Effects of a self-regulation lifestyle program for post-cardiac rehabilitation patients

Janssen, V.R.

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Long-Term Follow-Up of a Lifestyle Program for Post-Cardiac Rehabilitation Patients: Are Effects Maintained?

Janssen, V. / De Gucht, V. / Van Exel, H. / Maes, S. (in revision)
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Abstract

Background As maintenance of lifestyle change and risk factor modification following completion of cardiac rehabilitation (CR) has been shown to be notoriously difficult, we developed a brief self-regulation lifestyle program for post-CR patients.
Design Randomized-controlled trial.
Method Following completion of CR 210 patients were randomized to receive either a lifestyle maintenance program (n=112) or standard care (n=98). The program was based on self-regulation principles and consisted of a motivational interview, 7 group sessions and home assignments. Risk factors and health behaviors were assessed at baseline (end of CR), and 6 and 15 months thereafter.
Results ANCOVAs showed a significant effect of the lifestyle program after 6 months on blood pressure, waist circumference and exercise behavior, the latter of which remained significant at follow-up. After 15 months, a significantly greater proportion of patients in the lifestyle intervention group achieved the secondary prevention target goals for physical activity and obesity. In addition, patients in the intervention group had significantly fewer uncontrolled risk factors as compared to the control group.
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. It is suggested that patients may need ongoing attention and guidance, for example in the form of (internet-based) booster sessions, as long-term consolidation of changes is arduous.
Trial Registration ISRCTN06198717 Controlled-trials.com

Keywords: Cardiac Rehabilitation; Self-Regulation; Randomized Controlled Trial; Lifestyle; Risk Factors; Adherence; Maintenance

Introduction

Cardiac rehabilitation (CR) focuses on promoting health behavior change and risk factor modification by offering comprehensive, multi-disciplinary programs that involve prescribed exercise, education, stress-management and structured lifestyle counseling (1). Despite the demonstrated benefit of such cardiac rehabilitation programs on health outcomes (2,3), lifestyle changes necessary to modify risk factor profiles seem to be difficult to maintain in the long run. Studies show that up to 60% of patients relapse within six months (4–6) and that 1.5 years after discharge from hospital most beneficial effects of CR on risk factor profiles have been lost (7). While existing lifestyle maintenance programs in cardiac patients show inconsistent results (8–10), trials and meta-analyses in various domains show that lifestyle modification programs based on self-regulation theory have more lasting effects, for example in terms of sustenance of weight loss (11,12), physical activity (13–15), or healthy eating (16). Self-regulation theories presume that all behavior is goal-directed and that lasting health behavior change can be achieved by setting salient goals and regulating behavior, thoughts and emotions in order to attain these goals. On the basis of this tenet, intervention strategies have been developed that promote the skills and cognitions elementary to goal attainment and maintenance. However, within the field of cardiac rehabilitation there are no comprehensive lifestyle maintenance programs based on this perspective.

We developed a brief self-regulation program focused on maintenance of lifestyle change and risk factor modification in post-CR patients. Following a three-month outpatient CR program, patients were randomized to either the lifestyle intervention or the control condition. As previously reported, we found the self-regulation program to show effects on several risk factors and related lifestyle behaviors at 6-month follow-up (17). Benefits were evident for blood pressure, waist

circumference and exercise behavior. The primary aim of the present paper is to investigate whether the self-regulation lifestyle program is capable of sustaining changes in risk factors and related health behaviors at 15-month follow-up. A secondary aim was to investigate the proportion of patients that achieve target goals for secondary prevention at both 6 and 15-month follow-up.

Method

Trial design

Upon completion of a comprehensive outpatient CR program, patients were randomized to either the intervention (lifestyle program) or the control group (individual interview + standard care). Patients were examined 6 and 15 months thereafter. The primary outcome was changes in modifiable risk factors and related health behaviors.

Participants and procedure

Participants were recruited between January 2008 and January 2010 from a major cardiac rehabilitation center (Rijnlands Revalidatie Centrum) in the Netherlands. All Dutch-speaking patients under 75 who had been diagnosed with ischemic 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 program, 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 behaviors were assessed, and self-report questionnaires were completed (T1). Using the same procedure, follow-up assessments were carried out 6 (T2) and 15 months (T3) thereafter by trained health psychologists who were blind to treatment allocation.

