither the change from baseline depression in both groups ($p=0.95$), nor the change within the exercise ($p=0.49$) and the relaxation groups ($p=0.39$) were significant (95%CI –1.01;0.95). Cronbach's alpha coefficient (0.38) indicates a poor internal consistency for a 6-item scale.

ANXIETY

Seven subjects (6.7%) in the exercise group and one subject in the relaxation group reported an above average (9/18) on the anxiety scale before the intervention. After the intervention, 100% of subjects reported anxiety levels of less than 8 out of 18 on the scale.

Item six did not contribute to the reliability of the construct as measured by Cronbach's alpha (0.60) and was therefore excluded.

The change from baseline anxiety was not significant (p=0.16) when the two groups were compared (95%CI –0.30;1.80), but the change within the groups were significant (p< 0.01) in both instances as demonstrated in Table 5.9.

POSITIVE WELL-BEING

The difference in change from baseline positive well-being in the exercise group was not significantly different (p=0.80) from the baseline in the relaxation group (95%CI –0.61;0.47). However, the change from baseline within the experimental and the relaxation groups (Table 5.9), respectively, was significant (p<0.01). Cronbach's alpha coefficient (0.82) indicates an excellent internal consistency for the sub-scale.

GENERAL WELL-BEING

The change from baseline in the general well-being score of the exercise group was significant (p<0.01), as was the change within the relaxation group (p<0.01). When comparing the two groups, the difference was not significant (p=0.37) (95%CI-2.52;0.95).

TABLE 5.9 THE DIFFERENCE IN MEANS WITHIN THE EXERCISE AND RELAXATION GROUPS[5]

The difference in means within the exercise and relaxation groups with respect to the quality of life questionnaire results is demonstrated in Table 5.9.

Variable	Group	N	Mean(sd)	Comparison of means within the exercise and relaxation groups from baseline	
				95%CI	p-value
Perception of Health	Exercise	75	3.51(0.58)	(2.36;4.67)	<0.01
	Relaxation	73*	3.22(0.51)	(2.20;4.25)	<0.01
Satisfaction with treatment	Exercise	75	5.05(0.37)	(4.32;5.79)	<0.01
	Relaxation	73	5.01(0.39)	(4.23;5.8)	<0.01
Anxiety	Exercise	75	-3.65(0.41)	(-4.46;-2.84)	<0.01
	Relaxation	73	-2.89(0.35)	(-3.58;-2.2)	
Positive well-being	Exercise	75	0.84(0.22)	(0.41;1.27)	<0.01
	Relaxation	73	0.71(0.16)	(0.4;1.03)	<0.01
General well-being	Exercise	75	4.76(0.71)	(3.35;6.17)	<0.01
	Relaxation	73	3.88(0.52)	(2.84;4.91)	<0.01
Depression	Exercise	75	-0.27(0.39)	(-1.04;0.5)	0.49
	Relaxation	73	-0.27(0.32)	(-0.9;0.36)	0.39

* one case missing

[5] The paired t-test was used to calculate a p value for the comparison of means within the exercise and relaxation groups respectively.

GENERAL DATA

TABLE 5.10

SUMMARY OF GENERAL FEEDBACK ON BENEFITS OF EXERCISE

The results of the general feedback data are presented in Table 5.10

Benefit (frequency)	Frequency of response	
	Exp (n=75)	Control (n=74)
More energy(33)	19	14
Feel relaxed(20)	10	10
Improved flexibility(14)	5	9
Healthy and strong (47)	21	26
Improved sexual life(4)	1	3
Less pain(10)	7	3
Lost weight(32)	14	18
Cope better with life(5)	5	0

All the subjects in the exercise and relaxation groups enjoyed the intervention and wished to continue with it. The composition of the total intervention consisting of exercise or relaxation group support and education was enjoyed by most of the subjects in both groups (84%: 86.5%). They felt more energetic and healthy after the intervention as can be seen in Table 5.10.

