African Journal for Physical, Health Education, Recreation and Dance (AJPHERD)
Supplement (March), 2012, pp. 77-89.

Exercise compliance and health outcome in a chronic disease management programme

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Abstract

The objective of the study was to determine if exercise compliance or non-compliance with a chronic disease management programme (CDM programme) influenced shifts measured in clinical parameters over a period of 12 months. A retrospective analysis was done on data collected (30 months) from 206 men and 194 women (medical aid scheme members) participating in a CDM programme. Hypertension and/or hyperlipidemia and/or diabetes mellitus (type 2) were inclusion criteria. Clinical parameters, i.e. blood pressure, blood lipid levels, blood glucose levels, body mass index, body fat percentage and cardiac risk percentages were measured every three months. Exercise compliance was defined as exercising twice a week. Results indicated that the exercise compliance trend decreased drastically over time. Statistically significant decreases were demonstrated in systolic (Month 3, $p = 0.007$) and diastolic (Month 6, $p = 0.012$) blood pressure, body mass index (Month 6, $p = 0.072$ and Month 12, $p = 0.000$), cardiac risk percentage (Month 6, $p = 0.003$) and body weight (Month 6, $p = 0.003$ and Month 12, $p=0.000$) in the exercise compliant group. In conclusion, compliance with the CDM programme of two sessions per week was sufficient for deriving significant physical health benefits. It is recommended that future studies measure blood pressure and cholesterol more frequently, and that dietary fat intake be monitored.

Keywords: Chronic disease management, exercise compliance, blood pressure, cardiac risk, body mass index.

How to cite this article:
Rossouw, F., Du Plessis, R. & Reynecke, F. (2012). Exercise compliance and health outcome in a chronic disease management programme. *African Journal for Physical, Health Education, Recreation and Dance*, March (Supplement), 77-89.

Introduction

A chronic disease can be classified as a disease that is slow in its progress and long in its continuance (Booth, Gordon, Carlson & Hamilton, 2000). An individual crosses a threshold called a *clinical horizon* to manifest (and be diagnosed with) a multi-factorial chronic disease, generally years after the original causes of the disease have taken effect (Booth et al., 2000). That implies that the physiological mechanisms underlying some chronic diseases have usually been active long before a person shows signs and symptoms of the particular condition. Examples of chronic diseases (CDs) are cardiovascular-related diseases (CVDs), e.g. atherosclerosis, heart failure, hypertension, stroke and hyperlipidaemia. Type 2 diabetes mellitus (DM), some cancers and osteoporosis are also classified as CDs (Booth et al., 2000).

The prevalence of CDs worldwide as well as in South Africa could be viewed as being of grave concern. The World Health Organization's statistical report for 2008 predicted that globally by the year 2030 there would be more deaths from CVD than from the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/Aids) (World Health Statistics, 2008). In South Africa in 2002, 18% of all deaths were caused by CDs of which 20% of these deaths occurred in the age group 34 to 64 years (Steyn & Fourie, 2006). In 2004, the prevalence of chronic diseases of lifestyle was estimated at 12.3% in South Africa (Council of Medical Schemes, 2005).

Not only is the prevalence of CVD another major concern, but also the costs involved in cases of CVD. It was reported that in 2000 the national health care costs of CVD in the United States of America amounted to almost one trillion dollars (Booth et al., 2000; Morrow, Krzewinski-Malone, Jackson, Bungum & FitzGerald, 2004). By 2005 the total cost of CVD was approximately one billion rand per year in South Africa (Council for Medical Schemes, 2005).

As mentioned above, the causes of CVD are linked to risk factors such as elevated blood cholesterol, hypertension, smoking, age and DM (Steyn & Fourie, 2006). Physical inactivity or the lack of doing exercise potentiates at least 17 unhealthy conditions, and all of these unhealthy conditions are CDs or risk factors for CDs (Booth et al., 2000). For an individual to benefit from exercising, compliance with an exercise routine is crucial (Covera-Tindel, Doering, Gomez & Dracup, 2004). According to the American College for Sports Medicine (ACSM), exercise training should be conducted at a moderate to vigorous intensity for a minimum of three times a week for 20 minutes at a time (Franklin, Balady, Berra, Gordon & Michael, 1998). Most health care providers are aware that compliance with an exercise regimen is critical for the patient's recovery or improvement of clinical parameters (Seckin, Gündüz, Bornman & Akyüz, 2000). A third of patients in exercise training studies are non-compliant with the exercise protocol (Covera-Tindel et al., 2004). For most organised exercise programmes, it is believed 50% of patients will stop exercising within the first three to six months (Dishman, 1988). Thus, health care providers must be taught to manage a patient's compliance with an exercise programme (Frederich, Gittler, Halberstadt, Cermark & Heiller, 1998).

