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Original Scientific Paper

Comparative outcome one year after formal cardiac rehabilitation: the effects of a randomized intervention to improve exercise adherence

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Background **Methods to ensure sustained benefits of cardiac rehabilitation need to be explored. The aim was to assess the effect of a home-based intervention (INT) on exercise adherence and risk factors after cardiac rehabilitation.**
Design **Prospective randomized study.**
Methods **We evaluated patients who were followed for 1 year after either inpatient (ICR) or outpatient cardiac rehabilitation (OCR) by assessment of exercise capacity, physical activity, risk factors and quality of life, both at the completion of rehabilitation, and after 1 year. Patients were randomized to either be instructed how to use a diary of physical activities complemented by quarterly group meetings (INT) or to receive standard treatment (usual care).**
Results **Two hundred and sixty-one patients gave consent to be reevaluated after 1 year. Of these patients 33 were lost to follow-up (two deaths); thus 228 patients had complete 1-year follow-up data (195 male and 33 female, 91% with coronary artery disease). At 1-year follow-up significantly more patients of the INT group than of the control group adhered to regular physical activity (73 vs. 40%, $P<0.0001$). Moreover, INT patients showed a better evolution of body mass index and lipid values. In a stepwise multiple regression analysis the following variables showed a significant impact on regular physical activity at follow-up: study INT [odds ratio (OR): 4.19, $P<0.0001$], previous cardiac surgery (OR: 2.50, $P=0.008$), BMI at baseline (OR: 0.89, $P=0.018$) and quality of life at baseline (OR: 1.58, $P=0.041$).**
Conclusion **Sustained benefits of cardiac rehabilitation can be documented 1 year after both inpatient and outpatient programmes. Self-monitoring of physical activity greatly increased long-term adherence to regular exercise, which in turn was associated with greater improvements of risk factors and quality of life.** ***Eur J Cardiovasc Prev Rehabil*** **15:306–311**
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Keywords: cardiac rehabilitation, exercise intervention, long-term follow-up

Background

Until recently, cardiac rehabilitation was thought to be important mainly to overcome sequelae of prolonged patient immobilization after myocardial infarction or cardiac surgery. Furthermore, psychosocial and psychosomatic reassurance was shown to be important, and cardiac rehabilitation has gained a key role for implementing measures of secondary prevention in patients with atherosclerosis [1,2]. Both pharmacological measures and lifestyle modification seem to be of equal and proven importance to reduce the risk of further morbidity and mortality [3,4]. Motivation and long-term adherence to a healthy lifestyle, however, remain the most difficult problems for these patients [5,6], although to a lesser extent than in the general population [7,8]. As regular physical activity is a key element of a healthy lifestyle, we tested the hypothesis that a simple instruction to keep a diary of daily physical activities combined with group sessions every 3 months would improve compliance with

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regular physical exercise and risk factor control during 1 year following a cardiac rehabilitation programme.

Methods

Patients were approached at the end of either a 4-week inpatient or a 12-week outpatient cardiac rehabilitation programme. Those willing to be reevaluated after 1 year, and who gave written informed consent, were enroled in the study and were randomized into an intervention (INT) group and a usual care (UC) group.

Patients

A total of 565 patients were asked, and 261 patients were enroled in the study; 103 after a 4-week inpatient programme and 158 after a 12-week outpatient programme. These programmes have been described in detail elsewhere [9,10]. The patients were examined clinically and by an exercise test at baseline, that is, at the completion of the rehabilitation programme. Information on risk factors and medication was also obtained. Patients were asked to fill in a quality-of-life questionnaire. We used a validated German version of the MacNew questionnaire, which consists of 27 items from which four scales are built (global scale, physical, emotional and social scales, all ranging from 1 to 7) [11]. INT patients were instructed on how to use a diary sheet, in which physical activities had to be described and quantitated in minutes. Patients were invited to take part in a physician-supervised group exercise session once every 3 months, where the diary sheets were collected and questions were discussed at the individual and group levels. In contrast, UC patients were only asked to come back after 1 year for reevaluation without further instructions. After 1 year all baseline clinical, exercise and laboratory variables including risk factor and quality-of-life assessments were repeated.

Definitions

Smoking was defined as cigarette consumption of ≥ 5 per day.

Regular physical activity was defined as being active to noticeably increase pulse rate and breathing ≥ 3 times per week for ≥ 30 min.

