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Abstract

Background: As lifestyle adherence and risk factor management following completion of cardiac rehabilitation (CR) have been shown to be problematic, we developed a brief self-regulation lifestyle programme for post-CR patients.

Design: Randomized-controlled trial.

Methods: Following completion of CR 210 patients were randomized to receive either a lifestyle maintenance programme ($n = 112$) or standard care ($n = 98$). The programme was based on self-regulation principles and consisted of a motivational interview, seven group sessions, and home assignments. Risk factors and health behaviours were assessed at baseline (end of CR) and 6 months thereafter.

Results: ANCOVAs showed a significant effect of the lifestyle programme after 6 months on blood pressure, waist circumference, and exercise behaviour.

Conclusion: This trial indicates that a relatively brief intervention based on self-regulation theory is capable of instigating and maintaining beneficial changes in lifestyle and risk factors after CR.

Keywords

Adherence, cardiac rehabilitation, lifestyle, maintenance, randomized controlled trial, risk factors, self-regulation

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Introduction

The modification of risk factors and related health behaviours lies at the very core of adequate cardiac disease management. Meta-analytic reviews have shown cardiac rehabilitation (CR) programmes to have positive effects on blood pressure, cholesterol, body weight, smoking behaviour, physical exercise dietary habits, mortality and new cardiac events.^{1,2} Nevertheless, evidence is emerging that the majority of patients fail to achieve secondary prevention targets in the long term.^{3–6} Seemingly, many cardiac patients adopt healthier lifestyles during CR, but relapse into old habits when returning to everyday life.^{7,8} Research on the maintenance of CR benefits shows that up to 60% of patients relapse over the first 6 months.^{9–11} Qualitative research on patients' perspectives suggest that motivation for lifestyle change tends

to wane around 3 months after the event – a time when most patients start feeling better and the initial shock has worn off.^{12,13} Typically, most cardiac rehabilitation programmes in Europe commence soon after hospital discharge and terminate around 8–12 weeks thereafter. Thus, patients are left to their own devices at an especially vulnerable time under the erroneous assumption that they will be able to self-maintain their new, healthy lifestyles. Consolidating lifestyle habits, however, requires continued attention and appropriate guidance.

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That being said, merely extending programme duration or increasing contact frequency is not sufficient to prevent deterioration of risk factors and lifestyle behaviour.^{14,15} Rather, programmes should be tailored to the psychological mechanisms specific to the maintenance of behaviour, as these differ from those involved in the adoption of new behaviour.^{16,17} For example, whereas planning and implementation strategies play a role in moving from resolution to action, maintenance of the changed behaviour is governed by, for instance, outcome satisfaction, coping self-efficacy, provision of feedback, and social support.^{16,18,19} Thus, lifestyle maintenance interventions should be stage-matched and draw upon theory-based behaviour change techniques.^{18,20}

Self-regulation theories of behaviour are centred on the idea that all behaviour is goal-directed and outline the skills and cognitions elementary to the different phases of goal-attainment, such as self-efficacy, goal-setting, planning, self-monitoring, feedback, anticipatory coping, or coping self-efficacy. Trials and meta-analyses in various domains show that lifestyle modification programmes based on self-regulation theory are successful in sustaining weight loss,^{21,22} physical activity,^{8,23,24} and healthy eating.²⁰ Within the field of cardiac rehabilitation, there are no comprehensive lifestyle maintenance programmes based on self-regulation theory that we are aware of. Existing lifestyle maintenance programmes show inconsistent results.^{25–32} Furthermore, these programmes are invariably of long duration (i.e. 12–36 months) and most involved frequent patient contact (i.e. between 50–100 sessions).

We developed a relatively brief self-regulation programme targeting maintenance of lifestyle change and risk factor modification in post-CR patients. Following a 3-month outpatient CR programme, patients were randomized to either the lifestyle intervention or the control condition. The aim of the present study is to investigate whether this self-regulation lifestyle programme is capable of instigating and maintaining changes in risk factors and related health behaviours at 6-month follow up.

Method

Trial design

Upon completion of a comprehensive outpatient CR programme, patients were randomized to either the intervention (lifestyle programme) or the control group (individual interview + standard care). Patients were examined 6 months thereafter. The primary outcome was changes in modifiable risk factors and related health behaviours.