Intervention

Patients in the intervention group and the control group both attended a comprehensive three-month outpatient CR program in accordance with the Dutch Guidelines for Cardiac Rehabilitation (18). Upon completion of CR, patients in the intervention group entered the self-regulation program focused on maintenance of lifestyle change. The program started with an individual one-hour motivational counseling 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 two-hour group sessions (weeks 3, 5, 7, 9 and 11) and two two-hour follow-up sessions (weeks 15 and 19) at the cardiac rehabilitation center. Group sessions were structured around the self-regulatory phases of goal pursuit, 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 behavior, 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 behavior change techniques (19).
Patients in the control group were also invited for a one-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 (20). Waist circumference was measured to the nearest 0.1 cm at the level of the umbilicus while standing using inflexible tape (21). Fasting blood lipid samples were collected and analyzed 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 (Roche direct HDL reagent, HDLC3), and triglycerides (Roche TRIGL reagent) were measured from fasting serum, using the Roche Cobas C and Cobas Integra systems (Roche Diagnostics, Almere, the Netherlands). The Roche 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 behaviors. Exercise behavior was assessed using Yamax Digiwalker (SW-200) pedometers, which have been validated

for accuracy and reliability (35). Participants were asked to wear the pedometer on seven consecutive days, positioning the pedometer on the thigh, and record the steps accumulated over the day in an activity log. Dietary behavior 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 (22,23). Fruit and vegetable intake was calculated in grams per day. Dietary fat is expressed in terms of a fat score, which ranges between 12 and 60, with higher scores reflecting higher fat intake. Smoking behavior 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.

Statistical Analyses

Based on previous meta-analyses of lifestyle modification programs for CHD patients (1,2,41) effect sizes of 0.1 to 0.3 can be expected. A priori analyses carried out in G*Power (24) 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 analyzed 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. Mixed model repeated measures analyses of covariance (ANCOVA) controlling for age, disease severity and cardiac history were computed across time points in order to test the interaction between group participation (intervention

vs. control) and the change from baseline to follow-up (T2, T3). Analyses were repeated without covariates (25). Prior to analyses, the assumptions for repeated measures ANCOVA, including normality, homogeneity of variance and covariance, and sphericity were checked. The difference in distribution of risk factor management variables was examined using Chi square tests.

Data are reported as mean value ± standard deviation or 95% CI. 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 (in total: 4.4% missing) 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 (26). Because the data showed an arbitrary missing data pattern, the Markov Chain Monte Carlo algorithm was used to generate 5 imputation data sets, which were analyzed individually using repeated measures ANCOVAs 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 program. The flow diagram is displayed in Figure 1. 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 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) of the self-regulation intervention program (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). A total of 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 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 (SD=0.98, n = 94).
In accordance with the Dutch Guidelines for Cardiovascular Risk Management (27), all patients in the study were treated with ß-blockers, ACE inhibitors, antiplatelet agents and statins.

Risk factor change

As is shown in Table 3, repeated-measures ANCOVAs revealed a significant time by group interaction for systolic blood pressure ($F(2,169)=4.04$, $p=0.02$) and waist circumference ($F(2,169)=4.24$, $p=0.02$). Statistical contrasts showed that for both outcomes the changes were significant from baseline (T1) to 6-month (T2)

follow-up, but not from baseline to 15-month (T3) follow-up. The mean change in systolic blood pressure in the intervention group from T1 to T2 was -6.36 mmHg (95% CI -9.17 to -3.55) and from T1 to T3 -1.17 mmHg (95% CI -5.40 to 1.51). In the control group, this was respectively -1.13 mmHg (95% CI -4.30 to 2.97; T1 to T2) and -1.22 mmHg (95% CI -2.75 to 4.11; T1 to T3). For waist circumference, the mean change in the intervention group was -1.25 cm (95% CI -2.21 to -0.38) for T1 to T2 and -0.04 cm (95% CI -1.16 to 1.07) from T1 to T3. In the control group, the mean changes were +0.78 cm (-0.33 to 1.86; T1 to T2) and +1.42 cm (0.09 to 2.75; T1 to T3). There were no significant group differences for diastolic blood pressure, BMI, or any of the cholesterol outcomes neither at T2 nor at T3.
Repeating the repeated-measures ANCOVAs using intention-to-treat (LOCF procedure) confirmed this pattern of results for waist circumference ($F(2,203)= 3.37$, $p=0.02$), but not for systolic blood-pressure, which became a trend towards significance ($F(2,203)= 2.40$, $p=0.10$).