Exercise compliance is a multi-faceted construct and may be seen as a behavioural pattern (Steyn & Fourie, 2006). Thus, the role that attitude, behavioural patterns and social skills plays in adopting and maintaining regular exercise is warranted (Dishman, 1994).

The purpose of this study was to determine whether or not exercise compliance or non-compliance over a training period of 12 months would influence shifts measured in a group of participants' clinical parameters (i.e. blood pressure, blood lipid levels,

blood glucose levels, body mass index, body fat percentage and cardiac risk percentage). The emphasis was on compliance with exercise as an indicator of the anticipated improvement of physical and clinical parameters of people registered on a chronic disease management programme.

Methods and Material

Participants

Data from 400 members, who were registered on the Best Med/Access Health Chronic Disease and Lifestyle Management Programme (BM/AH-DM Programme) from July 2003 to December 2006, were analysed, retrospectively. The demographic characteristics of the members are provided in Tables 1 and 2. The inclusion criteria for participation in the programme were the presence of one or more of the following CVDs: hypercholesterolemia and/or hypertension and/or DM.

Table 1: Gender distribution for members on the BM/AH-DM Programme

Gender Distribution		
Gender	n	%
Male	206	51.5
Female	194	48.5

Symbols: n is used to indicate the number of members

Table 2: Age distribution for members on the BM/AH-DM Programme

Age Group Distribution		
Age group	n	%
<=30	21	5.26
31-40	25	6.27
41-50	118	29.57
51-60	166	41.6
>60	69	17.29

Symbols: n is used to indicate the number of members; < is used to indicate "less than"; > is used to indicate "more than"; = is used to indicate "equal to"

The Ethics Committee of the Faculty of Humanities at the University of Pretoria, South Africa granted permission for the study.

Best Med Medical Aid invited certain members (according to the criteria, as mentioned above) to take part in the BM/AH-DM Programme. When a member

agreed to participate in the BM/AH-DM Programme, he/she signed an informed consent form with Best Med Medical Aid. Both Best Med Medical Aid and Access Health (SA) are the owners of the data collected during the course of the BM/AH-DM Programme. The researchers thus received letters of permission from Best Med Medical Aid and Access Health SA, according to the procedures of the Promotion of Access to Information Bill (PROATIA), to conduct this study on their data.

Clinical parameters measured

Blood pressure (BP) was measured (Foss & Keteyian, 1998) at baseline and at three-month intervals. A manual blood pressure cuff and sphygmonometer were utilised. All the blood pressure readings were measured on the member's right arm. The CardioChek® PA Analyzer and appropriate cholesterol and blood glucose strips were used to test total blood cholesterol and blood glucose values via random (finger prick) testing (CardioChek®, 2006) at baseline and at three-month intervals.

Body mass index (BMI) was determined at baseline and at three-month intervals. This was calculated by dividing body weight in kilograms by height in metres squared (Foss & Keteyian, 1998).

Body fat percentage was measured by means of a bioelectrical impedance analysis (BIA). BIA is a non-invasive low frequency electrical current. Gel electrodes are placed on the hand and foot, and the electrical frequency is conducted from the hand to the foot. BIA measures the impedance or the resistance to the flow of the electrical current. Muscle tissue and water assist in conducting the current, while fat tissue creates resistance to the current (Balady, Berra, Golding, Gordon, Mahler, Myers & Sheldahl, 2000). Impedance is proportional to body water volume. Measured impedance is converted to a corresponding estimate of body water volume (based on previous prediction equations). The muscle mass is then calculated from the above estimate, using an assumed hydration fraction for muscle mass. The fat percentage is then calculated as the difference between the body weight and muscle mass. Thus, no participant was allowed to drink any fluids an hour prior to the assessment (McArdle, Katch & Katch, 2001).