Participants and procedure

Participants were recruited between January 2008 and January 2010 from a major cardiac rehabilitation centre (Rijnlands Revalidatie Centrum) in the Netherlands. All Dutch-speaking patients under 75 who had been diagnosed with ischaemic coronary heart disease and who were currently not receiving psychiatric treatment were eligible for participation. Approval from the relevant Medical Ethics Committee was obtained for the study. Upon completion of a 3-month CR programme, eligible patients were invited for participation in the study by their physical therapists. Upon receiving written informed consent, participants were randomized to either the intervention group or the control group using blocked randomization. In order to allow for attrition in the intervention group, participants were allocated in unequal numbers to the arms of the study. For every block of 30 participants, 14 were allocated to the control group and 16 were allocated to the intervention group by means of a random-number table. Randomization was carried out by the coordinating secretariat using opaque sealed envelopes. All participants were invited for a structured interview during which biometrical measurements were taken, risk factors and health behaviours were assessed, and self-report questionnaires were completed (T1). Using the same procedure, posttreatment assessment of outcomes was carried out 6 months thereafter (T2) by trained health psychologists who were blind to treatment allocation.

Intervention

Patients in the intervention group and the control group both attended a comprehensive 3-month outpatient CR programme. In accordance with the Dutch Guidelines for Cardiac Rehabilitation,³³ the comprehensive CR programme comprised: (a) physical training sessions three times a week, consisting of cycling and weight training at a level of intensity of 70% of initial VO₂ max (supervised by a physical therapist); (b) four 2-hour psycho-educational sessions on the pathophysiology of arteriosclerotic heart disease (led by a physician), healthy eating (led by a dietician), exercise (led by a physical therapist), and psychological adjustment (led by a social worker); (c) a 2-hour practical session on progressive relaxation (led by a physical therapist); and (d) if appropriate, consultations and sessions on weight reduction, quitting smoking, and stress reduction and/or stress management (led by psychologists, dieticians, and social workers).

Upon completion of CR, patients in the intervention group entered the self-regulation programme focused

on maintenance of lifestyle change. The average time between the end of CR and the start of the intervention was 2–4 weeks. The programme started with an individual 1-hour motivational counselling session with a health psychologist (week 1). During the interview important (life) goals for the patients were explored, on the basis of which a personal health goal was set. Potential barriers to goal achievement, and costs and benefits of change were examined. Patients then attended five 2-hour group sessions (weeks 3, 5, 7, 9, and 11) and two 2-hour follow-up sessions (weeks 15 and 19). These sessions were held at the cardiac rehabilitation centre and included up to 12 members/group. Group sessions were structured around the self-regulatory phases of goal pursuit,¹⁸ in particular the maintenance phase, and focused on enhancing the relevant self-regulation skills. For instance, patients were encouraged to self-monitor their goal-related behaviour, develop specific action plans when necessary, form realistic outcome expectancies, obtain progress-related feedback, and discuss problem-solving strategies. Patients were also encouraged to bring their partner (or a significant other) to

one of the sessions in order to increase social support. Sessions were led by a health psychologist. Table 1 describes the content of the sessions classified according to the CALORE-taxonomy of behaviour change techniques.³⁴ Psychological trials have been criticized for poor and imprecise reporting of intervention content;^{34,35} CALORE offers a standardized means of reporting the intervention content of behaviour change interventions.³⁴

The cost of providing the lifestyle intervention was estimated by considering professional time spent and additional general and/or administrative costs. This included the time expenditure of the health psychologists performing clinical duties, such as intake interviews and running the group sessions. Professional time spent designing the programme and developing the intervention was not included. Based on 12 participants/group, it was estimated that health psychologists spent an average of 45 hours/group: approximately 30 hours of which were spent on preparing and leading the group sessions, and approximately 15 hours spent on the individual intake interviews. General and administrative costs included the printing of the intervention