Health behavior change

Repeated-measures ANCOVAs showed a significant time by group interaction for physical activity ($F(2,169)=11.03$, $p=0.00$, Table 4). Statistical contrasts showed that changes were significant from T1 to T2, as well as from T1 to T3. The mean change in the intervention group was +1599 steps per day (95% CI 398 to 2015) from T1 to T2, and +1065 steps per day from T1 to T3 (95% CI -49.1 to 1597). In the control group this was respectively -559 steps per day (95% CI -1139 to 52.9; T1 to T2) and -233 steps per day (95% CI -1063 to 252; T1 to T3). There were no significant group differences for dietary behavior (fat intake and fruit & vegetable intake; Table 4) neither at T2 nor at T3. Repeating the repeated-measures ANCOVAs using intention-to-treat (LOCF procedure) confirmed the significant result for physical activity ($F(2,189)= 5.17$, $p=0.01$). With regards to quitting smoking, there were few smokers in the cohort at baseline (n=4 in the

intervention group and n=7 in the control group) and groups did not differ significantly at any measurement point: T1 $\chi^2(1, N=173) = 0.99$, $p = 0.32$, T2 $\chi^2(1, N=171) = 0.71$, $p = 0.40$) and T3 $\chi^2(1, N=172) = 1.03$, $p = 0.31$).

Secondary Prevention

In correspondence with the guidelines (27,28) inadequate control of risk factors was defined as follows: blood pressure ≥140/90 mmHg (and ≥130/80 mmHg in patients with diabetes), total cholesterol/HDL-cholesterol ratio ≥ 4.0 mmol/l, obesity: BMI ≥ 30 kg/m, waist circumference ≥ 102 cm for men and ≥ 88 cm for women, current smoking, and physical inactivity: average steps per day < 8000 (29). As is shown in Table 5, both groups did not differ significantly in prevalence of uncontrolled risk factors at baseline (completion of CR). At 15-month follow-up, the percentage of patients presenting with 0-1 risk factor versus 2-6 risk factors was greater in the intervention group (52.3%) than in the control group (36.9%) and this difference was significant, $\chi^2(1, N=175) = 4.11$, $p = 0.04$. At 6-month assessment (T2), achievement of target goals was worse in the control group for most individual risk factors, and this difference was significant for raised blood pressure (30% in the control group versus 14% in the intervention group, $\chi^2[1, N=175] = 7.22$, $p = 0.01$) and physical inactivity (62% and 33% respectively, $\chi^2[1, N=175] = 14.82$, $p = 0.00$). At 15-month follow-up (T3), the proportion of patients not achieving target levels was greater in the control group for almost all individual risk factors except total cholesterol/HDL-cholesterol ratio. Differences were significant for obesity (34% in the control versus 19% in the intervention group, $\chi^2[1, N=175] = 4.83$, $p = 0.03$) and physical inactivity (57% versus 39% respectively, $\chi^2[1, N=175] = 5.46$, $p = 0.02$).

Discussion

The self-regulation lifestyle intervention for cardiac patients showed effects on blood pressure, waist circumference and exercise levels and at 6 months post CR. At 15-month follow-up, the intervention group still showed lower systolic blood pressure and waist circumference, but these differences were no longer significant. For physical activity, however, the treatment effect remained. We observed a significant increase in physical activity for the intervention group as compared to a reduction for the control group. Current guidelines for physical activity recommend 30-60 minutes per day of moderate-intensity physical activity on ≥5 days per week (28), which equates to 8000-9000 steps per day (29). Our results show that a significantly greater proportion of patients in the lifestyle intervention group adhered to these recommended levels of physical activity. Finally, the prevalence of uncontrolled risk factors in the lifestyle intervention group compared favorably to that observed in the control group, with over 50% of the intervention group presenting most risk factors at goal (0 or one uncontrolled risk factor) versus 37% in the control group at follow-up (15 months).

Existing lifestyle maintenance programs in cardiac patients show inconsistent results. In most trials, effects largely waned over time after termination of the program (8,30,31). In two trials, however, effects were maintained (9,10). Both offered an ongoing intervention program, with risk factor counseling sessions continuing for two to three years. Our self-regulation lifestyle program was shorter, but patients were provided with pedometers, trained in self-monitoring and feedback skills, and encouraged to continue the monitoring of their exercise behavior after termination of the program. Thus, one of the reasons for the lasting treatment effect we observed may be the ongoing provision of performance-related feedback with regards to exercise. This notion is supported by recent evidence

from a review of exercise adherence interventions post CR that showed that the continued tracking of exercise behavior using pedometers, exercise logs or activity diaries, was a very successful strategy in promoting sustenance of exercise after completion of CR (15).

