Q J Med 2004; **97**:343–351
doi:10.1093/qjmed/hch061

#6290

Effect of exercise versus relaxation on haemoglobin A_{1C} in Black females with type 2 diabetes mellitus

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Received 9 December 2003 and in revised form 4 March 2004

Summary

Background: Evidence suggests that populations in Africa develop Type 2 diabetes mellitus (DM) at an increasing rate as they reject their traditional lifestyles. Diabetes is the tenth most common cause for total life years lost in females in South Africa. Physical activity is under-used in the management of type 2 DM in South Africa.

Aim: To investigate the efficacy of an exercise intervention programme compared to relaxation exercises to decrease $HbA1_c$ over a period of 12 weeks, in type 2 DM female subjects.

Design: Single blind, double-intervention randomized trial.

Methods: Clinical measurements were done before and after the 12-week exercise and relaxation interventions. The interventions consisted of education and aerobic exercise for the exercise group, and education and relaxation for the second group.

Results: Adjusted baseline HbA_{1c} change from baseline in the exercise group after 12 weeks was −0.39% (95%CI −0.80 to 0.02) and in the relaxation group −0.97% (95%CI −1.38 to 0.55) ($p=0.052$). The results for the BMI were $-0.07\,kg/m^2$ (95%CI −0.2 to 0.14) in the exercise group versus $-0.23\,kg/m^2$ (95%CI −0.44 to 0.02) in the relaxation group ($p=0.28$). The difference from baseline in distances covered following the 6 min walk test was statistically significantly greater ($p<0.01$) in the exercise group: 46.76 m (95%CI 36.20–57.32) vs the relaxation group 22.7 m (95%CI 12.07–33.33).

Discussion: The exercise intervention failed to reduce the HbA_{1c} to a greater extent than in the relaxation control group. Both groups improved significantly from baseline, probably due to the study effect.

Introduction

Over 140 million people worldwide suffer from diabetes mellitus, with a projected increase to 300 million by the year 2025.[1] With urbanization, the prevalence of type 2 diabetes mellitus (type 2 DM), which currently accounts for 80–90% of the diabetic population, appears to be increasing rapidly. This is of great concern internationally, and particularly in South Africa. In South Africa, it has been estimated that there are at least one million known diabetics, and possibly an equal number currently undiagnosed.[2] Micro- and macrovascular complications of diabetes mellitus have been clearly linked to poor glycaemic control (as monitored by HbA_{1c}).[3]

Several recent randomized controlled trials have shown that an increase in physical activity has beneficial effects on metabolic control, over and above the effect it has on body weight.[4–6] The cornerstones of diabetes care in South Africa are education, hypoglycaemic agents and exercise.[7] However, the overall physical activity level, of both

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daily living and occupational physical activities is low among South African urban black females with type 2 DM.[8]

The aim of this study was to investigate the efficacy of an exercise intervention compared to a relaxation intervention program, to decrease HbA_{1c} over a period of 12 weeks, in type 2 DM Black female subjects, aged 40–65 years. Secondary outcomes investigated were body mass index and walking distance.

Methods

The Protocol and Ethics Committee of the University of Pretoria approved the study.

Patients

The study participants were Black women between the ages of 40 and 65 years, with type 2 DM and known duration of the disease for at least one year.

The subjects were randomly allocated to the exercise intervention or to the relaxation intervention group. 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 than the men to keep research-related appointments. For a one-sided test, only improvement is considered. A total sample of 144 participants with 72 in each group, with $\alpha = 0.05$ and $\beta = 0.20$ (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. 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.[9] Cases where there was uncertainty regarding the aforementioned conditions were referred to the attending specialist physician (PR), for clinical evaluation. All consecutive eligible patients attending the clinic over a period of 6 months were approached and invited to take part in the study.

In an effort to avoid patients 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 patients, did the baseline and 12 week post-trial measurements.