Table 1. Content of the intervention by session based on the CALO-RE Taxonomy³⁴

Behaviour change techniques (number on CALO-RE Taxonomy)	Session						
	1	2	3	4	5	6	7
Information on consequences (1,2)	x						
Self-monitoring of behaviour (16)	x	x					
Normative information (4)		x					
Focus on past success (18)	x	x					
Goal-setting (5, 6)		x					
Action planning (7)			x				
Set graded tasks (9)			x				
Agree behavioural contract (25)			x	x			
Use prompts/cues (23)				x			
Environmental restructuring (24)				x			
Plan social support (29)				x			
Prompt practice (26)				x	x		
Barrier identification/problem-solving (8)					x		
Self-monitoring of behaviour/outcome (16, 17)				x	x	x	x
Feedback on performance (19)					x	x	x
Facilitate social comparison (28)						x	
Rewards contingent on success (24)						x	
Use of follow-up prompts (27)							x
Review of goals (10, 11)						x	x
Stress management/emotional control (36)					x	x	
Relapse prevention/coping planning (35)						x	x

Sessions 1–5 were biweekly over a period of 3 months. Sessions 6 and 7 were booster sessions in the 4th and 5th month. Session 4 included the patient's partner or a 'significant other'.

materials and costs associated with securing meeting space for the group sessions. Thus, the projected cost of running one lifestyle group with 12 group members would total an approximate of 1500 Euros.

Patients in the control group were also invited for a 1-hour individual interview with a health psychologist. During the interview, patients were encouraged to set a salient personal health goal. However, no motivational interviewing techniques were used to increase motivation for change and the interview was not followed up by group sessions.

Patients in both the intervention and the control group received standard care, which consisted of regular follow-up appointments with the patient's cardiologist.

Outcome measures

Physiological measurements. Body weight was measured with shoes removed using calibrated digital weighing scales (Microlife WS100). Blood pressure was measured using calibrated automated blood pressure monitors (Microlife BPA100) according to the American Heart Association recommendation for blood pressure measurement.³⁶ Waist circumference was measured to the nearest 0.1 cm at the level of the umbilicus while standing using inflexible tape.³⁷ Fasting blood lipid samples were collected and analysed by SCAL Diagnostic Services (Leiden, the Netherlands), a major medical laboratory in the region. Total cholesterol (CHOL2 reagent; Roche Diagnostics, Almere, the Netherlands), high-density lipoprotein (HDL) cholesterol (direct HDL reagent, HDLC3; Roche), and triglycerides (TRIGL reagent; Roche) were measured from fasting serum, using the Cobas C and Cobas Integra systems (Roche). The cholesterol assays meet the National Institutes of Health/National Cholesterol Education Program goals for acceptable performance. Low-density lipoprotein (LDL) cholesterol was calculated by SCAL Diagnostic Services using the Friedwald formula.

Health behaviours. Exercise behaviour was assessed using Yamax Digiwalker SW-200 pedometers, which have been validated for accuracy and reliability.³⁸ Participants were asked to wear the pedometer on 7 consecutive days, positioning the pedometer on the thigh, and record the steps accumulated over the day in an activity log. Dietary behaviour was assessed using a validated 56-item food frequency questionnaire which assesses dietary fat and fruit and vegetable intake and includes the types of food most frequently consumed in the Netherlands.^{39,40} Fruit and vegetable intake was calculated in g/day. Dietary fat is expressed in terms of a fat score, which ranged between 12 and 60, with

higher scores reflecting higher fat intake. Smoking behaviour was measured using self-report.

Clinical data. Disease severity, admitting diagnosis, cardiac history, comorbidity, and information on currently prescribed medications were obtained from medical records and scored by a physician. The New York Heart Association (NYHA) functional capacity was used to index disease severity.

Psychosocial variables. Self-reported demographic data included age, gender, marital status, and education. Depression was assessed with the Dutch version of the Symptom Check List-90 (SCL-90), which is a well-validated and widely used self-report scale for the measurement of psychological distress, including depression.⁴¹ The depression sub-scale consists of 16 items that are scored on a 5-point scale, ranging from 0 (no complaints) to 4 (maximal complaints).

Statistical analysis

Based on previous meta-analyses of lifestyle modification programmes for CHD patients,^{1,2} effect sizes of 0.1–0.3 can be expected. A priori analyses carried out in G*Power⁴² showed that a sample of 164 patients would be sufficient to detect an effect size of at least 0.1 with 80% power at the 5% significance level.