Taken together, this suggests that long-term health behavior change may be facilitated by strategies and devices that aid the monitoring and feedback of (goal-related) performance upon termination of the program. Innovative and cost-effective ways of offering such continued care might well involve telemedicine technology, which allows for the simultaneous monitoring of the multitude of indicators important in cardiac risk factor management. Promising examples of such novel models of care come from the area of heart failure. A systematic review showed positive results for internet-based interventions that combined home-based monitoring of blood pressure, body weight, heart rate, medication and bodily symptoms with online feedback from health professionals (32). These findings are now being extended to other patient groups. Currently, a trial is running with myocardial infarction patients, which aims to improve risk factor management using a combination of self-management skills training and telemonitoring. Thus, patients upload data concerning their risk factors and related health behaviors in their personal health records, and are subsequently provided with tailored web based education, feedback and self-management support (33).

Strengths and Limitations

We designed this trial to investigate the effects of a theoretically-based lifestyle intervention in terms of changes in health behaviors and risk factor management. Future intervention trials might investigate the benefits of such a program in a design powered to also detect changes in cardiovascular end points, such as clinical events and mortality. Furthermore, whereas our study relied on objective measures of

outcome for risk factor assessment and exercise behavior, we included self-report measures for smoking and dietary behavior. The reliable measurement of dietary behavior is known to be difficult at best. Food frequency questionnaires have been criticized for socially desirable responding and underreporting intake (34). Future research might benefit from a more direct method of assessing dietary behavior, for example by the use of daily food reports, and from calibrating outcome data against objective measures of energy expenditure. Considering the importance of quitting smoking in risk reduction, the validity of a self-report outcome might be verified using biochemical methods of assessment. Finally, our intervention focused on a population of CR patients. Further research might investigate whether these findings can be generalized to 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, theory-based lifestyle program is capable of inciting and maintaining improvements in lifestyle and risk factor modification at 15 months post CR, with treatment resulting in better exercise adherence and a significantly greater proportion of patients in the lifestyle intervention group achieving the secondary prevention target goals for physical activity and obesity.

Table 1.
Content of the intervention by session based on the CALO-RE Taxonomy (34)

Behaviour Change Techniques (number on CALO-RE Taxonomy)	**Sessions**						
	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

Note: Session 1, 2, 3, 4, 5 were bi-weekly over a period of 3 months. Session 6 and 7 were booster sessions in the 4th and 5th month. Session 4 included the patient's partner or a 'significant other'.

Table 2.
Demographic and clinical characteristics of patients who received the allocated condition.

	Intervention (n = 102)	Control (n = 97)
Gender		
Men	80 (78.4)	81 (84.4)
Women	22 (21.6)	15 (15.6)
Age	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 §	5 (4.9)	5 (5.2)
Antecedent Cardiac History ‡		
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)
Systolic Blood Pressure (mm/Hg)	138 ± 15.1	139 ± 17.4
Diastolic Blood Pressure (mm/Hg)	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
Total/HDL-ratio	3.36 ± 0.92	3.55 ± 1.02
Smoking	7 (6.9)	8 (8.4)
Physical activity (steps per day)	8047 ± 3328	8061 ± 3971
Dietary Behaviour		
Fat intake (fat score)	16.5 ± 6.05	16.3 ± 6.00
Fruit & Vegetable intake (grams/day)	470 ± 229	429 ± 212

Note: Values are shown as n(%) or mean ± SD where appropriate.
 # CABG, Coronary Artery Bypass Surgery
† PCI, Percutaneous Coronary Intervention
§ Prosthetic valve or valve repair surgery (Intervention n=3, Control n=2), angina pectoris (Intervention n=2, Control n=3)
‡ Includes antecedent cardiac events such as myocardial infarction, CABG, PCI or arrhythmias