Subjects were informed about the study in an African language and after consent was obtained, they were randomized to either the intervention or the relaxation group. Allocation concealment was ensured by means of sequentially numbered, sealed, opaque envelopes. A computer-generated list was used. Subjects were randomized into either an exercise group or a control group in 17 blocks of 10 each by the principal researcher. Allocation was done telephonically from a central site, and was concealed until interventions were assigned. To ensure that the research assistant and laboratory staff were blind to the randomization of the participants, the only form of identification on the questionnaires, EDTA-tubes and the clinical data forms, were the names, hospital file numbers and the study numbers of the subjects.

In the baseline evaluation, demographic data were recorded, a non-fasting HbA_{1c} sample was obtained and analysed with the SYNCHRON system.[10] Published protocols were followed for measuring body mass index (BMI)[11] and blood pressure.[12] The 6-min walk test was conducted in an enclosed area on a 33 m course, according to published guidelines and precautions.[13] The subject was instructed to walk from end to end, covering as much ground as she could during the allotted time of 6 min. The subject was also instructed to stop the test and to report if she experienced chest pain, light-headedness, severe tiredness or any other adverse effect 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 walked was recorded. A calibrated Avant Sport timer was used to time the 6 min for all the subjects.

The Borg Perceived Exertion Scale[14] was used to evaluate the subjects' perception of exertion during the walk test, and this information was used to prescribe the intensity of exercise for a home programme. 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 well-related to the relative metabolic rate and to the relative heart rate in most individuals.[14] Lactate threshold (LT) appears to be an important threshold that is not affected by the state of training or gender point for the perception of effort during exercise. 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 13–14.

The post-intervention measurements after 12 weeks of participation by each subject were done in exactly the same way.

Exercise and relaxation groups

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. Patients were instructed to increase walking at home from 10 to 45 min sessions over the 12 weeks of training. Subjects were instructed to walk twice a day, starting with 5 min per session, and to increase their total daily walking time by 10 min every two weeks, up to 45 minutes per day. Instructions were to walk briskly whilst swinging the arms.[15] Subjects were encouraged to work up a slight sweat and a faster respiratory rate, thus working at a moderate RPE of 12–14, or 'somewhat hard' according to the Borg scale of perceived exertion.[16] 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 at stretching the major muscle groups and maintaining range of motion. Subjects were urged to do their home exercises at least 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.[17] 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 spent 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 when attending the fortnightly exercise sessions at the hospital. The physical activity logs were checked, problems discussed and new logs 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 min each at the Mamelodi hospital were used to educate the subjects about exercise, to demonstrate the home exercises and to address problems experienced with home programmes.

Exercises consisted of low-impact aerobic 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, obtaining 55–69% of maximal heart rate and a relative perceived exertion (RPE) of 12–14.[18]

The relaxation group

In order to ensure that the two groups received comparable treatment other than the specific exercise intervention investigated, an appropriate comparative group intervention was necessary. 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 patients 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.[19] The duration of the relaxation exercises was 20 min per session.

Education

The education was the same for both the exercise and the relaxation groups and consisted of interactive 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 sample examples were used to show subjects the different 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 because not all subjects could read the fine print on the labels, due to poor eyesight and lack of glasses in this sample.

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.

Statistical analysis

Data were analysed 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. Analysis of co-variance (ANCOVA) was used to compare the experimental and relaxation groups with respect to changes in $HbA1_c$, in BMI, and 6 min walking distance, using the baseline values as covariate.[20] A p value < 0.05 was regarded as significant.

Results

Data capture commenced on 13 March 2002 and ended on 12 November 2002. Progress through the various stages of the study, including the flow of participants, withdrawals and the timing of primary and secondary outcomes, is shown in Figure 1. The baseline characteristics of the eight subjects who did not complete the program (five exercise and three relaxation subjects) did not differ from the baseline characteristics of those 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 or side-effects were reported in either group.