Data were analysed using SPSS for Windows version 18.0. Differences between participating and non-participating patients and differences in baseline characteristics between the experimental and the control group were tested using t-tests with Bonferroni correction and Pearson's chi-squared tests as appropriate. Repeated-measures analyses of covariance (ANCOVA) controlling for age, disease severity, and cardiac history were computed across time points in order to test the change from baseline. Analyses were repeated without covariates.⁴³ Prior to analyses, the assumptions for ANCOVA, including normality and homogeneity of variance and covariance, were checked. Data are reported as mean \pm standard deviation and 95% confidence interval. Categorical data are reported as counts and percentages. Data from 89 patients in the intervention group and 87 patients in the control group were available for analysis. To address potential bias created from missing data, missing values (3.79 ± 2.91) were imputed using multiple imputation. Multiple imputation is a missing-data technique that calculates plausible estimates of missing values using the other outcome and control variables as predictors and has been shown to be more robust than other methods of handling missing data in trials.⁴⁴ Because the data showed an arbitrary missing data pattern, the Markov Chain Monte Carlo

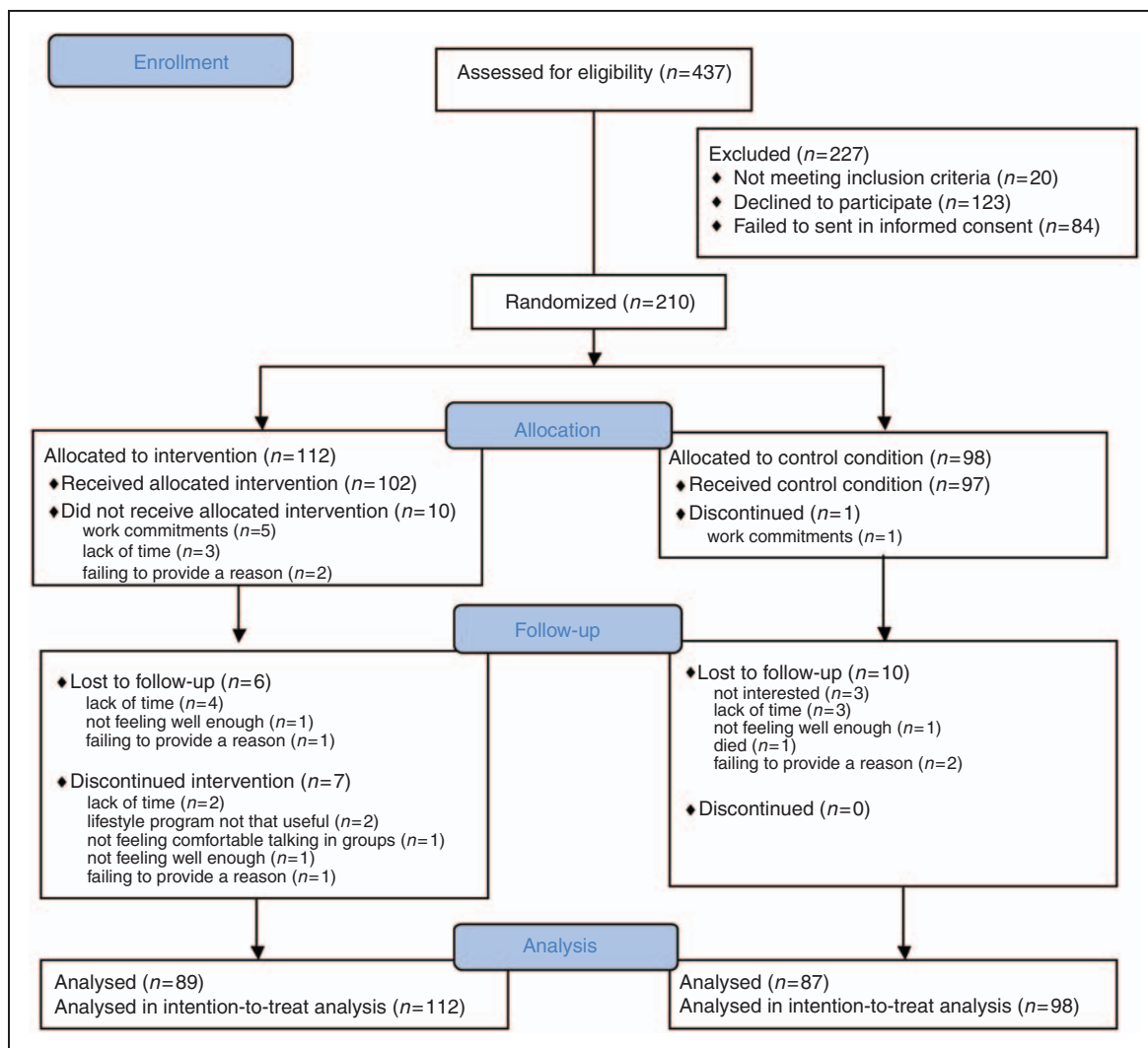


Figure 1. Participant flow.

