EFFECT OF EXERCISE VERSUS RELAXATION ON HEALTH-RELATED QUALITY OF LIFE IN BLACK FEMALES WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT: ***Background:*** *Physical activity may improve health-related quality of life of Black female subjects with Type 2 DM in South Africa.*
Aim: *To establish the efficacy of an exercise intervention programme compared to relaxation exercises to improve health-related quality of life over a period of 12 weeks, in Type 2 DM female subjects.*
Methods: *A single blind, double intervention randomized clinical trial design was used.*
Results: *The adjusted baseline perception of health change in the exercise group after 12 weeks was 17.56(95%CI 11.78 to 23.34) and in the relaxation group 16.86 (CI 11.62 to 22.10) (p=0.86). The results for general well-being were 4.76(95%CI 3.35 to 6.17) in the exercise group versus 3.97 (95%CI 2.94 to 5.01) in the relaxation group (p=0.37).*
Conclusions: *Health-related quality of life improved significantly within both the exercise and the relaxation groups, but no significant difference between groups could be demonstrated.*

KEY WORDS: SOUTH AFRICAN BLACK FEMALES, TYPE 2 DIABETES MELLITUS, EXERCISE, RELAXATION, HEALTH-RELATED QUALITY OF LIFE.

ABBREVIATIONS: HbA1c, Hemoglobin A_{1c}; Type 2 DM, Type 2 diabetes.

INTRODUCTION

Over 140 million people worldwide suffer from diabetes mellitus, with a projected increase to 300 million by the year 2025 (Preston 1998). With urbanisation, the prevalence of Type 2 Diabetes Mellitus (Type 2 DM), which currently accounts for 80% to 90% of the diabetic population, appears to be increasing rapidly. This is of great concern internationally and particularly in South Africa, because it has been estimated that there are at least one million known diabetics and possibly up to an equal number who are currently undiagnosed in South Africa (Bonnici et al 1997). Newly released figures by the Medical Research Council of South Africa indicate that diabetes is the tenth most common cause for total life years lost in females in South Africa (South African Medical Research Council 2003). Due to the high morbidity and mortality of the disease, Type 2 DM has been targeted as one of the chronic diseases in South Africa, which is in need of special attention, especially at primary health care level (Huddle 1997).

Type 2 DM is a chronic and challenging disease, which affects the emotions, way of life and thus health-related quality of life (HQOL) of the individual with diabetes. HQOL reflects the subject's subjective evaluation of general well-being, rather than the health care professional's view. There seems to be a relatively weak association between subjects' objective health status and their subjective life quality as illustrated by low correlations between subjective well-being and HbA_{1c} (Snoek 2000). Lower HQOL was however, reported in women with a longer duration of diabetes, obesity and the presence of diabetes-related complications (Redekop et al 2002; Bopape 2000). Furthermore, diabetic subjects have been shown to be more susceptible to depression, poorer functioning and general health than the general population (Gavard et al 1993). Westaway and co-workers (2002) reported that black diabetic subjects in poor general health were significantly less satisfied with the interpersonal, logistical and technical quality of their care than subjects in good health. Sameul-Hodge and co-workers (2000) showed that lower perceived HQOL might affect day-to-day self-management by women with Type 2 DM, which may influence glycaemic control and diabetes complications. Diabetes subjects often report feelings of stress and not coping with their disease (Bopape 2000). 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 (Van Rooijen et al 2002). It is recognized that stress may disrupt glycaemic control directly

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through the effects of stress hormones and via deterioration of self-care behaviors (Snoek and Skinner 2002). Lane and co-workers (1993) suggested that relaxation therapy might be a non-pharmacological means to moderate the negative effects of stress-induced changes in counter-regulatory hormones on the metabolic control in some subjects with Type 2 DM. In two studies by Westaway and co-workers (2001; 2002) it was shown that black Type 2 DM subjects reported significantly better functioning and well-being with acceptable blood glucose control than subjects with poor control.