Demographic data

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

Clinical data (Table 2)

The adjusted baseline mean $HbA1_c$ change in the exercise group after the 12 week trial period was −0.39% (95%CI −0.8 to 0.02), and difference from the mean for the relaxation group −0.97% (95%CI −1.38 to 0.55) was just outside statistical significance ($p = 0.052$).

The adjusted baseline mean BMI change in the exercise group was $-0.07\,kg/m^2$ (95%CI −0.28 to 0.14) and was not significantly different ($p = 0.29$) from the mean change for the relaxation group $-0.23\,kg/m^2$ (95%CI −0.44 to −0.02).

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

Significant within-group improvements in both the exercise and the relaxation groups were demonstrated in the means of HbA_{1c}, and walking distance (Table 3, Figures 2 and 3). The relaxation group also showed a significant improvement in BMI.

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.

Discussion

The primary outcome of the study demonstrated that an exercise intervention to decrease HbA_{1c} 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. However, the HbA_{1c} did improve in both groups, and there was a marked improvement in the relaxation group.

The improvement in the HbA_{1c} level of 0.39% in the exercise group is in keeping with the results by Dunstan and co-workers[21] who reported a reduction of 0.34% in their moderate exercise group. Given that the exercise intervention failed to reduce HbA_{1c} to a greater extent than the relaxation group, this reduction could be interpreted as being due to the subjects' participation in the trial, and interest shown by the health care workers (study effect) rather than the exercise *per se*.

The exercise intervention may be judged as not intensive enough. The general recommendation