algorithm was used to generate five imputation data sets, which were analysed individually using ANCOVA and showed similar results. Furthermore, intention-to-treat analyses were carried out using the last-observation-carried-forward (LOCF) procedure including all randomized patients ($n = 210$) for whom baseline data were available.

Results

Participant flow

A total of 437 consecutive patients were informed about the study by their physiotherapist three weeks before the end of the cardiac rehabilitation programme. The flow diagram is displayed in Figure 1. A total of 123 non-participants consented to the release of self-report data for comparison purposes. A series of t-tests with

Bonferroni correction and Pearson's chi-squared tests showed that non-participants did not differ significantly from participants on demographic characteristics or self-reported cardiac risk factors (data not shown). The most frequently mentioned reasons for refusal were dislike of the format (group meetings) or the self-regulation intervention programme itself ($n = 23$), lack of time ($n = 21$), lack of interest ($n = 16$), the idea that their lifestyle did not need further improving ($n = 14$), and not wanting to dwell on their cardiac disease ($n = 10$). Further reasons included work commitments ($n = 7$), transportation problems ($n = 5$), can deal with it myself ($n = 5$), failing to provide a reason ($n = 7$), or 'other reasons' ($n = 15$). 294 patients indicated that they were willing to participate, of whom 210 sent in informed consent. Hereafter, 11 patients dropped out due to work commitments ($n = 6$), lack of time ($n = 3$), and failing to provide a reason ($n = 2$), leaving a total of

Table 2. Demographic and clinical characteristics

Characteristic	Intervention (n = 102)	Control (n = 97)
Gender		
Men	80 (78.4)	81 (84.4)
Women	22 (21.6)	15 (15.6)
Age (years)	56.6 ± 9.2	58.8 ± 9.3
Marital status		
Single/divorced	19 (18.8)	14 (14.7)
Married/partnered	82 (81.2)	81 (85.3)
Education		
Primary education	5 (5.0)	6 (6.3)
Secondary education	66 (65.3)	67 (70.5)
Tertiary education (college/university)	30 (29.7)	22 (23.2)
Type of work		
Full-time or part-time	54 (53.5)	47 (50.0)
Home/retired	47 (46.5)	47 (50.0)
Diagnosis		
Myocardial infarction	42 (41.2)	46 (47.4)
CABG	32 (31.4)	23 (23.7)
PCI	19 (18.6)	16 (16.5)
Arrhythmias	4 (3.9)	7 (7.2)
Other ^a	5 (4.9)	5 (5.2)
Antecedent cardiac history ^b		
Yes	54 (52.9)	41 (42.7)
No	48 (47.1)	55 (57.3)
NYHA		
I	63 (63.0)	57 (63.3)
II	26 (26.0)	23 (25.7)
III	11 (11.0)	8 (8.8)
IV	0 (0.0)	2 (2.2)
Blood pressure (mmHg)		
Systolic	138 ± 15.1	139 ± 17.4
Diastolic	84.2 ± 9.58	83.36 ± 9.11
BMI (kg/m ²)	28.0 ± 3.60	28.0 ± 3.90
Waist circumference	102 ± 10.1	103 ± 10.8
Cholesterol (mmol/l)		
Total	3.96 ± 0.92	3.98 ± 0.91
HDL	1.22 ± 0.30	1.17 ± 0.33
LDL	2.09 ± 0.76	2.12 ± 0.83
Triglycerides	1.57 ± 0.92	1.75 ± 0.99
Smoking	7 (6.9)	8 (8.4)
Physical activity (steps/day)	8047 ± 3328	8061 ± 3971
Dietary behaviour		
Fat intake (fat score)	16.5 ± 6.05	16.3 ± 6.00
Fruit and vegetable intake (g/day)	470 ± 229	429 ± 212

Values are n (%) or mean ± SD. ^aProsthetic valve or valve repair surgery (intervention n = 3, control n = 2), angina pectoris (intervention n = 2, control n = 3). ^bIncludes antecedent cardiac events such as myocardial infarction, CABG, PCI, and arrhythmias. BMI, body mass index; CABG, coronary artery bypass surgery; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.