The psychosocial factors, such as HQOL, self-care behavior and physical health outcomes should therefore be addressed in any planned intervention to improve diabetes self-management. Evidence from several recent randomized controlled trials indicates that an increase in physical activity has beneficial effects on metabolic control, on body weight and HQOL (Goldhaber-Fiebert et al 2003; Loreto et al 2003; Keyserling et al 2002). More general benefits of physical activity are increased muscle strength and flexibility, improved joint mobility and a sense of well-being (Horton 2000). Physical activity also represents positive health advice to subjects, reduces the need for medication and reduces risk factors for diabetic complications such as hypertension and obesity, which may contribute to poor HQOL (Albright et al 2000).

The aim of this study was to establish the efficacy of an exercise intervention compared to a relaxation intervention program to improve health-related quality of life over a period of 12 weeks, in Type 2 DM black female subjects, aged 40-65 years. The clinical results of the study have been published elsewhere (Van Rooijen et al 2004) and are not the focus of this report.

Ethical considerations

The Protocol and Ethics Committee of the University of Pretoria approved the study. Each participant gave verbal consent prior to the testing and written informed consent prior to randomisation. Each participant received a signed copy of the consent form.

The interventions groups only differed with regard to the exercise and the relaxation. Since a clinical trial is an experiment on human beings, the ethical aspects of the study are indisputable. The findings of the previous studies 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 program (Van Rooijen AJ, Rheeder P, Eales CJ, Molatoli HM 2002). It was also clear during the recruitment of subjects at the Diabetic Out subject 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 and clearly expected an exercise intervention of some kind. It was therefore decided to do self-relaxation training with the non-exercise group to control for the non-specific social and psychological aspects for exercise. For ethical reasons, care was taken to keep the interventions beneficial to both groups and interesting to the subjects, to assure the subjects' adherence to the program.

Subjects

The study was conducted at the Mamelodi Community Hospital, East of Pretoria, in the Gauteng Province of South Africa. 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 they were more likely to keep research-related appointment visits than the men.

The study participants were black women between the ages of 40 and 65, with Type 2 DM and known duration of the disease for at least one (1) year.

All consecutive eligible subjects attending the clinic over a period of six months were approached and invited to take part in the study.

For exclusion purposes subjects were screened for chest pain on effort, possible previous myocardial infarction and intermittent claudication, cerebro-vascular incidents, arthritis, general health and retinopathy by means of the London School of Hygiene Cardiovascular Questionnaire (Rose et al 1982). Cases where there was uncertainty regarding the aforementioned conditions were referred to the attending specialist physician (PR), for clinical evaluation.

Subjects were informed about the study in their preferred home language. After written consent was obtained they were randomised by means of a computer-generated list into the exercise or the relaxation group in 17 blocks of 10 each by the principle researcher. Allocation concealment was ensured by means of sequentially numbered, sealed, opaque envelopes. Allocation was done telephonically from a central site and was concealed until interventions were assigned. To ensure that the research assistant was blinded to the randomisation of the participants, the only form of identification on the questionnaires, were the subject names, hospital file numbers and the study numbers of the subjects.

The measurement of the HQOL was a secondary outcome of a study to establish the efficacy of an exercise intervention compared to a relaxation intervention to decrease HbA1c over a period of 12 weeks in this sample of subjects. For the purpose of the primary outcome a total sample of 144 participants with 72 in each group, with α=0.05 and β=0.20 (80% power), was required to detect a difference of 1% in HbA_{1c} levels, given a SD of 2.23% between groups at the end of 12 weeks. In anticipation of a dropout rate of 10% the recruitment goal was determined to be 80 participants in each group. The same number of subjects was used for the measurement of the HQOL.

Instruments and Method

In an effort to avoid subjects (not blinded), from either group adopting the programme of the other, groups were referred to as either the Monday or the Friday group, and they were also seen separately on these days. The research assistant, who was blinded to the group allocation of the subjects, did the baseline and 12 week post-trial measurements.