The cardiac risk input data is based on research in the Framingham study (Dawber, 1980). The cardiac risk percentage determines the percentage risk of an individual having a heart attack in the next ten years (from the date the cardiac risk is done). Certain risk factors were measured (Figure 1) and each one carried a certain weight, which contributed to the total risk percentage. The software program (Lipo-Trak®, 2000) took into consideration both non-avoidable risk factors (age, gender, family history of heart attack and stroke) and avoidable risk factors (systolic blood pressure, diastolic blood pressure, total blood cholesterol values, physical activity level, body weight and smoking status).

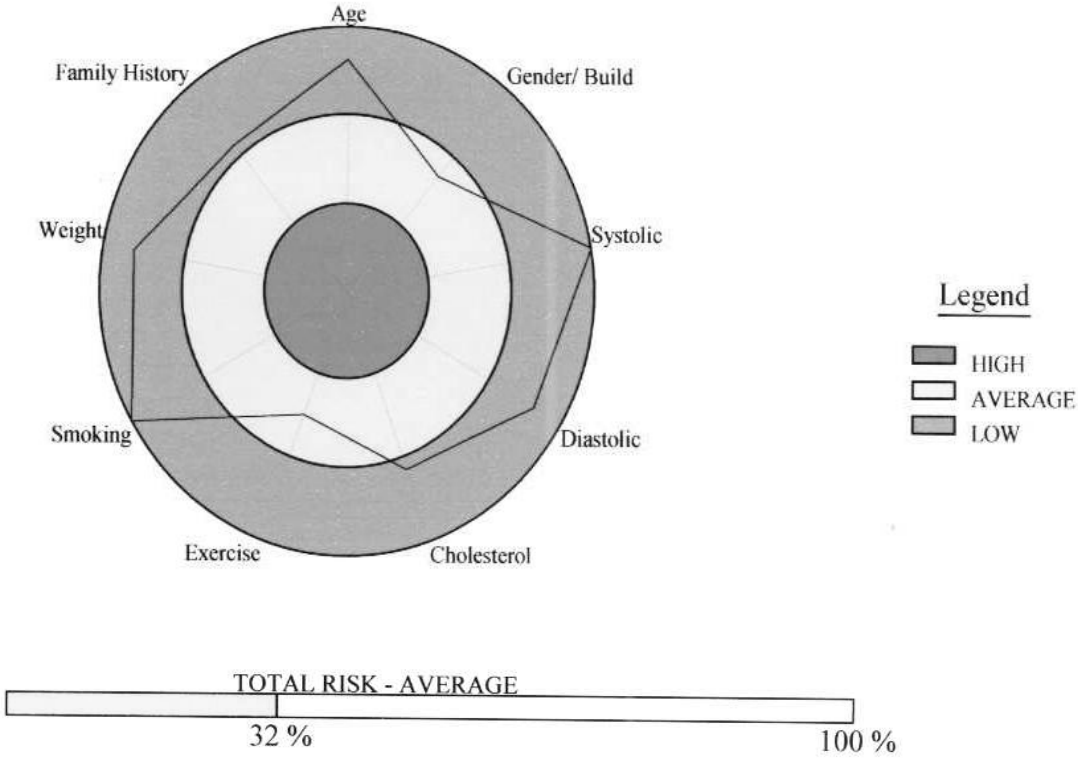

Figure 1: Example of the cardiac risk profile utilised (Lipotrak™)

Statistical methods

The most commonly used quasi-experimental design, namely a non-equivalent group design (Thomas & Nelson, 1996), was used in this study. It required a pre-test and post-test for an experimental (compliant) group and control (non-compliant) group, based on their exercise compliance.

The groups were not created through random assignment. Data were analysed retrospectively. Although this may be considered a threat to internal validity, the purpose of the chosen quasi-experimental design was to fit a research design to the real world in order to increase external and ecological validity, while still controlling as many threats to internal validity as possible. The results can thus be generalised to similar settings where disease risk management has been done. It was envisaged that descriptive statistics (means, standard deviations, etc.) were to be utilised, while the t-test or the Mann-Whitney test (an equivalent non-parametric technique) would be applied to determine significant differences between groups.
Baseline and three-month interval assessment values for each clinical parameter (blood pressure; total blood cholesterol; blood glucose; BMI; body fat percentage

and cardiac risk percentage) were calculated for the entire group (n = 400). Descriptive statistics were also used to determine the entire group's exercise compliance for the three and a half year period.

According to data analyses and the descriptive statistics, after 12 months the exercise compliance trend for the entire group decreased to such an extent that no statistical significant test could be done. Therefore, it was decided that only a 12-month analysis would be done on exercise compliance and clinical parameters.