199 patients who received the allocated intervention or control condition. Demographic and clinical characteristics are displayed in Table 2.

Compliance and pharmacological treatment

In the intervention group, 83.7% of patients attended at least five out of seven sessions, 69.4% attended six sessions, and 31.6% attended all sessions. Patient satisfaction with the self-regulation intervention was high. On a scale from 0–10, with higher scores reflecting greater satisfaction, patients' average rating of the intervention was 8.1 ± 0.98 (n = 94).

In accordance with the Dutch Guidelines for Cardiovascular Risk Management,⁴⁵ all patients in the study were treated with β-blockers, ACE inhibitors, antiplatelet agents, and statins.

Risk factor change

As is shown in Table 3, repeated-measures ANCOVAs revealed a significant time × group interaction for systolic blood pressure and waist circumference. The mean change from T1 to T2 in systolic blood pressure in the intervention group was −6.86 mmHg (95% CI −9.45 to −4.27), whereas in the control group this was −1.45 mmHg (95% CI −4.80 to 1.89). For waist circumference, the mean change in intervention group was −1.18 cm (95% CI −2.00 to −0.37) and the mean change in the control group was +0.63 cm (95% CI −0.31 to 1.57). Furthermore, there was a near-significant (p = 0.067) time × group effect for diastolic blood pressure (mean change in intervention group −3.80 mmHg, 95% CI −5.64 to −1.95; mean change in control group −1.16 mmHg, 95% CI −3.32 to 0.10). There were no significant group differences for BMI or any of the cholesterol outcomes. Repeating the repeated-measures ANCOVAs using intention-to-treat (LOCF procedure) showed that significant results remained with the exception of systolic blood pressure, which became a trend towards significance ((F1,204) = 3.54, p = 0.061).

Health behaviour change

Repeated-measures ANCOVAs showed a significant time × group interaction for physical activity (Table 4). The mean change in the intervention group was +1142 steps/day (95% CI 338 to 1947), whereas in the control group this was −522 steps/day (95% CI −1039 to −5.45). There were no significant group differences for dietary behaviour (fat intake and fruit and vegetable intake; Table 4). Repeating the repeated-measures ANCOVAs using intention-to-treat (LOCF procedure) confirmed the significant result for physical activity

Table 3. Change in risk factors between end of cardiac rehabilitation (T1) and 6-month follow up (T2)

Variable	Intervention (n = 89)		Control (n = 87)		Group effect ^a			
	T1	T2	T1	T2	Adjusted F (df = 1,171) ^b	p	Unadjusted F (df = 1,174)	p
Systolic blood pressure (mmHg)	138 ± 15	131 ± 14	139 ± 18	138 ± 17	6.28	0.013	6.49	0.012
Diastolic blood pressure (mmHg)	83.8 ± 9.7	80.0 ± 8.7	83.4 ± 9.3	82.3 ± 10.0	3.41	0.066	3.41	0.067
Waist circumference (cm)	102 ± 10	100 ± 10	103 ± 11	103 ± 11	8.63	0.004	8.45	0.004
BMI (kg/m ²)	27.8 ± 3.4	27.8 ± 3.5	28.0 ± 4.0	28.1 ± 4.3	0.63	0.428	0.51	0.478
Total cholesterol (mmol/l)	3.90 ± 0.88	3.83 ± 0.85	3.97 ± 0.90	3.95 ± 0.94	0.08	0.780	0.08	0.953
Triglycerides (mmol/l)	1.59 ± 0.99	1.50 ± 0.81	1.64 ± 0.83	1.65 ± 1.00	0.63	0.429	0.20	0.658
HDL (mmol/l)	1.19 ± 0.30	1.20 ± 0.75	1.18 ± 0.33	1.19 ± 0.33	0.003	0.957	0.005	0.942
LDL (mmol/l)	2.04 ± 0.75	2.03 ± 0.72	2.10 ± 0.83	2.04 ± 0.82	0.28	0.598	0.73	0.393

