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Long-term effect of rehabilitation in coronary artery disease patients: randomized clinical trial of the impact of exercise volume

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Objective: To assess whether exercise volume during phase II rehabilitation affects long-term clinical benefits in patients with coronary artery disease.
Design: Prospective randomized clinical trial with long-term follow-up.
Setting: Hospital outpatient clinic.
Subjects: Coronary artery disease patients (age 65 ± 9 years, 82% males) attending a phase II rehabilitation programme were randomized into two groups of exercise volumes: 40- versus 60-minute training sessions. Patients exercised for three days per week for seven weeks, at 65% of baseline oxygen uptake capacity. Next, they were followed up for 18 months. Out of 165 patients with coronary artery disease who completed the exercise intervention, 119 attended the 18-month follow-up assessment.
Main measurements: Body anthropometrics, resting haemodynamics, blood lipid profile, glycaemia, and C-reactive protein level, smoking behaviour, habitual physical activity, cardiovascular disease incidence and mortality.
Results: In total population, a significant worsening of various cardiovascular disease risk factors was found at 18 months follow-up ($P<0.05$), and few patients (27% of total group) adhered to the recommended minimal physical activity level. No difference in change of body anthropometrics, resting haemodynamics, blood lipid profile, glycaemia, and C-reactive protein level, and smoking behaviour was seen between different exercise volumes ($P>0.05$). In addition, total cardiovascular disease incidence (13% versus 22% in 40- versus 60-minute group, respectively) and habitual physical activity were not different between groups ($P>0.05$).
Conclusion: In patients with coronary artery disease following cardiac rehabilitation, the cardiovascular disease risk profile worsened significantly during long-term follow-up. A smaller exercise volume during phase II rehabilitation generated equal long-term clinical benefits compared to a greater exercise volume.

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Introduction

In the care of patients with coronary artery disease, cardiac rehabilitation prevents the recurrence of cardiovascular events, and increases life expectancy.[1–5] The lowering of cardiovascular disease and mortality risk could, at least in part, be attributed to an increase in exercise capacity,[6] lowering in visceral adipose tissue mass and systolic blood pressure,[7,8] improvement in blood lipid profile and glycaemic control,[9,10] and reduction in systemic inflammation.[11] As a result, clinical guidelines stress the importance of exercise training as part of cardiac rehabilitation, and recommend the implementation of this intervention strategy in the care of coronary artery disease patients.[12]

However, these clinical guidelines are limited by the lack of a detailed prescription of training modalities that should be preferred during exercise intervention.[12,13] In particular, the effect of a different exercise volume during training interventions in patients with coronary artery disease has received little interest.[14] Therefore, in a recent study we have examined the clinical benefits of a seven-week training intervention with a different exercise volume in patients with coronary artery disease.[14] It was found that training interventions with greater exercise volume did not generate more clinical benefits, in the early rehabilitation of patients with coronary artery disease.[14] Moreover, exercise interventions with a smaller volume seemed more effective in lowering waist circumference than exercise interventions with a greater volume.[14] From this study it remains to be established whether a different exercise volume during phase II rehabilitation will generate different clinical benefits during long-term follow-up. In fact, no single study has, to our knowledge, examined the effect of different training modalities during long-term follow-up, after phase II rehabilitation in patients with coronary artery disease.

In the present study, we assessed the effects of different training volumes in phase II cardiac rehabilitation on cardiovascular disease risk factors and disease incidence during a 18-month follow-up in patients with coronary artery disease.

Materials and methods

Subjects and study design

The subject selection and materials and methods in this study have been described previously.[14] In the previous study we examined the short-term effects of exercise intervention (at seven weeks) on cardiovascular disease risk factors and exercise capacity. In the current study we focus on the long-term clinical benefits of exercise intervention (after 18 months follow-up). Briefly, patients with coronary artery disease who completed phase II cardiac rehabilitation were invited to come for a follow-up examination 18 months after programme completion. Of these, some patients were unable (because of death or hospitalization, see Figure 1) and/or unwilling to take part. At baseline, patients presented with an acute myocardial infarction, or were referred to the unit because of revascularization of stable coronary artery disease. A majority of these patients were revascularized by percutaneous coronary intervention or coronary artery bypass graft surgery, while some received only medical treatment. The following exclusion criteria were applied on this sample: presence of severe pulmonary and renal comorbidity, and/or orthopaedic limitations precluding participation in the exercise intervention. Also, those patients presenting with myocardial ischaemia and/or severe ventricular arrhythmias during baseline cardiopulmonary exercise testing were excluded.