Data on general health, well-being and treatment satisfaction were captured by means of a structured questionnaire. The questionnaire was available in English, Afrikaans, isiPedi/isiSotho/isiTswana and isiZulu. It had been standardised and validated for all these languages by testing it on 173 subjects (85 black and 88 white subjects) attend-

ing the Kalafong and Pretoria Academic Hospitals during October/ November 2001(Westaway et al 2002). The questionnaire was compiled based on previous research with the health, well-being and treatment satisfaction measures (Westaway 2002) and 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 perceptions of general health (Stewart 1996). 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 point for poor general health is a score of 70 or less. Reliability coefficient for the scale is 0.98 (Westaway 2002).

The Diabetes Treatment Satisfaction Questionnaire (DTSQ)

This questionnaire has been specifically designed to measure satisfaction with diabetes treatment regimens in people with diabetes (Bradley and Lewis 1990). 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 (2002).

Well-being

The Well-being scales, designed by Bradley and her associates (1990) 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 are 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 recorded by Westaway (2002) ranged between 0.66 and 0.70 for the Depression scale, between 0.76 and 0.88 for the Anxiety sub-scale and between 0.88 and 0.89 for the Positive Well-being sub-scale respectively.

The exercise group

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 program; the use of daily physical activity records and six fortnightly supervised aerobic exercise classes.

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. The fact that the participants were women, who needed to exercise in a safe environment, also contributed to this decision. Participants were encouraged to form small groups of women, living near each other to join in the exercises. Subjects were instructed to increase walking at home from 10 to 45 minute sessions 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. Instructions were to walk briskly whilst swinging the arms (Pollock et al 1998). Subjects were encouraged to work up a slight sweat and a faster respiratory rate, thus working at a moderate RPE of 12 to 14 or "somewhat hard" according to the Borg scale of perceived exertion (Lamonte and Ainsworth 2001). This moderate-intensity protocol was used since the subjects did not undergo exercise stress testing. The traditional method of monitoring heart rate by pulse palpation could not be followed due to the fact that most of the subjects do not wear watches. Each subject also received a notebook with instructions and illustrations of the gentle flexibility exercises aimed to stretch the major muscle groups and maintain range of motion. Subjects were urged to do their home exercises daily, but no less than five times per week.

Physical activity log

The aim of the physical activity log was to provide a detailed account of habitual daily activities and their associated duration (Ainsworth et al 2000). A physical activity log with illustrations of some of the most used physical activities at home was compiled. Subjects in the exercise group were instructed to keep a daily record of the time they spend on each of the activities in the diary. The metabolic equivalent intensity levels (MET) for these activities are known and could be calculated. Subjects had to bring the completed logs with them when attending the fortnightly exercise sessions at the hospital. The physical activity logs were checked; problems discussed and new logs were handed out for the next fortnight. Adherence to the home programme was discussed with individual subjects when subjects attended the fortnightly exercise sessions at the hospital.

Hospital based aerobics class

The fortnightly exercise sessions of 45 minutes each at the Mamelodi hospital were used to educate subjects about exercise, to demonstrate the home exercises and to address problems experienced with home programmes.

Exercises consisted of low-impact aero-

bic large range movements performed to rhythmic music in the gymnasium, which had suitable lighting and ceiling fans. The intensity of the training was set at moderate level, obtaining 55% to 69% of maximal heart rate and a relative perceived exertion (RPE) of 12 to 14 (American Diabetes Association Position statement 2003).

The relaxation group

The relaxation group was also required to visit the hospital fortnightly, as did the exercise group. It was felt that by only providing education at these sessions there would not be sufficient motivation for the subjects to attend regularly and it was decided that relaxation exercises would be given to the second group.

The subjects in the relaxation group did not receive any home exercises and were not advised to exercise at home. Subjects were instructed to progressively tense, and then relax alternating muscle groups (Sotile 1996). The duration of the relaxation exercises was 20 minutes per session.