The main benefits for the exercise group was that they felt more energetic, relaxed, stronger, had less pain and could cope better with life.
The relaxation group also felt more relaxed, healthier and stronger and more flexible. Participants in both groups were glad that they had lost weight. Responsibilities at home would be the main barrier to attending sessions in both groups. However, both groups agreed that the venue was suitable and that they were interested in becoming group leaders for small groups in their immediate environment. For the exercise group, Mondays was a good day for exercise, while the relaxation group preferred Fridays.

TABLE 5.11

FREQUENCY DISTRIBUTION OF GENERAL FEEDBACK ON THE INTERVENTION

Variables		Frequency	
		Exercise (n= 75)	Relaxation (n=74)
Enjoyment	Yes	75	74
	No	0	0
Aspect enjoyed most	Exercise / Relaxation	11	9
	Education	0	1
	Groups	1	0
	Everything	63	64
	Not applicable	0	0
Continuation	Yes	75	73
	No	0	1
Barriers to attending	Responsibilities home	54	49
	Transport fees	6	11
	Nothing	13	12
	Other	2	2
Day of week	Monday	43	10
	Tuesday	5	2
	Wednesday	2	5
	Thursday	1	2
	Friday	24	55
Venue	Yes	74	73
	No	1	1
Group leader	Yes	74	73
	No	1	1
Benefited	Yes	75	74
	No	0	0

ADHERENCE TO THE INTERVENTIONS

One hundred percent adherence of the exercise or relaxation sessions at the Mamelodi Hospital was set at six sessions (fortnightly for 12 weeks). Adherence to the exercise group among the 80 subjects averaged 91%. For the 77 subjects in the relaxation group it was 94%. Of the five subjects in the exercise group who did not receive the standard intervention as allocated, two missed more than half of the sessions, while three subjects missed one to three sessions.

Psychosocial problems, death of family members and colds were the main reasons for not attending the sessions.

DISCUSSION

The primary outcome of the study demonstrated that an exercise intervention to decrease $HbA1_c$ over a period of 12 weeks, in Type 2 DM female subjects, aged 40 to 65 years, was no more efficacious than a supervised self-relaxation training intervention in the relaxation group. The hypothesis is thus rejected.

The present results are in agreement with results reported by Keyserling and associates. [152] They reported minimal changes in HbA_{1c} ($p>0.05$) in all the groups) and weight gain after six and 12 months follow-up in their intervention to improve self-care behaviours of African American women with Type 2 DM. The authors were of the opinion that their programme had little effect on glycaemic control, because it did not address diabetes medication adherence, which could also be true for the present study. The improvement in the HbA1c level of 0.39% in this exercise group is also in line with the results by Dunstan and co-workers [147] who reported a reduction of 0.34% in their moderate exercise group. The decrease in HbA_{1c} levels of 0.39% in this study must be viewed against the decrease of 1% to 2% with medication, which is seen as clinically significant.

Therefore, the exercise interventions together with the use of medication may contribute to the achievement of a HbA_{1c} level of lower than 7.5% and thus reduced morbidity. [25]

In contrast, Goldhaber-Fiebert and co-workers [153] reported a more substantial reduction of 1.8 ± 2.3% in HbA_{1c} in their 12-week lifestyle intervention. This intervention included 11 weekly nutrition classes and supervised walking groups three times per week. The high contact time and direct supervision of exercise may have contributed to the success of the study.

These trials, as well as the present study are indicative of the complexity of behaviour change in the diabetic patient.

The difficulty of measuring change in physical activity in free-living populations remains unresolved. Included in this is the type of physical activity that is most likely to be beneficial to long-term risk management and the amount of activity that is required to have a health benefit.

A criticism of the exercise intervention may be that it was not intensive enough. The general recommendation that subjects should accumulate 30 minutes of moderate intensity aerobic exercise on most days of the week was followed in the present study. [27,271] Although 91% of participants in the exercise group attended the hospital sessions, it was clear from the results that compliance with exercise at home was unsatisfactory.