Patients were randomly assigned by coin to a 40- or 60-minute exercise session group, and included in a seven-week supervised exercise intervention. The group allocation was not blinded to the participating subjects. After the initial seven weeks of exercise training, the programme could be prolonged for another five weeks maximally. At entry of the intervention programme and at 18 months after programme completion, changes in body anthropometrics, resting haemodynamics, smoking behaviour, medication prescription, and blood parameters were collected. In addition, at 18 months of follow-up, habitual physical activity was assessed, and cardiovascular disease incidence and mortality rate was collected.

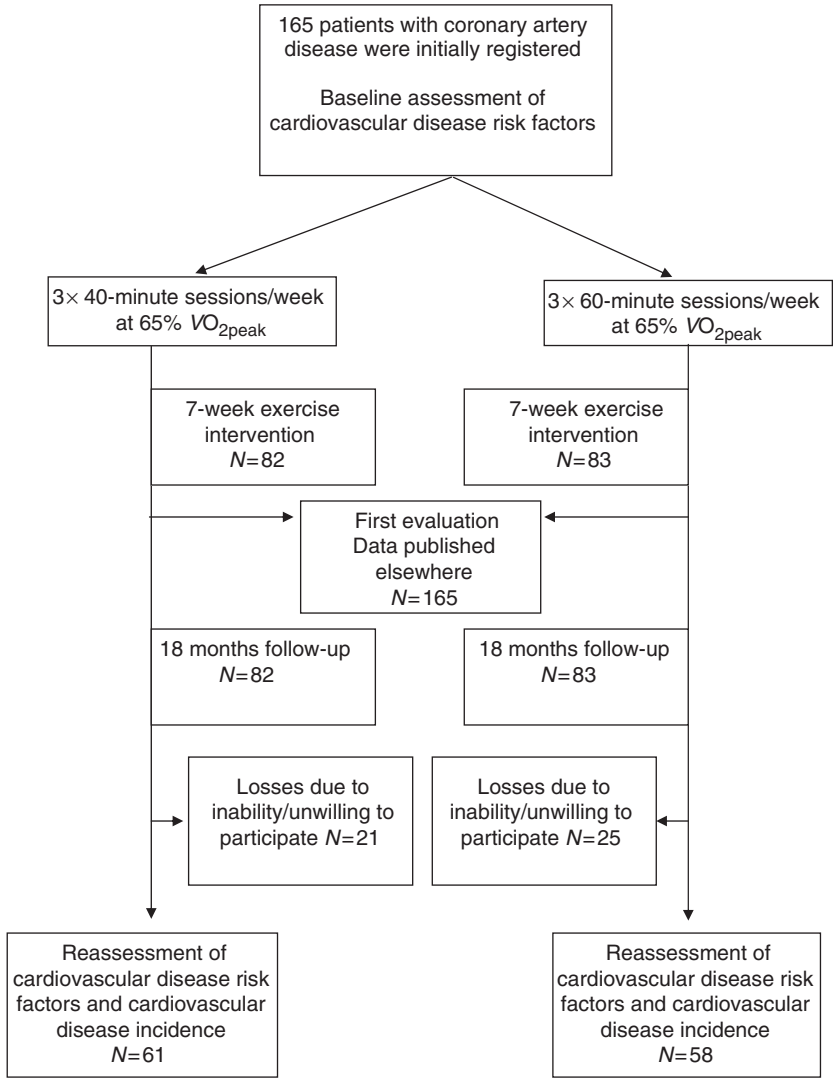

Figure 1 Study flowchart. VO_{2peak}, whole-body oxygen uptake capacity.

Measurements

All measurements were executed by the same investigators, regardless of subject group allocation. The investigators were blinded for group allocation. Data were collected and analysed by one investigator who was aware of subject group allocation (DH). Except for habitual physical activity and cardiovascular morbidity and mortality, the baseline and follow-up measurements were the same.