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. The subjects received education on the management of Type 2 diabetes 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 samples were used to show subjects different food products and also to teach them to interpret information on the labels of 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.

A registered dietician gave lectures on food portion size and use of fat, fibre and salt in the diet. A checklist was kept to ensure that all subjects received all aspects of the education.

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. No subject came on the wrong day.

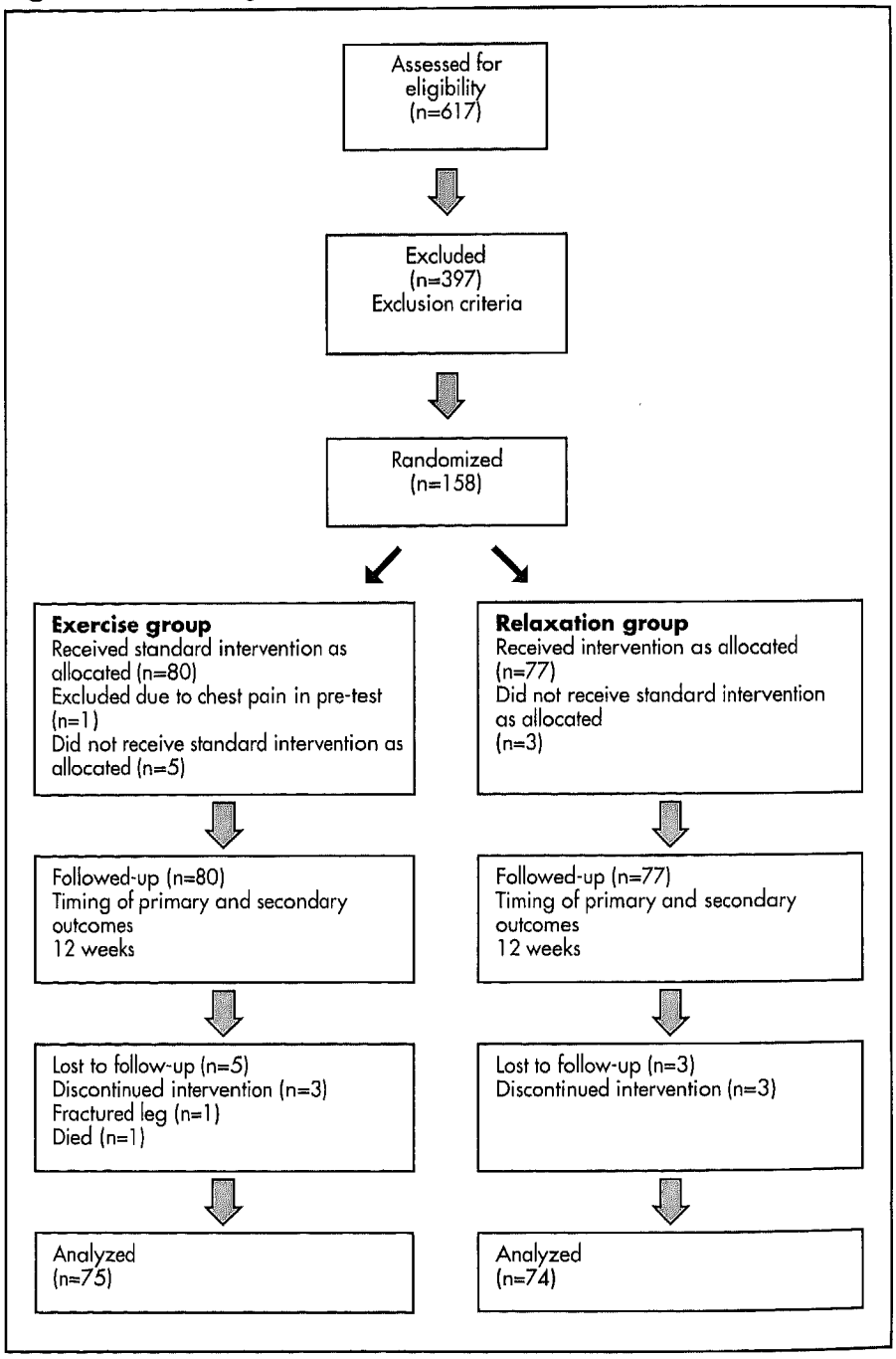
STATISTICAL ANALYSIS

Data were analyzed with Statistix ® and Stata ® software. Data are presented as means, ± SD, frequencies and percentages. The paired t-test was used to calculate a p value for the comparison of means within the experimental- and relaxation groups respectively. An analysis of co-variance (ANCOVA) was used to compare the experimental and relaxation groups with respect to changes in perception of health, satisfaction with treatment, anxiety, depression, positive and general well-being using the baseline values as covariate (Altman 1992). A p-value < 0.05 was regarded as statistically significant.

RESULTS

The progress through the various stages of the study, including the flow of participants, withdrawals and the timing of primary and secondary outcomes are demonstrated in Figure 1. One hundred and fifty eight subjects were randomized. Eight subjects were lost to follow-up.

Figure1: Flow diagram of progress through the phases of 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. Psychosocial problems, death in the family and illness were reasons for not attending sessions at the hospital. No intention to treat analysis was done. Subjects were followed up by means of telephone calls, letters and at the diabetes outpatient clinic. No adverse events or side effects were reported in the exercise group or the relaxation group.

Demographic data

The mean ages of the exercise and relaxation groups were respectively 54(7.9) and 55(7.3) years. The frequency distribution of the other demographic variables is demonstrated in Table 1.