The physical activity diaries and exercise notebooks with instructions were used to encourage subjects to be more active at home. The physical activity records were handed in and checked fortnightly and the home program was discussed with the individual patients when they reported for the exercise sessions at the hospital.
It was clear that the subjects did not complete the physical activity forms correctly.

Poor responses may have been due to the fact that subjects engaged in activities other than those listed on the log. At least three subjects admitted that they depended on grandchildren to complete the log, and poor individual recall ability may have played a role in recording the data.[269]

Keyserling et al [152] reported physical activity levels of 44.1 kcal/day and 33.1 kcal/day assessed by means of the Caltrac accelerometer compared to the present study's 19.3 kcal/day. The Caltrac accelerometer may have been a more objective tool to assess physical activity at home.

The fact that home exercises were not supervised influenced the adherence to the home exercises. Studies that reported significant improvements in HbA_{1c} involved intensive individual counselling, group sessions [146,152] and also supervised exercise sessions. [126,146,152] The contact time with patients was too limited to facilitate behaviour change in the individual patients. Each patient has her own health perceptions, personality, motivation, values and preferences, which will influence the outcome and adherence to any planned intervention. McNabb et al [108] recommended that at least one and a half hours (1.5) hours individual contact time per week was necessary to facilitate behaviour change.

The lack of access to exercise facilities was a problem in this study. The suburb of Mamelodi is unsafe for women walking unescorted. In future sampling should be stratified to the adjacent neighbourhoods in Mamelodi. Exercise interventions should be offered at suitable venues within the neighbourhoods, such as churches or other centres to improve accessibility for the participants. Sessions in venues familiar to the participants may enhance exercise adherence, because they are accustomed to going there on a regular basis. [108] Since exercise represents positive health advice, it is advisable that participants go to a community setting for exercise, rather than a hospital where they go for medical attention. [16]

The sample also came from a culture where regular exercise, other than tasks of daily living, is not the norm. Tshabalala and Gill [22] report that in the African tradition, older people are usually excluded from exercise and hard physical work due to their seniority. They furthermore suggest that this traditional practice must be kept in mind when prescribing exercise. It is therefore difficult for the patient to change a long-established, culturally acceptable and habitual lifestyle.

Behaviour change is a long and complex process. When considering the Readiness for Change Model, [180] it is possible that the participants were in the action stage. They started to exercise at the hospital, but the influences of the environment, lack of social and cultural support in the community and family impacted negatively on their home exercise programme. The physical and emotional energy required to maintain the change in behaviour may have been too much for the patients to cope with. [180] Since the women were not routinely engaging in exercise, the exercise intervention could have added "mental stress" to the exercise group. This perceived stress could have adversely affected any possible physiological effects brought on by exercise. [272]

The fact that the score for perception of health of this experimental group placed them in the poor health perception category (≤ 70) and that they had between five and 10 years of schooling may have acted as a motivational barrier to doing exercise. Hays and Clark [238] found that individuals who were older, had equal or less than 12 years of education and who perceived their health as fair or poor, were less likely to be physically active.

Being tired seems to be viewed as a symptom of having diabetes by diabetics, rather than a sign of poorly controlled diabetes. This factor could also have influenced the frequency and intensity with which this exercise group performed their home exercises. [203,258]

The three-month study period was long enough to observe changes in the primary and secondary outcomes, but too short to have sustainable results.

Middle-aged sedentary and older participants may need a longer adaptation period to enjoy the optimal benefits from the program. [180]

Beliefs and attitudes of black patients with Type 2 DM also play a role in their adherence to exercise. The degree of westernisation, the level of education, socio-economic circumstances and status of the individual participants may have influenced their decisions to do exercise. [202]

The conflict between traditional health beliefs, where the patient is usually a passive participant and the western health care, where the patient is expected to be an active participant in the management of her disease may have influenced acceptance of self-responsibility to exercise in this exercise group. [22,27,202]

Bopape also illustrated this. [195] She reported dependence on the health care professional and medication by 80% of the South African diabetics in her study. It has been shown that beliefs held by an individual may influence her decision to comply with preventative action. The patient also needs the support and resources to act on information about behaviour change. [172] According to Tshabalala and Gill: [22] "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". It is also inappropriate for black women to walk fast.