Body mass was measured to the nearest 0.1 kg using an analogue weight scale (Tanita model TBF-300, Tanita Corp., Tokyo, Japan) and height was measured to the nearest 0.1 cm. Body mass index was calculated from the ratio of weight (kg) to height (m^2). Waist circumference was

measured in standing position according to International Society for the Advancement of Kinanthropometry (ISAK) guidelines[15]: waist girth was quantified at the level of noticeable waist narrowing located approximately half way between costal border and iliac crest. The circumference was assessed twice, with averaging of two measurements.

At entry of exercise intervention, resting systolic and diastolic blood pressure were assessed on three non-consecutive days within one week at the same time of day, with averaging of three measurements. At 18 months of follow-up, resting systolic and diastolic blood pressure were assessed twice at the same day, with a 5 minute interval between measurements, and averaged. During this measurement, patients were seated for approximately 5 minutes, and blood pressure was measured manually.

Subjects arrived at the hospital by car or public transportation and reported at the laboratory at 08:00 following an overnight fast. After 20 minutes of rest, a venous blood sample was collected. Blood samples were immediately centrifuged at 1000 *g* and 4°C for 5 minutes, and analysed for following parameters: total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, and glycaemia by enzymatic colorimetry (Beckman Synchron LX 20 Analyzer, Beckman Coulter Inc., USA), and C-reactive protein by near-infrared particle immunoassay detection (Beckman Synchron LX 20 Analyzer, Beckman Coulter Inc., USA). Baseline blood samples were obtained prior to exercise intervention. The second blood sample was obtained after 18 months of follow-up.

Subjects were requested to report whether they were actively smoking, and how many cigarettes were smoked each day.

The International Physical Activity Questionnaire (IPAQ)[16] was used to assess habitual daily physical activity related to recreation and sports (of the last two weeks) at 18 months of follow-up. During a standard week, minutes engaged in moderate and vigorous sports physical activity were reported.

The rate of re-occurrence of cardiovascular events (coronary (re)stenosis, acute myocardial infarction, and/or need for coronary revascularization), and mortality, were collected during the 18-month follow-up period. Patients underwent a clinical examination every six months by the cardiologist, and were referred to our hospital in case of angina pectoris or suspected myocardial ischaemia. The (re)occurrence of coronary artery disease had to be confirmed by significant ECG changes during maximal exercise testing and/or coronary angiography. The need for repeat coronary revascularization was decided by the interventional cardiologist and/or cardiothoracic surgeon.

Interventions

The exercise training intervention included endurance exercises, as previously described.[14] No strength training exercises were executed. All subjects exercised under close supervision three days per week for a total duration of seven weeks. We exercised the subjects for seven weeks because most previous studies examining the effects of exercise intervention in patients with myocardial infarction used on average eight-week programmes.[13] Subjects were allowed to prolong the supervised exercise intervention (with continued registration of exercises), but this was not obligatory. Exercise training intensity was determined by baseline oxygen uptake capacity (VO_{2peak}) assessment: subjects exercised at a heart rate corresponding to 65% of baseline VO_{2peak}. One subgroup exercised for 60 minutes each exercise training session, and the other subgroup for 40 minutes each exercise training session. In both groups, exercise time for each training session was apportioned as follows: 42% on the treadmill, 33% on the cycle ergometer and 25% on the arm cranking device. The training intensity was guided by heart rate monitoring (Polar, Oy, Finland). The target heart rate was kept constant during exercise intervention. When beta-blocker treatment was changed, a new target heart rate was formulated by retesting the workload–heart rate relationship during cycling after four days of adjusted beta-blocker therapy.

In addition to exercise intervention, all patients followed education sessions about healthy nutrition and its relation to cardiovascular disease, and cardiovascular disease risk factor management. During these sessions, patients were advised

to adhere to a healthy food pattern and medication prescription, exercise regularly, quit smoking and avoid or cope with psychological stress.

All participating subjects signed an informed consent, stating the aim and protocol of this study. The hospital's ethical committee approved this study.

Statistical analysis

All data are expressed as means ± SD, and analysed by SPSS software programme for Microsoft Windows, version 15.0 (SPSS Inc., Chicago, IL, USA). We analysed data of those subjects who completed the entire study. At baseline, groups were compared by one-way analysis of variance (ANOVA) or by a chi-square test. During follow-up, changes of variables were compared between groups by ANOVA with repeated measures (with 95% confidence interval (CI) in each test). A two-tailed probability level of $P < 0.05$ was considered to be significant.