Statistics

Analyses were made according to the intention-to-treat, regardless of the amount of exercise patients actually took in the INT and UC groups.

Descriptive statistics are presented as means $\pm$ 1 standard deviation or as percentages. Categorical variables were compared using the χ^2 test. Continuous variables were compared using the Student's *t*-test. All *P* values were two-sided and considered statistically significant if ≤ 0.05. In addition, a stepwise forward logistic regression analysis was made. Data acquisition and statistical analysis were performed using the SPSS version 14.0 (SPSS Inc., Chicago, Illinois, USA) software as well as the generic KarData software (kaSoft Development Kaufmann, Münsingen, Switzerland, *www.kasoft.ch*).

Results

Baseline characteristics

Initially, 261 patients consented to the study and were randomized to the INT ($n = 129$) and the UC groups ($n = 132$), respectively. Thirty-three of these patients (15%) were females. The patients had a mean age of 61 ± 10 years, and 91% of these had coronary artery disease. Of these, two patients died (one in each group) and 31 patients withdrew consent or were not available for follow-up reevaluation after 1 year, such that 105 INT and 123 UC patients formed the study population available for this analysis. At baseline there were no differences between the two groups on any relevant parameter (Table 1).

Clinical events during follow-up

Of the 228 patients with complete follow-up data, four had recurrent acute coronary syndromes, 25 were hospitalized for other cardiac reasons, mostly for repeat angiography and percutaneous coronary intervention (PCI). Cardiac events, especially repeat angioplasty, occurred more often in the INT group (Table 2).

Noncardiac hospitalizations occurred in 40 patients during follow-up. Noncardiac events were evenly distributed with no differences between the two groups.

Assessment after 1 year

The most important clinical and testing variables at the 1-year follow-up are summarized in Table 2.

Table 1 **Baseline variables according to the study groups**

	INT	UC
N	105	123
Female, *n* (%)	14 (13)	19 (16)
Age (years)[a]	61 ± 10	61 ± 9
Previous cardiac surgery, *n* (%)	45 (43)	51 (42)
Previous angioplasty, *n* (%)	64 (61)	68 (55)
Inpatient rehabilitation, *n* (%)	36 (34)	49 (40)
Exercise capacity (Watt)	153 ± 52	144 ± 52
Body mass index (kg/m^2)[a]	27 ± 4	27 ± 4
Total cholesterol (mmol/l)	4.36 ± 1.10	4.22 ± 1.11
LDL-cholesterol (mmol/l)[a]	2.69 ± 0.98	2.52 ± 0.92
HDL-cholesterol (mmol/l)[a]	1.06 ± 0.26	1.11 ± 0.86
Triglycerides (mmol/l)	1.83 ± 0.90	1.74 ± 0.73
Smokers, *n* (%)	61 (58)	67 (55)
Hypertension, *n* (%)	51 (49)	73 (59)
Diabetes, *n* (%)	11 (11)	15 (12)
MacNew global score[a] Baseline	5.72 ± 0.69	5.68 ± 0.76

All differences not significant between groups. HDL, high-density lipoprotein; INT, intervention; LDL, low-density lipoprotein; UC, usual care. [a]Values given are mean ± SD.

Table 2 Comparison of patients in the intervention (INT) and usual care (UC) groups 1 year after completion of a formal cardiac rehabilitation programme