The decrease in the control group's HbA_{1c} of 0.97% was an unexpected finding. The fact that the control group's drop in HbA_{1c} was more than that of the experimental group may be incidental; however the baseline characteristics of the experimental and the control groups do not suggest selection bias. An improvement in HbA_{1c} in both groups may be ascribed to the Hawthorne effect. [273] The subjects' participation in the trial and interest shown by the health care workers may have contributed to the improvement in both groups rather than the exercise per se.

The benefits of both the relaxation program and emotional support could also have influenced the outcome in the relaxation group.

The change in the HbA_{1c} of 0.97% is however, a clinically important finding, because according to data from the United Kingdom Prospective Diabetes study [59], a reduction of 0.6% in HbA_{1c} can reduce the risk of micro-vascular complications by 25%.

This finding is in agreement with the finding by Surwit and co-workers, [211] who reported an improvement of 0.5% in the HbA_{1c} after 12 months, in their study on the efficacy and feasibility of cost-effective outpatient group-stress management training.

In the case of the control group, participants were not expected to do anything other than to attend a group session once fortnightly. They could therefore enjoy the relaxation without any intermediate impact of perceived stress due to exercise that they are not used to. Furthermore, the group sessions provided social support, which was one of the expected outcomes expressed during the second phase of the study.

It is furthermore well known that exercising muscles use glucose, which leads to independent insulin secretion. The insulin sensitivity of the muscle is also improved and this effect can persist for several hours. [38,69] The progressive muscle contraction during relaxation classes could have contributed to the improved use of glucose by the major muscle groups, as they take up approximately 40% of the body mass. [38] Therefore, the combination of stress relief and muscle contraction may have contributed to the improvement in HbA_{1c} levels in the relaxation group.

The participants in the relaxation group also received general health advice at the baseline visit and at the fortnightly sessions at the hospital. Although they were not instructed to exercise at home, it is possible that they increased their physical activities on the basis of their new knowledge about the benefits of exercise. [114]

It is also possible that the participants practiced the relaxation exercises at home in between the fortnightly sessions at the hospital, and this might have led to improved insulin-sensitivity of the large muscle groups used during relaxation.

Other documented physical benefits of relaxation include reducing anxiety, heart rate, respiratory rate, and muscle tension, improving self-esteem, decreasing fear and an enhanced sense of self-importance. [214] The physical benefits of relaxation may have contributed to less stress and anxiety in the relaxation group and improved self-esteem of the participants. [214] Bopape [195] reported that diabetic patients were stressed by the physical complications that are caused by disease. They felt that it limited their physical ability and made them feel disabled. An observation made by the research assistant during this study was that many patients asked for a certificate in order to apply for a disability grant. Jacobson et al [196] reported that self-management was better in diabetics who have a good self-esteem. In a previous study on the barriers to and expectations of performing physical activity in a similar sample of females with Type 2 DM, relaxation was identified by 51% of the respondents as an outcome expectation. [258] It is clear that this outcome expectation has been met and this could have contributed to the better results in the relaxation group.

Average scores placed both the exercise and relaxation groups in the poor health perception category before the intervention. Westaway et al [260] reported an average health perception score of 60.4 (34.6) in a sample of 160 black diabetic patients. The baseline average score in this study was higher than the one reported by Westaway. [260] The reason for this is unknown. The health perception scores improved significantly within both groups, indicating that the intervention contributed to an improved perception of health in both groups.

The subjects in both groups of this study reported low levels of depression and anxiety. The Cronbach's alpha coefficient of 0.38 for the depression scale indicates a poor consistency for a six-item scale. It is therefore possible that the subjects did not understand the questions.
Both groups scored high on the positive well-being scale, which agrees with the score of 20.7 reported by Westaway et al [260] While the difference in positive and general well-being between the exercise and relaxation groups was not significant, the general well being improved significantly within both groups, demonstrating that both groups benefited from the interventions.