Results

Subjects ($n = 119$, body mass index $26.1 \pm 2.9\,kg/m^2$, age 65 ± 9 years) were revascularized by percutaneous coronary intervention, coronary artery bypass graft surgery or received medical treatment, and were using cardioprotective and/or lipid-lowering medications. Subjects were randomly assigned to the training regimen with 40- or 60-minute training sessions. Subjects' characteristics are reported in Table 1. All subjects completed the seven-week exercise intervention: 17.7 ± 2.8 and 17.0 ± 2.8 supervised exercise sessions were attended in the 40- and 60-minute training session groups, respectively, without differences between groups ($P > 0.05$). In the 40- and

Table 1 Baseline patient characteristics in the two groups

	40-minute sessions	60-minute sessions	*P*-value
General patient characteristics			
n	61	58	
Gender (*n* male)	50	48	0.91
Age (years)	63 ± 8	66 ± 9	0.09
Average follow-up (months)	20 ± 1	20 ± 2	0.19
Cardiac pathology/intervention			
Referred to hospital with			
Acute myocardial infarction (*n*)	26	28	0.54
Angina pectoris (*n*)	35	30	
Coronary arteries treated with			
Percutaneous coronary intervention (*n*)	43	33	0.07
Coronary artery bypass graft (*n*)	13	23	
Medical treatment (*n*)	5	2	
Medication prescription			
Ca antagonists (*n*)	15	9	0.22
Beta-blockers (*n*)	42	43	0.52
Nitrates (*n*)	13	18	0.23
ACE inhibitors (*n*)	36	31	0.54
Antiplatelets (*n*)	59	54	0.37
Statins (*n*)	45	46	0.48
Fibrates (*n*)	2	2	0.96
Metformins (*n*)	4	4	0.96
Other antidiabetics (*n*)	4	2	0.44
Exercise intervention features			
Supervised training sessions	17.7 ± 2.8	17.0 ± 2.8	0.18
Interval discharge-rehabilitation entry (days)	18 ± 9	21 ± 9	0.13

Data are expressed as means ± SD.

Table 2 Cardiovascular disease risk factors during 18 months of follow-up

	40-minute sessions		60-minute sessions		Overall effect	Interaction effect
	Baseline	18-month follow-up	Baseline	18-month follow-up	Follow-up	Session duration
Blood parameters						
Total cholesterol (mg/dL)	156 ± 35	162 ± 29	147 ± 29	160 ± 33	<0.01	NS
HDL-cholesterol (mg/dL)	47 ± 14	51 ± 15	46 ± 12	49 ± 12	<0.001	NS
LDL-cholesterol (mg/dL)	92 ± 31	97 ± 25	82 ± 25	96 ± 32	<0.01	NS
Triglycerides (mg/dL)	93 ± 39	114 ± 61	96 ± 45	122 ± 65	<0.001	NS
C-reactive protein (mg/dL)	0.39 ± 0.50	0.31 ± 0.32	0.39 ± 0.77	0.22 ± 0.20	0.08	NS
Glycaemia (mg/dL)	104 ± 16	108 ± 20	103 ± 14	112 ± 24	<0.001	NS
Resting haemodynamics						
Systolic blood pressure (mm/Hg)	127 ± 11	133 ± 16	124 ± 8	129 ± 16	<0.001	NS
Diastolic blood pressure (mm/Hg)	73 ± 6	71 ± 8	73 ± 5	70 ± 7	<0.01	NS
Actively smoking (*n*)	9	5	5	4	0.20	
Body anthropometrics						
Body weight (kg)	76.2 ± 12.4	75.4 ± 12.7	73.3 ± 11.0	74.5 ± 11.4	0.83	
Body mass index (kg/m^2)	26.0 ± 3.1	25.7 ± 3.4	25.9 ± 2.7	26.4 ± 3.2	0.81	
Waist circumference (cm)	95.2 ± 10.7	94.4 ± 11.2	94.2 ± 11.4	93.3 ± 10.0	<0.05	NS

No significant differences were found between groups at baseline ($P<0.05$).
HDL, high-density lipoprotein; LDL, low-density lipoprotein; NS, not significant.
Data are expressed as means ± SD.