Values are mean ± SD. ^aTime × treatment interaction by repeated-measures ANOVA. ^bAdjusted for age, disease severity, and cardiac history. BMI, body mass index; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Table 4. Change in health behaviours between end of cardiac rehabilitation (T1) and 6-month follow up (T2)

Variable	Intervention (n = 89)		Control (n = 87)		Group effect ^a			
	T1	T2	T1	T2	Adjusted F (df = 1,171) ^b	p	Unadjusted F (df = 1,174)	p
Physical activity (steps/day)	8093 ± 3508	9235 ± 3852	8156 ± 4280	7634 ± 3844	11.75	0.001	11.86	0.001
Dietary behaviour								
Fat score	16.8 ± 5.9	16.3 ± 5.8	16.5 ± 5.9	16.8 ± 5.9	1.44	0.232	1.02	0.314
Fruit and vegetable intake (g/day)	467 ± 228	494 ± 234	441 ± 211	457 ± 199	0.46	0.498	0.11	0.743

Values are mean ± SD. ^aTime × treatment interaction by repeated-measures ANOVA. ^bAdjusted for age, disease severity, and cardiac history.

($F(1,190) = 8.63$, $p = 0.004$). As depression can impede lifestyle change and maintenance, we repeated the analyses including depression amongst the covariates. This did not alter the results. With regards to quitting smoking, there were too few smokers in the cohort ($n = 11$) to conduct meaningful analyses.

Discussion

The lifestyle intervention for post-CR patients showed effects on several risk factors and related lifestyle behaviours at 6-month follow up. Benefits were evident for blood pressure, waist circumference, and exercise behaviour (average steps/day). Furthermore, the intervention was well received by patients as indicated by high satisfaction ratings and good adherence to the sessions. Meta-analyses of lifestyle modification programmes for cardiac patients typically report small effect sizes for risk factors and small to moderate effect sizes for lifestyle changes.^{1,2,14} However, evidence from large population studies suggests that risk factors are multiplicative and that, jointly, small individual reductions lead to clinically meaningful improvements in risk

factor profile.⁴⁵ We found reductions of 6.9 mmHg in systolic blood pressure for the intervention group as compared to 1.5 mmHg for the control group. This is comparable to the magnitude of changes found by earlier effective trials of lifestyle modification in cardiac patients.^{28,46} Evidence from healthy population studies suggests that relatively small reductions in blood pressure can lead to large reductions in CHD-related mortality, with systolic blood pressure being 2-mmHg lower than usual leading to a 7% decrease in mortality.⁴⁷ Furthermore, we observed a reduction in waist circumference of -1.2 cm in the intervention group as compared to an increase of 0.6 cm in the control group. Earlier trials have reported changes of the same order of magnitude for waist circumference.^{48,49} A recent meta-analysis from individual patient data showed that high waist circumference is directly related to mortality in CHD patients.⁵⁰ However, evidence is emerging that it may be the combined effect of central adiposity and low cardiorespiratory fitness that is especially detrimental.⁵¹ Therefore, (relatively small) reductions in waist circumference in combination with improved fitness levels may be able to meaningfully

alter the association with mortality. We observed an increase in physical activity from 8093 to 9235 steps/day for the intervention group as compared to a reduction in daily steps from 8156 to 7634 for the control group. Current guidelines for physical activity recommend 30–60 minutes/day of moderate-intensity physical activity on ≥ 5 days/week.⁵² This equates to 8000–9000 steps/day;⁵³ a target that is reached by the lifestyle intervention group, but not the control group. As large reductions in mortality have been reported for exercise adherence in CHD patients,⁵⁴ it is promising that a relatively brief lifestyle intervention post cardiac rehabilitation is capable of maintaining and even further increasing this behaviour.