This is an important finding, since it has been documented that improvement in quality-of-life outcomes could have indirect, longer term benefits not evaluated in the assessment of biomedical endpoints immediately after intervention. [196]

No relationship between the health-related quality of life outcomes and diabetes control (HbA_{1c}) could be shown. This finding supports previous research reports of low correlation between diabetes control and subjective well being. [274]

The significant increase in walking distance of the exercise group in this study is in agreement with the Position statement of the American College of Sports Medicine [27] that low-fit, sedentary and clinical populations can improve fitness with lower-intensity, longer-duration exercise sessions. The exercise group has therefore improved their initial sedentary status. However, the improvement did not translate into the expected improvement in glycaemic control.

Another critism of the exercise intervention could be that exercise stress testing should have been performed to provide data about the sub maximal heart rate and blood pressure responses during strenuous exercise. In this way a more optimal exercise prescription might have been compiled. [20,25,34] Such an exercise test is however not practical for this sample.

Patients should be trained in the use of the Borg scale of perceived exertion [264] because a recent research report by Beling et al [275] has shown that subjects may underestimate their heart rate by means of palpation by as much as 15% while exercising. In any case, most of the participants did not have wrist watches to be able to determine their heart rates. Using the Borg scale of perceived exertion the exerciser is allowed to subjectively rate his or her feelings during exercise, taking into account personal fitness level, environmental conditions and general fatigue levels. It is easily understood and a cardio respiratory training effect can be obtained by exercising at a rating of "somewhat hard" which is more or less a rating of 12-16 on the category scale. [27]

The fact that the difference in change in the mean BMI between the groups was not significantly different ($p = 0.28$), stresses the importance of a lifestyle intervention including weight loss monitoring, as well as supervised exercise groups. Weight loss is one of the cornerstones of diabetic management, but it difficult for diabetics to loose weight. [62] A combination of a low-calorie diet and physical activity results in a greater weight loss than either diet or physical activity in isolation. [64]

The low educational level of the participants, illiteracy and language proficiency may have had an influence on the understanding of the educational material about good dietary practices. While the educational material was available in isiZulu and isiSotho, it may be possible that some patients did not understand it. Furthermore, some of the illiterate patients had to depend on family members to read the handouts for them, which might have led to misunderstandings. Measuring body mass during the fortnightly exercise sessions to monitor weight loss could have contributed to better weight loss results.

Due to poor socio-economic circumstances in the community, participants reported that they often did not have money to buy the correct foods. Participants using the money paid for transport purposes during the study to buy fresh products illustrated this.

Furthermore, food eaten and offered is a reflection of social status and prestige in many areas. [276] Participants reported that it was rude to refuse food offered by the hosts when attending community gatherings such as weddings and funerals. Since regular attendance of these community gatherings are very important, it can have a negative impact on weight control by these patients.

The attendance of exercise sessions (Group1) was high at 91%. It is possible that the participants attended the sessions at the hospital for the transport money, which they used to buy food. It was observed that many of the participants reported poor socio-economic and domestic circumstances. However, the qualitative data showed that the outcome expectations of the participants had been met and that they had enjoyed the programme.

In conclusion it can be stated that participants in both groups benefited from the intervention. It also demonstrated the need for education and support in the diabetic community.

As the Department of Health of South Africa [8] supports management of diabetes at primary care level, patients should be taught to exercise safely in a community setting. Conducting action research in the community, involving community leaders, community health workers and persons with diabetes to establish exercise facilities away from the hospital that are more accessible to all, may facilitate the promotion of educating diabetics in self-management.

Cognitive behavioural strategies, such as contracting and rewards for exercise programme attendance to increase physical activity and exercise adherence should be investigated and implemented to meet the unique needs of the women in this community. [277] An example of such a reward may be free medication or food parcels to patients who maintained good glucose control.