60-minute session group, 9 ± 8 and 11 ± 8 training sessions were additionally completed in the rehabilitation centre ($P>0.05$ between groups). From study entry up to the long-term screening, patients were followed for 20 ± 1 and 20 ± 2 months, in the 40- and 60-minute session group, respectively, without differences between groups ($P>0.05$).

During follow-up, medication intake did not change significantly ($P>0.05$) for ACE inhibitors (from 56% to 60%, $n=$ from 67 to 71), nitrates (from 25% to 17%, $n=$ from 30 to 20), calcium antagonists (from 20% to 19%, $n=$ from 24 to 23), statins (from 76% to 75%, $n=$ from 90 to 89), fibrates (from 3% to 3%, $n=$ from 4 to 4), metformins (from 7% to 6%, $n=$ from 8 to 7), and other antidiabetics (from 5% to 4%, $n=$ from 6 to 5). Intake of beta-blockers (from 71% to 53%, $n=$ from 84 to 63), and antiplatelets (from 95% to 79%, $n=$ from 113 to 94) decreased significantly during follow-up ($P<0.05$), but without differences between groups ($P>0.05$).

Plasma total cholesterol, HDL-cholesterol, LDL-cholesterol, triglyceride and glycaemia levels increased significantly during long-term follow-up ($P<0.05$), without differences between groups ($P>0.05$) (see Table 2). Plasma C-reactive protein levels showed a trend for a decrease during follow-up ($P=0.08$), without differences between groups ($P>0.05$).

Systolic blood pressure increased significantly during follow-up ($P<0.05$), without differences between groups ($P>0.05$) (see Table 2). Diastolic blood pressure decreased significantly over time ($P<0.05$), without differences between 40- and 60-minute session groups ($P>0.05$).

During follow-up, waist circumference decreased significantly ($P<0.05$), without differences between groups ($P>0.05$) (see Table 2). No changes were observed for body weight and body mass index ($P>0.05$).

Total cardiovascular disease incidence, as well as type of cardiovascular events, was not different between 40- and 60-minute session groups at 18 months of follow-up ($P>0.05$) (Table 3).

At 18 months of follow-up, total habitual physical activity, as well as moderate-intensity and vigorous-intensity physical activity, was not different between groups (Table 3). Moreover, the number of patients achieving the minimally recommended physical activity was not different between groups ($P>0.05$).

Table 3 Cardiovascular disease incidence and habitual physical activity at 18 months of follow-up

	40-minute sessions	60-minute sessions	*P*-value
n	61	58	
Total cardiovascular disease incidence % (*n*)	13.1 (8)	22.4 (13)	0.18
Coronary (re)stenosis % (*n*)	9.8 (6)	17.2 (10)	0.24
Repeat coronary revascularization % (*n*)	9.8 (6)	13.8 (8)	0.50
Acute myocardial infarction % (*n*)	1.6 (1)	3.4 (2)	0.53
Death % (*n*)	3.3 (2)	1.7 (1)	0.53
Habitual physical activity			
Moderate-intensity (minutes/week)	107 ± 204	77 ± 131	0.36
Vigorous-intensity (minutes/week)	30 ± 96	29 ± 108	0.96
Total (minutes/week)	137 ± 226	106 ± 158	0.40
Achieving minimal physical activity % (*n*)[a]	29.5 (18)	25.8 (15)	0.66

[a]At least 150 minutes of exercise/week.
Data are expressed as means ± SD.

Discussion

In this randomized clinical trial, we found a progressive worsening of various cardiovascular disease risk factors during follow-up, and a low habitual physical activity in the total group. In addition, no significantly differences were found in changes of cardiovascular disease risk factors, as well as cardiovascular disease incidence at 18 months of follow-up, between groups who were randomized to a high or a low exercise training volume.