	INT	UC	*P* value INT vs. UC	*P* value baseline vs. follow-up
N	105	123		
Nonfatal cardiac events, *n* (%)	17 (16)	12 (10)	<0.01	
PCI, *n* (%)	4 (4)	1 (1)		
CABG, *n* (%)	0	0		
Other, *n* (%)	13 (12)	11 (9)		
Exercise capacity (Watt)[a]				
Baseline	153±52	144±52		
Follow-up	163±49*	154±47*		<0.0005*
Double product (HR × SBP)[a]				
Baseline	24770±5927	23794±6113		
Follow-up	28594±6063*	26642±6298*	<0.01	<0.0001*
Body mass index (kg/m^2)[a]				
Baseline	26.5±4	26.8±4		
Follow-up	26.6±4	27.1±4*		<0.05*
Total Cholesterol (mmol/l)[a]				
Baseline	4.36±1.1	4.22±1.1		
Follow-up	4.36±0.9	4.53±0.9*		0.02*
LDL-cholesterol (mmol/l)[a]				
Baseline	2.69±0.98	2.52±0.92		
Follow-up	2.44±0.81*	2.55±0.69		<0.05*
HDL-cholesterol (mmol/l)[a]				
Baseline	1.06±0.26	1.11±0.86		
Follow-up	1.24±0.31*	1.38±1.0		<0.05*
Triglycerides (mmol/l)				
Baseline	1.83±0.90	1.74±0.73		
Follow-up	1.62±0.86*	1.74±0.82		0.012*
On antiplatelet therapy				
Baseline, *n* (%)	91/105 (87)	111/122 (91)	0.036	
Follow-up, *n* (%)	92/105 (88)	112/122 (92)	0.035	
On statin				
Baseline, *n* (%)	97/105 (92)	113/122 (93)		
Follow-up, *n* (%)	91/105 (87)	102/122 (84)*		<0.05*
On β-blockers				
Baseline, *n* (%)	92/105 (88)	110/122 (90)		
Follow-up, *n* (%)	86/105 (82)	105/122 (86)	0.055	
On ACEI				
Baseline, *n* (%)	54/100 (54)	60/110 (55)		
Follow-up, *n* (%)	54/100 (54)	59/110 (54)		
MacNew global score[a]				
Baseline	5.72±0.69	5.68±0.76		
Follow-up	5.96±0.72	5.97±0.74		
Persistent smokers				
Follow-up, *n* (%)	5/61 (8)	11/67 (16)	0.07	
Physically active				
Follow-up, *n* (%)	74/101 (73)	46/115 (40)	<0.0005	

N reduced for some variables owing to missing information. ACEI, angiotensin converting enzyme inhibitor; CABG, coronary artery bypass grafting; HDL, high-density lipoprotein; HR, heart rate; LDL, low-density lipoprotein; PCI, percutaneous coronary intervention; SBP, systolic blood pressure. [a]Values given are mean±SD.

Whereas exercise capacity and quality of life improved in both groups, there were no differences between the groups. The maximum rate–pressure product, however, was higher in INT compared with UC patients.

INT patients remained nicotine-free in a higher percentage and maintained a stable body mass index (BMI) when compared with UC patients. Over the follow-up year cholesterol values showed a favorable evolution (lower total cholesterol and low-density lipoprotein, and higher high-density lipoprotein fractions) in INT patients, whereas they remained unchanged or even showed a deterioration in UC patients.

Adherence to medication was excellent overall, but significantly more UC patients discontinued their statin drug.

Most importantly, 74 of 105 (73%) INT patients remained physically active as defined for this study, whereas only 46 of 123 patients (40%) of the UC group remained active (Fig. 1).

Comparison of patients after inpatient and outpatient rehabilitation

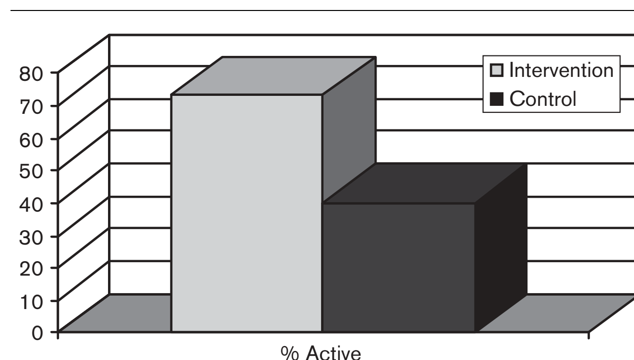
A comparison of patient subgroups after inpatient and outpatient rehabilitation programmes, respectively, revealed the following differences at baseline: older age, a higher rate of patients after surgery, lower exercise capacity and lower quality-of-life scores; all reflecting a somewhat sicker population undergoing inpatient rehabilitation (Tables 3 and 4).

Despite these differences at baseline, similar improvements of exercise capacity, lipid profile and quality-of-life scores were noted in the year following both inpatient and outpatient programmes. Abstinence from nicotine, regular physical activity and a small decline in adherence to medication (especially in the UC patients) was again similar in both subgroups after inpatient and outpatient rehabilitation, respectively.

Multivariate analysis

A stepwise forward multiple logistic regression analysis was made using all 11 variables showing significant associations or trends in the univariate analysis with the

Fig. 1



Proportion of patients exercising ≥3 times a week for at least 30 min 1 year after completing a cardiac rehabilitation programme in the usual care group (*N*=74/105) and in the group with self-kept activity diaries (*N*=46/123).