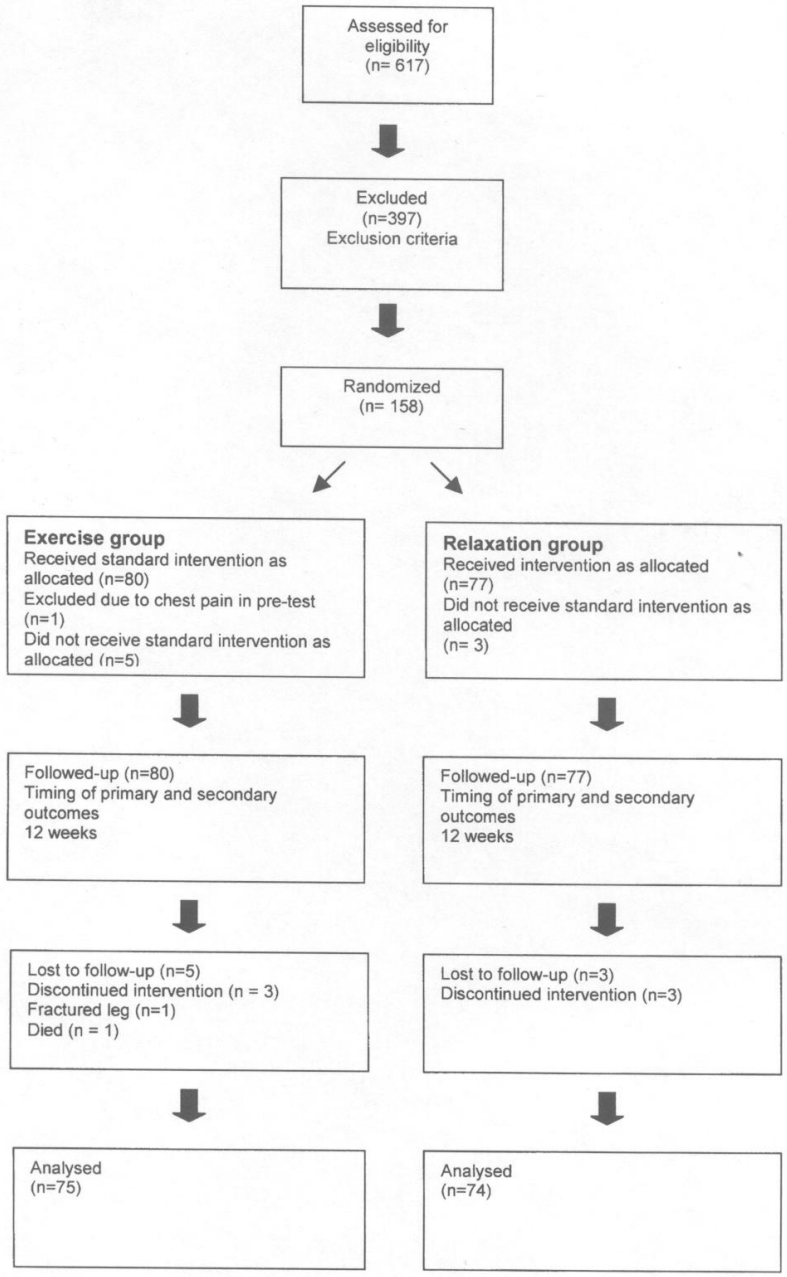

Figure 1. Flow diagram of progress through the phases of the trial.

that subjects should accumulate 30 min of moderate intensity aerobic exercise on most days of the week was followed in the present study.[22] Participants were requested to do the home programme regularly to achieve this goal. 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 logs and exercise notebooks with instructions were compiled and handed out to encourage subjects to be more active at home. The physical activity records were handed in and checked fortnightly, and the home programme was discussed with the individual patients when

Table 1 Frequency distribution of demographic variables

Demographics	Exercise group ($n=80$)	Controls ($n=77$)
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	51(63.8)	50(64.9)
OHAs + insulin	5(6.3)	7(9.1)
Diet alone	1(1.3)	0

Figures are numbers (%). OHAs, oral hypoglycaemic agents.

they reported for the exercise sessions at the hospital. It was clear that the subjects did not complete the physical activity forms correctly. At least three subjects admitted that they depended upon their grandchildren to complete the log, and poor individual recall ability may have played a role in the data. [16] These subjects had to wait until their grandchildren returned from school or had time to complete the log. Although subjects confirmed fortnightly that they did their home exercises, it may not have been regularly enough or intense enough. A supervised walk program may have been more appropriate in this sample.

Therefore the increase in physical activity at home might have been insufficient to improve metabolic control. Poor responses may have been due to the fact that subjects engaged in activities other than those listed in the log.

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 achieve the optimal benefit from the program. Beliefs and attitudes of Black patients with type 2 DM also play a role in their adherence to exercise. Cultural factors may also have influenced the results: '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'.[23] It could also be deemed undignified for these women to be seen walking at a rapid pace.

Behaviour change is a long and complex process.[24] Participants started to exercise at the hospital, but the influences of the environment, lack of social and cultural support in the community and family could have impacted negatively on their compliance with the 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.[25] Since the women were not routinely engaged in exercise, the exercise intervention could have added 'mental stress' to the exercise group. This perceived stress might have obscured true positive physiological effects possibly resulting from exercise.

The decrease in the $HbA1_c$ by 0.97% in the relaxation group was an unexpected finding. The fact that the group's decrease in $HbA1_c$ was more than that of the exercise group may be incidental. However the baseline characteristics of the two groups do not suggest selection bias.

The benefits of both the relaxation program and emotional support could also have influenced the outcome. This finding is in agreement with that of Surwit and co-workers,[26] who reported an improvement of 0.5% in HbA_{1c} after a 12 month study on the efficacy and feasibility of cost-effective outpatient group-stress management training. The participants in the relaxation group also received general health advice at the baseline and 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 regarding the benefits of exercise.[27]

Table 2 The difference in clinical outcomes between the exercise and relaxation groups

Variable	Timing	*n*		Mean (SD)		Comparison*	
		E	C	E	C	95% CI	p
$HbA1_c$ %	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)		
6-min walk (m)	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)		

E, exercise group; C, control group. *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, respectively