Despite the implementation of a phase II rehabilitation programme, various cardiovascular disease risk factors worsened during long-term follow-up in patients with coronary artery disease. Especially the significant increase in systolic blood pressure, plasma total cholesterol, LDL-cholesterol, glycaemia and triglyceride level might be an indication of suboptimal secondary cardiovascular disease prevention. Moreover, there was a lack of habitual physical activity at 18 months of follow-up: only 27% of the total group adhered to the minimal physical activity level that is required to obtain significant health benefits. The long-term change in cardiovascular disease risk factors after completion of phase II rehabilitation in patients with coronary artery disease has been investigated previously, and it is found that most cardiovascular disease risk factors tend to worsen over time.[17] Such worsening could, at least in part, be due to a lack of adherence to exercise prescription. Reid *et al*. found a significant decrease in habitual physical activity during long-term follow-up after hospital discharge in patients with coronary artery disease.[18] The decrease in habitual physical activity was most pronounced in females, patients with low habitual activity before revascularization and/or percutaneous coronary intervention.[18] Data from previous studies[17,18] are in support to our results, and seem to indicate that patients are not easily convinced to change their lifestyle habits permanently after short-term exercise intervention.

To improve exercise adherence during long-term follow-up in cardiac patients, telephone intervention, regular visits and/or counselling sessions are shown to be effective.[19–21] Such intervention might contribute to an improved secondary cardiovascular disease prevention. In accordance, the recently published GOSPEL trial by Giannuzzi *et al.* indicated that continued patient interaction and monitoring, as well as continuation of lifestyle intervention (phase III rehabilitation), is required to obtain long-term clinical benefits.[1] Previously published data are in support of this suggestion.[22,23]

Besides the continuation of therapy in a phase III rehabilitation setting to optimize the clinical benefits of exercise interventions in patients with coronary artery disease, it seemed plausible that changes in training modalities during phase II cardiac rehabilitation might affect long-term outcome. Recently, the short-term effect of exercise volume on clinical benefits during a seven-week

rehabilitation intervention in patients with coronary artery disease has been investigated by our laboratory.[14] A higher exercise volume did not improve short-term outcome and cardiovascular disease risk factor control with greater magnitude, when compared with a lower excercise volume. In the present study, a higher exercise volume during phase II cardiac rehabilitation had no greater impact on long-term clinical benefits. The lack of a long-term difference between groups might, at least in part, be related to the relatively short intervention period. It might be speculated that by prolonging the supervised exercise intervention, differences between groups might have occurred. In addition, the difference of exercise volume between trials might have been too small. It might be assumed that a greater difference in exercise volume between trials might increase the chance of detecting significant long-term differences groups. However, no data on this matter are available in the literature at this moment.

An important clinical implication of our data is that a progressive worsening of various cardiovascular disease risk factors occurs during long-term follow-up after completion of phase II cardiac rehabilitation. This worsening could not be prevented by an increase in exercise volume. The lack of habitual physical activity could be more related to the progressive worsening of the cardiovascular disease risk profile. Further study is needed to analyse the impact of different phase II and III rehabilitation approaches on long-term cardiovascular disease risk factor control in the care of patients with coronary artery disease. A suggestion might be to systematically incorporate regular patients visits, a closer follow-up and/or information sessions after completion of supervised phase II cardiac rehabilitation.

This study is prone to several limitations. First, there was a significant subject drop-out during long-term follow-up. Even though we attempted to reassess as many subjects as possible, our data should be interpreted with caution. Second, the exercise intervention was of a relatively short duration. However, we wanted to assess whether a difference in exercise session duration during short-term exercise intervention would contribute to different long-term lifestyle changes. Moreover, most patients with coronary artery disease prefer to participate in exercise regimens for such short durations. As a result, our study assessed the effects of cardiac rehabilitation as it is currently often executed. Third, data on food intake are lacking in this study. These data might have contributed to a greater understanding of the progressive worsening of various cardiovascular disease risk factors. Fourth, we used the IPAQ questionnaire to estimate habitual physical activity. Such a questionnaire should be accompanied by an objective measurement of habitual physical activity (such as heart rate monitoring).

In conclusion, during long-term follow-up, many of the benefits on cardiovascular risk factor control and lifestyle of a phase II rehabilitation programme tend to disappear. A smaller exercise volume during phase II cardiac rehabilitation generates the same long-term clinical benefits as a greater exercise volume.

Clinical messages

- After completion of phase II cardiac rehabilitation, many of the clinical benefits are lost.
- In the long term, smaller exercise volumes generate the same clinical benefits as greater exercise volumes, when exercising for seven weeks.

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Previous presentation or conflicts of interest

None.

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