Table 3 Comparison of the intervention (INT) and usual care (UC) subgroups of patients 1 year after completion of an inpatient cardiac rehabilitation programme

	INT	UC	*P* value INT vs. UC	*P* value baseline vs. follow-up
N	36	49		
Nonfatal cardiac events, *n* (%)	6 (17)	5 (10)	0.031	
PCI, *n* (%)	0 (0)	0 (0)		
CABG, *n* (%)	0 (0)	0 (0)		
Other, *n* (%)	6 (17)	5 (10)		
Exercise capacity (Watt)[a]				
Baseline	115.55 ± 43.62	116.61 ± 41.63		INT 0.00014
Follow-up	138.58 ± 47.74	146.07 ± 42.71		UC 2.10E-07
Double product (HR × SBP)[a]				
Baseline	22131 ± 5508	21066 ± 6095		INT 0.00013
Follow-up	25485 ± 5181	24522 ± 5868		UC 0.00062
Body mass index (kg/m²)[a]				
Baseline	26.46 ± 4.40	26.71 ± 3.14		INT 0.017
Follow-up	26.85 ± 4.54	27.01 ± 3.28		UC 0.099
Total cholesterol (mmol/l)[a]				
Baseline	4.09 ± 1.03	3.95 ± 0.99		INT 0.011
Follow-up	4.47 ± 1.13	4.48 ± 0.82		UC 0.0019
LDL-cholesterol (mmol/l)[a]				
Baseline	2.4 ± 0.76	2.15 ± 0.83		
Follow-up	2.44 ± 1.14	2.34 ± 0.78		
HDL-cholesterol (mmol/l)[a]				
Baseline	0.95 ± 0.19	0.93 ± 0.15		INT 0.0013
Follow-up	1.18 ± 0.29	1.22 ± 0.51		UC 0.0049
Triglycerides (mmol/l)				
Baseline	2.01 ± 0.89	1.72 ± 0.77	0.071	INT 0.064
Follow-up	1.79 ± 0.85	1.68 ± 0.83		
On antiplatelet therapy				
Baseline, *n* (%)	27/36 (75)	39/48 (81)	0.055	
Follow-up, *n* (%)	27/36 (75)	42/48 (88)	0.0088	
On statin				
Baseline, *n* (%)	32/36 (89)	40/48 (83)	0.058	
Follow-up, *n* (%)	30/36 (83)	39/48 (81)		
On β-blockers				
Baseline, *n* (%)	31/36 (86)	45/48 (94)	0.017	
Follow-up, *n* (%)	32/36 (89)	43/48 (90)		
On ACEI				
Baseline, *n* (%)	19/31 (61)	18/36 (50)		
Follow-up, *n* (%)	21/31 (68)	17/36 (47)	0.023	
MacNew global score[a]				
Baseline	5.51 ± 0.61	5.50 ± 0.86		INT 0.0011
Follow-up	5.92 ± 0.82	5.94 ± 0.76		UC 0.00048
Persistent smokers				
Follow-up, *n* (%)	0/16	0/21		
Physically active				
Follow-up, *n* (%)	28/32 (88)	16/42 (38)	1.48E-07	

ACEI, angiotensin converting enzyme inhibitor; CABG, coronary artery bypass grafting; HDL, high-density lipoprotein; HR, heart rate; LDL, low-density lipoprotein; PCI, percutaneous coronary intervention; SBP, systolic blood pressure. [a]Values given are mean ± SD.

Table 4 Comparison of the intervention (INT) and usual care (UC) subgroups of patients 1 year after completion of an outpatient cardiac rehabilitation programme