Considering the non-random assignment of members into groups inherent in the present study's quasi-experimental design, the following procedures were done to ensure the best possible homogeneity between the groups in terms of the clinical parameters. Each one of the clinical parameters was compared at baseline and at three-month intervals (i.e. base to three months; base to six months and base to 12 months). The shifts measured in every clinical parameter over the three-month intervals were compared to each group's exercise compliance (Tables 4 - 6). A t-test or Mann-Whitney test was applied to determine significant differences between groups. Multiple tests (on baseline values) were done. The Bonferroni Correction (Holm, 1979) was applied as a safeguard against multiple tests of significance on the same data to control for bias or a Type I error. For example, three independent hypotheses were tested on the same data at $\alpha = 0.05$ (significance level of 5%). Instead of using a $p-$value threshold of 0.05, a stricter threshold of $\frac{0.05}{3} = 0.0167$ was used (Holm, 1979).

Results

For the purpose of this study, the definition for being compliant with an exercise regimen was set at training two days a week. During baseline Months 0 to 3, the medical aid members were most complaint, with the median being training six days a month. During Months 4 to 12 the participants' exercise compliance decreased. They trained three days a month less than in the first three months. From baseline to 3 months, 30.9 % of the participants were in the compliant exercise group and by Months 10 to 12 there were only 13.6% participants in the compliant exercise group. Thus, the exercise-compliance statistics for the present study are consistent with those reported in the literature (Covera-Tindel et al., 2004; Steyn & Fourie, 2006) in as far as only a third of patients complied with their exercise regimen. Results indicate that even less than a third of the BM/AH-DM programme's participants remained compliant with time.

Clinical parameters of the medical aid members on the BM/AH-DM Programme were measured at baseline, three, six, nine and 12 months, and can be viewed in Table 3. The participants' mean BMI was 28.9 ± 5.4, thus falling within the

overweight category. They were also diagnosed with either one or more of the following risk factors: elevated blood cholesterol levels, hypertension and diabetes mellitus. Thus, in accordance with findings by Molenaar, Hwang, Vasan, Grobbee, Meigs, Agostino, Levy and Fox (2008) a positive correlation seems to exist between the participants' baseline BMI and their disease status.

The results of the association between clinical parameters and exercise compliance can be viewed in Tables 4 - 6. Significant decreases in systolic and diastolic blood pressures at rest, BMI, body weight and cardiac risk percentages were demonstrated when measured over time in the exercise compliant group (Tables 4 - 6). The total blood cholesterol of the compliant group decreased more than the non-compliant group, although this change was not statistically significant. All of the avoidable cardiac risk factors, with the exception of smoking status, were measured independently and compared to exercise compliance. Because there were statistically significant improvements in blood pressure and BMI (as influenced by the significant decrease in body weight), the cardiac risk percentage in the exercise compliant group from baseline to 6 months ($p = 0.003$) improved significantly.

Table 3: Values of clinical parameters of the members on the BM/AH-DM Programme measured at baseline, 3, 6, 9 and 12 months

Variable	N	Mean	Median	Standard Deviation	Minimum	Maximum
SYST0	340	125.8	120	18.7	80	180
DIAST0	340	85.3	85	10.6	60	110
BMI0	333	28.9	28.3	5.4	18.2	55
FAT0	339	30.5	28.4	9.5	5.19	55
GLUC0	329	5.8	5.5	1.5	1.2	17.8
CHOL0	339	5.4	5.4	1.1	2.95	9.64
CRISK0	340	42.1	42	7.2	15	64
SYST3	156	117.9	120	13.9	90	150
DIAST3	156	81.3	80	8.6	60	100
BMI3	155	28.3	28.1	4.8	19.6	44.6
FAT3	156	30.3	28.9	9.3	12.9	51.9
GLUC3	156	5.7	5.5	1.3	3.5	12.1
CHOL3	153	5.1	4.97	1.1	2.59	8
CRISK3	154	37.9	38	6.3	19	54
SYST6	225	118.0	120	14.7	90	160
DIAST6	225	82.0	80	9.5	60	106
BMI6	222	29.4	28.8	5.9	17.2	52.6
FAT6	225	30.9	27.6	9.8	12.4	60
GLUC6	213	5.8	5.4	2.0	3	20.6
CHOL6	225	5.1	5.09	1.1	2.59	7.66
CRISK6	226	39.1	39	6.9	18	57
SYST9	175	116.4	120	14.4	90	160
DIAST9	175	81.5	80	8.7	60	100
BMI9	175	28.7	28.2	5.0	18.3	45.5
FAT9	175	30.6	28.5	9.4	12.1	53.4
GLUC9	171	5.3	5.3	1.0	2.5	9
CHOL9	175	5.2	5.08	1.1	2.73	8.64
CRISK9	174	38.2	38	6.9	15	57
SYST12	141	113.6	110	14.9	85	160
DIAST12	141	79.9	80	9.5	55	100
BMI12	141	28.5	28.3	4.7	17.9	43.2
FAT12	141	30.5	29	9.6	13.6	52.9
GLUC12	139	5.4	5.1	1.4	2.4	13.8
CHOL12	140	5.2	5.275	1.1	2.59	8.16
CRISK12	140	38.3	39	6.6	18	54