Health-related quality of life data (Table 2)

Health perception

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). However, the change from baseline within the experimental and the control groups, both with p<0.01, respectively, was significant. (Table 3). 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). This may be a direct result of the education both groups received.

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 score (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 3.

Table 1: Frequency distribution of demographic variables.

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 medical conditions	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	Insulin	23(28.8)	20(26)
	OHAs[1]	51(63.8)	50(64.9)
	OHAs + insulin	5(6.3)	7(9.1)
	Diet alone	1(1.3)	0

[1] Oral hypoglycaemic agents

Table 2: The quality of life questionnaire results [2]

Variable	Timing	N		Mean(sd)		Comparison of groups with respect to change: baseline	
		Exer	Relax	Exer	Relax	95% CI	p-value
Perception of health	Pre-test	80	77	67.9(22.3)	69.16(22.87)	(-8.44;7.03)	0.86
	Post-test	75	74	85.19(12.33)	85.37(12.10)		
Satisf With Rx	Pre-test	80	77	30.61(2.38)	30.82(3.38)	(-1.08;1.03)	0.96
	Post-test	75	74	35.71(1.21)	35.96(0.26)		
Hyper-Hypo-Glycaemia (2 items)	Pre-test	80	77	3.21(3.13)	3.57(3.48)	(-1.82;0.44)	0.23
	Post-test	75	74	0.31(1.05)	0.04(0.20)		
Depression	Pre-test	80	77	4.96(2.47)	4.53(2.23)	(-1.01;0.95)	0.95
	Post-test	75	74	4.57(2.11)	4.26(2.15)		
Anxiety	Pre-test	80	77	4.1(3.24)	3.60(2.66)	(-0.30;1.80)	0.16
	Post-test	75	74	0.59(1.18)	0.72(1.15)		
Positive Well-being	Pre-test	80	77	17.11(1.94)	17.18(1.46)	(-0.61;0.47)	0.80
	Post-test	75	74	17.96(0.35)	18(0)		
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)		

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

Table 3: The difference in means within the exercise and relaxation groups [3]

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)	P=0.49
	Relaxation	73	-0.27(0.32)	(-0.9;0.36)	P=0.39

* one case missing

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

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 3), 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).