	INT	UC	*P* value INT vs. UC	*P* value baseline vs. follow-up
N	69	74		
Nonfatal cardiac events, *n* (%)	11 (16)	7 (10)	0.062	
PCI, *n* (%)	4 (6)	1 (1)		
CABG, *n* (%)	0 (0)	0 (0)		
Other, *n* (%)	7 (10)	6 (8)		
Exercise capacity (Watt)[a]				
Baseline	172.27 ± 45.97	162.17 ± 49.95		INT 0.071
Follow-up	175.67 ± 44.77	159.22 ± 49.04	0.021	UC 0.064
Double product (HR × SBP)[a]				
Baseline	25824 ± 5650	25532 ± 5539		INT 2.03E-07
Follow-up	29996 ± 6019	27866 ± 6328	0.023	UC 3.86E-05
Body mass index (kg/m²)[a]				
Baseline	26.57 ± 3.40	26.86 ± 3.77		
Follow-up	26.47 ± 3.55	27.13 ± 4.32		
Total cholesterol (mmol/l)[a]				
Baseline	4.55 ± 1.12	4.63 ± 1.17		INT 0.044
Follow-up	4.28 ± 0.74	4.61 ± 0.95	0.05	
LDL-cholesterol (mmol/l)[a]				
Baseline	2.73 ± 1.00	2.68 ± 0.90		INT 0.022
Follow-up	2.44 ± 0.78	2.58 ± 0.66		
HDL-cholesterol (mmol/l)[a]				
Baseline	1.10 ± 0.28	1.26 ± 1.14		INT 0.00091
Follow-up	1.26 ± 0.32	1.51 ± 1.26		
Triglycerides (mmol/l)				
Baseline	1.70 ± 0.90	1.77 ± 0.68		INT 0.049
Follow-up	1.50 ± 0.86	1.83 ± 0.82	0.057	
On antiplatelet therapy				
Baseline, *n* (%)	64/69 (93)	72/74 (97)	0.020	
Follow-up, *n* (%)	65/69 (94)	70/74 (95)		
On statin				
Baseline, *n* (%)	65/69 (94)	73/74 (99)	0.0017	
Follow-up, *n* (%)	61/69 (88)	63/74 (85)		UC 0.0011
On β-blockers				
Baseline, *n* (%)	61/69 (88)	65/74 (88)		INT 0.041
Follow-up, *n* (%)	54/69 (78)	62/74 (84)		
On ACEI				
Baseline, *n* (%)	35/69 (51)	42/74 (57)		INT 0.63
Follow-up, *n* (%)	33/69 (48)	42/74 (57)		
MacNew global score[a]				
Baseline	5.83 ± 0.71	5.81 ± 0.66		INT 0.019
Follow-up	5.99 ± 0.66	5.99 ± 0.72		UC 0.0066
Persistent smokers				
Follow-up, *n* (%)	5/45 (11)	11/46 (24)	0.046	
Physically active				
Follow-up, *n* (%)	46/69 (67)	30/73 (41)	2.41E-05	

ACEI, angiotensin converting enzyme inhibitor; CABG, coronary artery bypass grafting; HDL, high-density lipoprotein; HR, heart rate; LDL, low-density lipoprotein; PCI, percutaneous coronary intervention; SBP, systolic blood pressure. [a]Values given are mean ± SD.

outcome variable 'regular physical activity at follow-up' (study INT, age, BMI at baseline, exercise capacity at baseline, MacNew global score at baseline, previous cardiac surgery, hypercholesterolemia, smoking, noncardiac hospital admissions during follow-up, membership in a society and patient being active on his own). All other variables did not show any differences between active and inactive patients (sex, medication, other risk factors, LV function and type of rehabilitation programme) (Table 5).

In the multivariate analysis the following variables showed a significant impact on regular physical activity at follow-up: study INT (OR: 4.19, $P < 0.0001$), previous cardiac surgery (OR: 2.50, $P = 0.008$), BMI at baseline

Table 5 Results of a stepwise forward multiple logistic regression analysis using regular physical activity at follow-up as the dependent variable

Variable	*P* value	Odds ratio	95% Confidence intervals
Study intervention	<0.0001	4.19	2.16–8.13
Previous cardiac surgery	0.008	2.50	1.27–4.93
BMI at baseline	0.018	0.89	0.80–0.98
MacNew global score at baseline	0.041	1.58	1.02–2.47

BMI, body mass index.

(OR: 0.89, $P = 0.018$) and quality of life at baseline (OR: 1.58, $P < 0.041$).

Discussion

Effect of study intervention

Adherence to regular physical activity remains the most difficult achievement in secondary prevention of atherosclerotic disease. Even in this cohort of motivated patients who gave consent to be followed for 1 year after completion of a cardiac rehabilitation programme, it remained as low as 40% without INT. This study shows that this figure can be nearly doubled by a simple INT, that is, instructing patients to keep a diary of activities, combined with a 3-monthly recall for a group meeting (Table 2, Fig. 1). In the intention-to-treat analysis values for BMI and lipids showed a significantly better evolution during follow-up in these patients.