SYST indicates systolic blood pressure; DIAST indicates diastolic blood pressure; BMI indicates body mass index; FAT indicates body fat percentage; GLUC indicates serum (blood) glucose levels; CHOL indicates serum (blood) cholesterol levels; CRISK indicates cardiac risk percentage; 0, 3, 6, 9 and 12 indicate the months in which assessments were done.

Table 4: A summary of changes in clinical parameters from baseline to Month 3 for the compliant and non-compliant groups respectively

	NON-COMPLIANT				COMPLIANT				STATISTICAL COMPARISON		
Variable	n	Mean	Mean %	Std Dev	n	Mean	Mean %	Std Dev	p-value	p < 0.0167	Effect size
SYST03	98	4.78	3.91	15.444	58	11.24	8.65	16.011	0.0069	Significant*	Small-medium
DIAST03	98	2.67	3.19	9.212	58	3.26	3.84	9.193	0.3509		
BMI03	97	0.14	0.48	0.875	56	0.36	1.26	1.650	0.1738		
FAT03	98	0.06	0.18	3.148	58	0.09	0.31	4.301	0.4778		
GLUC03	97	0.04	0.64	1.408	57	0.11	1.99	1.317	0.3728		
CHOL03	96	0.36	6.58	1.183	56	0.38	7.30	1.133	0.4581		
CRISK03	97	3.30	7.92	4.388	57	4.43	10.66	5.874	0.1045		
WT03	97	0.34	0.41	2.263	57	0.93	1.09	4.321	0.1709		

Table 5: A summary of changes in clinical parameters from baseline to Month 6 for the compliant and non-compliant groups respectively

	Non-Compliant				Compliant				Statistical Comparison		
Variable	n	Mean	Mean %	Std Dev	n	Mean	Mean %	Std Dev	p-value	p < 0.0167	Effect size
SYST06	176	6.24	5.03	16.734	49	9.82	7.60	16.350	0.0924		
DIAST06	176	2.64	3.12	11.023	49	6.65	7.54	10.696	0.0122	Significant*	Small-medium
BMI06	168	0.04	0.13	1.309	48	0.60	2.03	1.668	0.0072	Significant*	Small-medium
FAT06	175	-0.32	-1.04	4.880	49	0.39	1.31	5.553	0.1906		
GLUC06	159	-0.02	-0.29	2.005	47	0.14	2.35	1.706	0.3182		
CHOL06	176	0.32	5.80	0.976	49	0.52	9.76	1.123	0.1008		
CRISK06	177	2.85	6.71	4.722	49	5.57	13.02	6.305	0.0033	Significant*	Small-medium
WT06	177	-0.11	-0.13	3.491	49	1.90	2.16	3.689	0.0003	Significant*	Small-medium

Table 6: A summary of changes in clinical parameters from baseline to Month 12 for the compliant and non-compliant groups, respectively

	Non-Compliant				Compliant				Statistical Comparison		
Variable	n	Mean	Mean %	Std Dev	n	Mean	Mean %	Std Dev	p-value	p < 0.0167	Effect size
SYST012	122	9.92	8.05	17.270	18	13.33	10.43	12.574	0.2106		
DIAST012	122	5.80	6.79	11.591	18	7.94	8.83	11.280	0.2313		
BMI012	118	-0.07	-0.25	1.167	18	1.00	3.37	1.246	0.0003	Significant*	Medium
FAT012	122	-0.42	-1.38	3.719	18	1.31	4.39	3.470	0.0327		
GLUC012	115	0.46	8.04	1.641	17	0.14	2.30	1.936	0.2268		
CHOL012	120	0.16	3.00	1.099	18	0.25	4.71	1.002	0.3732		
CRISK012	121	2.72	6.61	5.377	18	5.22	12.32	5.494	0.0344		
WT012	120	-0.32	-0.39	3.136	18	3.17	3.58	3.802	0.0000	Significant*	Medium