Variable	Group	*n*	Mean (SD)	Comparison*	
				95%CI	*p*
$HbA1_c$ (%)	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
6-min walk (m)	Exercise	75	46,36(6.5)	(33.43;59.28)	<0.01
	Relaxation	74	22.46(4.7)	(13.09;31.82)	<0.01

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

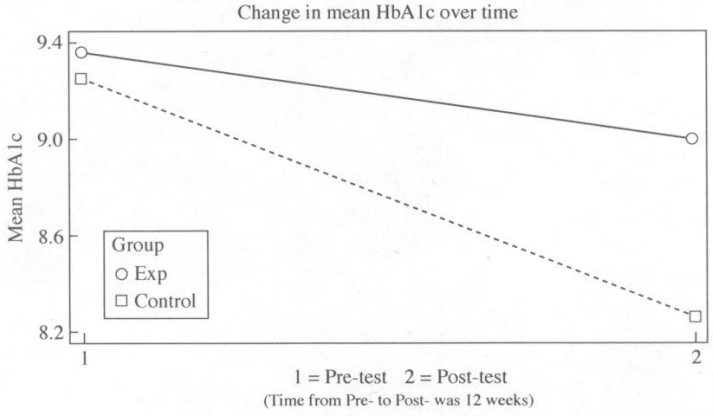

Figure 2. Comparison between the two groups of mean HbA_{1c} over 12 weeks.

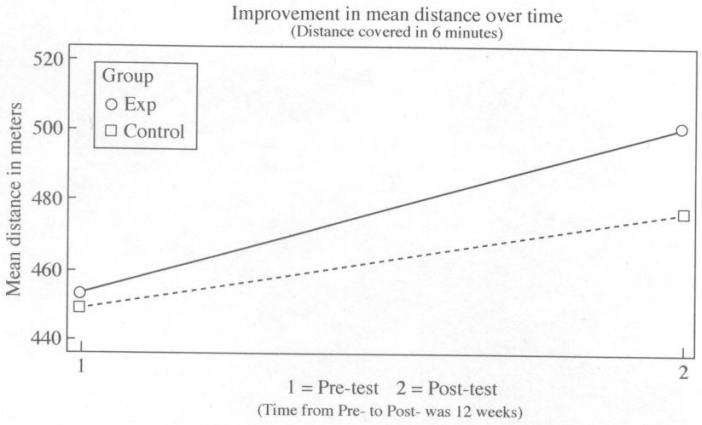

Figure 3. Comparison between the two groups of the improvement in mean walking distance over 12 weeks.

The decrease in HbA_{1c} by 0.97% observed in this group is, however, a clinically important finding, because according to data from the UK Prospective Diabetes Study,[3] a reduction of 0.6% in HbA_{1c} can reduce the risk of microvascular complications by 25%. It is, however, doubtful whether this improvement would be sustained after cessation of the intervention.

The walking distance improved in both groups, but was significantly better in the exercise group. However, the improvement did not translate into the expected improvement in glycaemic control.

The fact that the difference in adjusted baseline mean BMI change from baseline between the groups was not statistically significantly different ($p=0.28$), emphasizes the difficulty in achieving this goal in practice. 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.

In conclusion both these interventions improved HbA_{1c} levels, but it is most likely that these improvements were due to a study effect. An initial run-in period such as a period of education and small group meetings, before randomization into exercise and relaxation groups, might have distinguished between the effect of the exercise and the effect of study participation. The patients in the study had many risk factors for diabetes-related complications, and were representative of other urbanized South African populations. The socio-demographic profiles of patients in this study were similar to those of other international studies. We therefore consider the results of this study to be transferable to other populations.

Acknowledgements

This study was funded by the Medical Research Council of South Africa, and partially sponsored by the South African Sugar Association. Results of this report were presented at the 39th Society for Endocrinology Metabolism and Diabetes of South Africa Congress, Drakensberg, South Africa, 2003.

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