DISCUSSION

The outcome of the study demonstrated that an exercise intervention to improve health-related quality of life over a period of 12 weeks, in Type 2 diabetes female subjects, aged 40-65 years, was no more efficacious than a supervised self-relaxation training intervention. We have seen that an intervention of any kind is welcomed and enjoyed by the women with Type 2 DM, and that it contributed towards an enhanced quality of life for individual subjects as demonstrated by the improvements in health perception, positive and general well-being scores within groups in this study.

Average scores placed both the exercise and relaxation groups in the poor health perception category before the intervention. The baseline average score in this study was higher than the one reported by Westaway et al (2002). Westaway et al (2002) reported an average health perception score of 60.4 (34.6) in a sample of 160 black diabetic subjects. The reason for this is unknown. Of importance is that the health perception scores improved significantly within both groups, indicating that both the interventions contributed to an improved perception of health in both groups.

Treatment satisfaction improved in both groups, but was not significantly different between the two groups. The improvement within groups could be a result of the interpersonal nature of both interventions and the subjects' perception that they received more attention (Westaway 2002). The group sessions provided social support, which was one of the expected outcomes expressed in a preliminary study (Van Rooijen et al 2002).

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. One possible explanation may have been the average low education of the sample, since several of the subjects were illiterate and could not read the questions. The fact that the research assistant administered the questionnaire in all of the languages may also have been a limiting factor, due to her possible lack of ability to guide the subjects in languages other than her own preferred language.

Both groups scored high on the positive well-being scale, which agrees with the score of 20.7 reported by Westaway et al (2002). 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 (Jacobson et al 1994). The improved HbA1c in both groups after 12 weeks, (Van Rooijen et al 2004) could have contributed to the improved perception of health, treatment satisfaction and general well-being in both groups and supports the finding by Westaway and co-workers (2002). The reciprocal relationship among psychosocial factors, self-care behaviour and physical health outcomes is once again highlighted (Westaway 2002).

The improvement in HQOL-measures in the exercise group was expected and supports the findings of several recent randomised controlled trials (Goldhaber-Fiebert et al 2003; Loreto et al 2003; Keyserling et al 2002). The benefits of physical activity have been well documented (Albright 2000; American College of Sports Medicine 2000). The fact that the subjects improved their initial sedentary status and the significant increase in walking distance of the exercise group (Van Rooijen et al 2004) could have contributed to the improvement in HQOL in this group.

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 (Sotile 1996). The physical benefits of relaxation may have contributed to less stress and anxiety in the relaxation group and improved self-esteem of the participants. Jacobson et al (1994) reported that self-management was better in diabetics who have a good self-esteem. It is also possible that the relaxation group may have become more active due to the education on exercise that they received.

Of interest is an observation made by the research assistant during this study: that subjects in both groups asked for certificates in order to apply for a disability grant. This supports a finding by Bopape (2000), who reported that black diabetic subjects were stressed by the physical complications that are caused by disease. They felt that it limited their physical ability and made them feel disabled.

It was clear from the outcomes of this study, that doing exercise or relaxation compared to potentially nothing along with education did improve perception of health and general well-being for these women. Of further importance is the fact that the results were obtained by non-pharmacological means. The principal goal of clinical care is to improve patient outcomes. Improved patient outcomes would mean improved control of the disease and therefore less diabetes-related complications, improved functioning and perception of health and eventually overall quality of life (Wilson and Clearly 1995).

A limitation of the study was the lack of a control group. The control group should receive the usual care and be wait-listed for an intervention similar to the exercise or relaxation group after the study is completed. The exercise or

relaxation interventions should be repeated for at least one year with supervised exercise or relaxation sessions at community-based venues to establish the long-term outcomes on health-related quality of life.

In the words of one of the participants: "*I want to feel relaxed and peaceful.....now after we have exercised we will be laughing and we will feel very good afterwards.*"

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