The following explanation is given for the interpretation of Table 4, 5 and 6: Any statistical significance in a shift measured in a clinical parameter will be marked in

the specific clinical parameter's row with "Significant" and (*); Effect size measures the magnitude of a treatment effect; SYST indicates systolic blood pressure; DIAST indicates diastolic blood pressure; BMI indicates body mass index; FAT indicates body fat percentage; GLUC indicates serum glucose value; CHOL indicates serum cholesterol value; CRISK indicates cardiac risk percentage; WT indicates body weight; 03, 06 and 012 indicate shift measured, namely Baseline to Month 3, Baseline to Month 6 and Baseline to Month 12.

Discussion

The limitations of the current study were that only once-off blood pressure readings were recorded with the clinical assessments. No blood pressure readings during training sessions were taken before and after exercise. Therefore, no trend could be established.

The reason for the non-significant changes in total cholesterol values may be attributed to the fact that the participants' dietary fat intake and body weight were not managed in the BM/AH-DM Programme. Durstine (2008) indicated that total cholesterol and LDL-cholesterol levels were unlikely to decrease in the absence of reduced dietary fat intake and body weight. Also, each participant on the BM/AH-DM Programme followed an individualised training programme of which the energy expenditure was neither monitored nor recorded. Thus, caloric expenditure might have been less than the 500-600 kcal per session stipulated by Magkos (2009) to improve the blood lipid profile.

Statistically, the study reported significant decreases in systolic and diastolic blood pressures at rest, BMI, body weight and cardiac risk percentages when measured over time (Tables 4 - 6). All of these improvements in clinical and physical parameters were demonstrated by the exercise compliant group who were only training two or more days a week. The results therefore confirmed conclusions reached in the literature that exercising at least twice a week or more frequently, may improve blood pressure values (Pi-Sunyer & Look *AHEAD* Research Group, 2007), BMI and body weight (Coliac, Guimarães, D'Avila, Bortolotto, Doria & Bocchi, 2009). Larger improvements in total blood cholesterol, body fat percentage and blood glucose values were also demonstrated by the exercise compliant group, although these findings were not statistically significant ($p < 0.05$ / $p \leq 0.016$). Thus, the results support findings by Covera-Tindel et al. (2004) which indicated that compliance of at least twice a week is necessary to derive significant benefits from a chronic disease management exercise programme.

Long-term exercise compliance in the chronic disease management context poses a significant challenge to biokineticists. The present study indicated that the quality of data records and exercise compliance of the medical aid members on the BM/AH-

DM Programme progressively deteriorated over the three and a half year period, and that data collected after 12 months of participation in the chronic disease management exercise programme were scarce and often incomplete.

Conclusions

Compliance twice a week in the 12-month chronic disease management exercise programme was adequate to significantly improve participants' physical health by decreasing systolic and diastolic blood pressures at rest, BMI, body weight and cardiac risk percentage. As stated by other authors (Hemmingson & Ekelund, 2007; Krousel-Wood, Berger, Jiang, Blonde, Myers & Webber, 2009), exercise could have been one of the causal factors for the improvements in BMI measurements.

In a publication of Discovery Health, a prominent medical aid scheme in South Africa, Noakes (2009) reported that individuals who took part in the Discovery Vitality Programme (a rewards programme of the medical aid scheme) and who exercised regularly saved this medical aid scheme significant costs in terms of shorter hospitalisation times and faster recovery from surgery. However, apart from personal attention, it seems that the best motivational tool for exercise compliance in a chronic disease management programme is yet to be determined.

Recommendations

Future research designs for chronic disease management exercise programmes should:

- incorporate a full blood lipid profile, not just measurements of total blood cholesterol
- measure and record resting blood pressure at each training session
- record and manage dietary fat intake and total calorie intake
- provide prudent prescriptions with regard to exercise characteristics, especially total energy expenditures of exercise sessions
- measure and record blood glucose readings of DM patients separately from the other participants to establish a safe exercise environment
- incorporate a valid and reliable cardiac risk tool (if such a tool exists).

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