We did not find effects on any of the cholesterol outcomes but this may be explained by the use of lipid-lowering medication in our study cohort. Recommended target levels for cholesterol management include total cholesterol <4.0 mmol/l; LDL cholesterol <2.5 mmol/l; HDL cholesterol >1.0 mmol/l (men) and >1.2 mmol/l (women) and triglycerides <1.7 mmol/l.^{52,55,56} In our sample, mean cholesterol levels were all around or below these target levels (Table 3), indicating that the majority of patients met these standards both at T1 and T2. Similarly, our lack of findings with regard to dietary behaviour may be explained by ceiling effects, as evidenced by the relatively high fruit and vegetable intake and low fat scores in our sample. According to the joint WHO/FAO expert consultation,⁵⁷ the recommended fruit and vegetable intake to reduce the risk of CHD, stroke, and high blood pressure is ≥ 400 g/day. In our cohort, patients' fruit and vegetable consumption was already sufficient before the start of the intervention (467 g/day for the intervention group and 441 g/day for the control group) – and even slightly increased at 6-month follow up. The instrument used to assess fat intake did not allow computation of either dietary fat in g/day or daily percentage of energy from fat, which prevents absolute comparisons with recommended target levels. However, previous studies using this fat-questionnaire reported average fat scores of 27.2³⁹ and 27.5⁵⁸ in healthy Dutch populations. The recorded fat scores in our sample were well below these averages at 16.3 and 16.8 for the intervention and control group respectively. The 3-month outpatient CR programme that all participants attended prior to entering our study included a fairly intensive focus on healthy nutrition, which may have led to near-optimal nutrition habits at the start of the intervention.

Previous studies evaluating comprehensive maintenance programmes for cardiac patients show inconsistent results. Some found effects on both risk factor reduction and health behaviours³² and others showed benefits in terms of maintained lifestyle change but not

risk factors.^{29–31} Yet others showed no effects on either risk factors or health behaviours.^{25–27} Such differences in effectiveness are not uncommon. Several researchers have pointed out that the efficacy of both the various components of secondary prevention programmes and the behaviour change techniques used is unclear.^{59,60} A recent systematic review on physical activity programmes after CR showed that more extensive intervention programmes using a combination of cognitive techniques and behavioural strategies were most successful in sustaining exercise behaviour in post-CR patients.⁸ Earlier meta-analyses on secondary prevention programmes, however, showed that lengthy, more complex programmes are not necessarily better.^{2,14} Our findings suggest that a relatively brief, self-regulation intervention may be more effective than some of the longer, more complex, and expensive programmes. Future research should investigate what constitutes the optimal mix of duration, contact frequency, and (theory-based) behaviour change techniques for this type of maintenance interventions.

Limitations

Although adequately powered, the extent to which our findings can be generalized to the population at large may be limited by our relatively small sample size. Also, the small number of participants meant that clinical benefit in terms of mortality and reinidence could not be established as a result of low event rates. A second limitation concerns the use of self-report measures for the assessment of health behaviour. Considering the importance of smoking cessation in risk reduction, the validity of this self-report outcome could have been verified using biochemical methods of assessment. Furthermore, exercise was measured by pedometer assessment. Pedometers have been shown to be a more reliable and valid means of assessing exercise than physical activity questionnaires.⁶¹ Nonetheless, future studies might also include measures of cardiorespiratory fitness, such as maximal work capacity (max Watt) and maximal oxygen consumption (VO_2 max), that are based on cycle ergometer testing. Finally, our findings may be biased by self-selection; even though we found no differences between participants and non-participants, all patients were attending CR. Despite its effectiveness, in Europe typically less than 50% of patients participate in CR programmes.⁶² Thus, it may be only the highly motivated, health-conscious patients that are attracted to lifestyle interventions such as ours. It remains to be seen whether our findings can be generalized to clinical populations with heart disease and populations known to be at a disadvantage for participation in CR, such as women, ethnic minorities, or the elderly.

In conclusion, this trial indicates that a relatively brief, self-regulation-based lifestyle programme is capable of inciting and maintaining improvements in lifestyle and risk factor modification. The generalizability of these findings is limited by our relatively small sample size, but first results suggest that such a theory-based programme may be an efficient means of aiding patients in sustaining lifestyle change and risk factor reduction following CR. In addition, such an intervention is well received by patients as witnessed by high satisfaction rates and good session adherence. It remains to be seen whether the effects of the lifestyle maintenance intervention observed in our study will hold over time. A follow-up assessment at 15 months post CR is in progress.

Trial registration: ISRCTN06198717 (www.controlled-trials.com).

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Conflict of interest

The authors declare that there is no conflict of interest.

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