The INT and UC groups did not differ in most other aspects. Exercise capacity increased to a similar extent in both groups. The higher rate–pressure product achieved by INT patients possibly indicates their ability to sustain higher workloads.

The rate of nonfatal cardiac events was higher in INT patients, which is a disturbing finding at first sight, but which may be explained by a higher rate of redo-procedures partly because of a somewhat higher rate of angioplasty and possibly a closer follow-up mode in the INT group.

In a multiple logistic regression analysis the study INT was confirmed to be the most important variable influencing adherence to regular exercise, with an OR of 4.19 (Table 5). Only three other variables showed significant but markedly weaker associations with this outcome, and these were: previous cardiac surgery (leaving the patient by far more impressed with his illness and presumably more motivated for secondary prevention measures), BMI and quality of life at baseline (leaner patients with a better well-being being more likely to adhere).

The simple behavioural aid of a self-kept diary of activities seemed to help maintain physical activity in a majority of patients randomized in this cohort of motivated patients. Similar results have been reported from a more complex INT programme [6] and from a study using telephone calls during a 6-month follow-up [12]. In a short-term trial of 12 weeks duration, adherence with exercise was reported to be 90% [13]. In several other studies it has been reported to be as low as 20% [7,14]. To our knowledge, this is the first study to demonstrate clear-cut long-term benefits of exercise on risk factors as a result of a simple INT in cardiac patients.

Adherence to regular exercise

The favourable effects of regular physical activity have been extensively reported [2–4,15,16]. Regular physical activity is one of the most important modifiable risk factors as it applies to all patients. In our study, as in others, it was the secondary prevention measure least adhered to, but it was shown to be nearly doubled by a simple patient self-control aid. It seems worthy to apply such an aid on a broad basis, but it remains open to speculation if it would also be effective in patients with less self-motivation (i.e. those not willing to be enroled in this study). In the patients exercising regularly we observed higher quality-of-life scores in all dimensions measured by the MacNew questionnaire as reported in detail elsewhere [17]. This could be an important mechanism of maintaining adherence as any behavioural change is more likely to occur if it has immediate positive emotional effects. Similar INTs targeting self-regulatory skills have recently been shown to improve maintenance with exercise [18] and other lifestyle elements [5,19].

Other measures of secondary prevention

Nicotine abstinence is the second most important measure as it does not apply to all patients. It was achieved in 87% of the entire study population, a figure similar to those reported in other cohorts after rehabilitation [7]. The rate of persistent nonsmokers tended to be higher in the INT versus UC patients. Both in the INT and UC groups the overall compliance with secondary preventive medication (aspirin, statins and β-blockers) was 87–93% at baseline and 82–92% at follow-up, which compares favourably with data from the literature where statin adherence was reported to be 38–40% in the primary prevention AVIATOR study [20], whereas in populations of secondary prevention it was reported to be 71% [21] and 63% [22]. Adherence to statin therapy was maintained better in the INT group of our study population.

Comparison of patients after inpatient and outpatient rehabilitation

When comparing patients after inpatient and outpatient rehabilitation we found no relevant differences regarding adherence to secondary prevention during the follow-up year. This is remarkable as the patients undergoing

inpatient rehabilitation are older, sicker and more often had prior cardiac surgery. This finding corroborates the previously described findings [9] that formal rehabilitation has beneficial effects in different patient subgroups and when delivered within different frameworks. Similarly, quality-of-life measurements were found to be improved up to 3 months after both inpatient and outpatient rehabilitation [23]. Most importantly, the main study result, increasing adherence to regular exercise by the study INT, was equally significant in both subgroups, although being somewhat more pronounced in patients after inpatient rehabilitation.

Limitations of study

Favourable alterations in lipid profile were observed in the INT group, which may at least in part be due, not only to more physical activity but also to a better adherence to statin use in this group. This difference, although statistically significant, was numerically marginal in comparison with the magnitude of difference in activity.

No socioeconomic variables were available for analysis, which may be relevant for the adherence to exercise.

Conclusion

Regular physical exercise showed the least satisfactory adherence of all secondary prevention strategies during the year following cardiac rehabilitation. The use of a simple diary combined with 3-monthly group sessions, however, nearly doubled adherence with regular exercise in this randomized study. This was found in addition to good adherence to medication and nicotine abstinence. The benefit of regular exercise was not only reflected in better fitness but also in a better risk profile and improved quality of life.

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