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

Variable	Time	Intervention n = 89	Control n = 87	Group effect†					
				Adjusted F§ (df=2,172)	p	Unadjusted F (df=2,169)	p	Contrasts‡	p
Systolic blood pressure (mm/Hg)	Baseline 6-month FU 15-month FU	137 ± 15 131 ± 15 136 ± 16	139 ± 18 138 ± 17 138 ± 17	4.39	.01	4.04	.02	 Baseline to 6 mts Baseline to 15 mts	 .02 .10
Diastolic blood pressure (mm/Hg)	Baseline 6-month FU 15-month FU	83.2 ± 9.2 79.5 ± 10.3 82.0 ± 10.1	83.2 ± 9.5 81.0 ± 10.5 82.1 ± 9.7	1.51	.22	1.62	.20		
Waist circumference (cm)	Baseline 6-month FU 15-month FU	102 ± 10 100 ± 9.9 102 ± 10	103 ± 11 103 ± 11 104 ± 12	4.31	.02	4.24	.02	 Baseline to 6 mts Baseline to 15 mts	 .00 .18
BMI (kg/m²)	Baseline 6-month FU 15-month FU	27.9 ± 3.4 27.8 ± 3.5 28.1 ± 3.6	28.0 ± 4.0 28.2 ± 4.2 28.5 ± 4.3	1.76	.18	2.42	.09		
Total cholesterol (mmol/l)	Baseline 6-month FU 15-month FU	3.90 ± 0.88 3.83 ± 0.85 4.10 ± 0.93	3.97 ± 0.90 3.95 ± 0.94 4.04 ± 0.91	0.88	.35	0.65	.52		
Triglycerides (mmol/l)	Baseline 6-month FU 15-month FU	1.60 ± 0.99 1.50 ± 0.81 1.58 ± 0.96	1.64 ± 0.83 1.65 ± 1.00 1.59 ± 0.74	1.25	.29	1.02	.36		
HDL (mmol/l)	Baseline 6-month FU 15-month FU	1.19 ± 0.30 1.20 ± 0.32 1.28 ± 0.34	1.18 ± 0.33 1.19 ± 0.33 1.22 ± 0.30	0.69	.41	0.94	.39		
LDL (mmol/l)	Baseline 6-month FU 15-month FU	2.04 ± 0.75 2.03 ± 0.72 2.08 ± 0.85	2.10 ± 0.83 2.04 ± 0.82 2.10 ± 0.80	0.03	.98	0.08	.93		
Total cholesterol/ HDL-C ratio (mmol/l)	Baseline 6-month FU 15-month FU	3.36 ± 0.92 3.34 ± 0.96 3.44 ± 1.13	3.55 ± 1.02 3.40 ± 1.11 3.47 ± 0.87	0.64	.53	0.66	.52		

Data are presented as mean ± SD. Abbreviations: BMI, Body Mass Index; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol
†Time x group interaction by mixed model repeated measures ANOVA.
‡In case of a significant time x group interaction, contrasts were used to test the null hypothesis that changes between time points in the intervention group were equal to changes in the control group
§ Adjusted for age, disease severity (NYHA) and cardiac history

Table 4.
Change in health behaviors between baseline (end of cardiac rehabilitation T1), 6-month (T2) and 15-month (T3) follow-up.

Variable	Time	Intervention n = 89	Control n = 87	Group effect†					
				Adjusted F§ (df=2,172)	P	Unadjusted F (df=2,169)	P	Contrasts‡	P
Physical activity (steps per day)	Baseline 6-month FU 15-month FU	8031 ± 3362 9630 ± 3598 9096 ± 3689	7896 ± 4433 7337 ± 3767 7663 ± 3858	9.89	.00		.00	 Baseline to 6 mts Baseline to 15 mts	 .00 .01
Dietary Behavior (fat intake)	Baseline 6-month FU 15-month FU	16.8 ± 6.0 16.4 ± 5.8 16.5 ± 5.8	16.7 ± 5.9 16.9 ± 5.9 16.9 ± 5.4	0.51	.59		.38		
Dietary Behavior (fruit & vegetable intake)	Baseline 6-month FU 15-month FU	464 ± 244 491 ± 227 474 ± 228	435 ± 212 464 ± 205 440 ± 239	0.03	.98		.83		

Data are presented as mean ± SD. Abbreviations: BMI, Body Mass Index; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol

† Time x group interaction by mixed model repeated measures ANOVA.

‡ In case of a significant time x group interaction, contrasts were used to test the null hypothesis that changes between time points in the intervention group were equal to changes in the control group

§ Adjusted for age, disease severity (NYHA) and cardiac history

Table 5.
No (percentage) of CR patients presenting with risk factors at baseline (completion of CR) and follow-up.

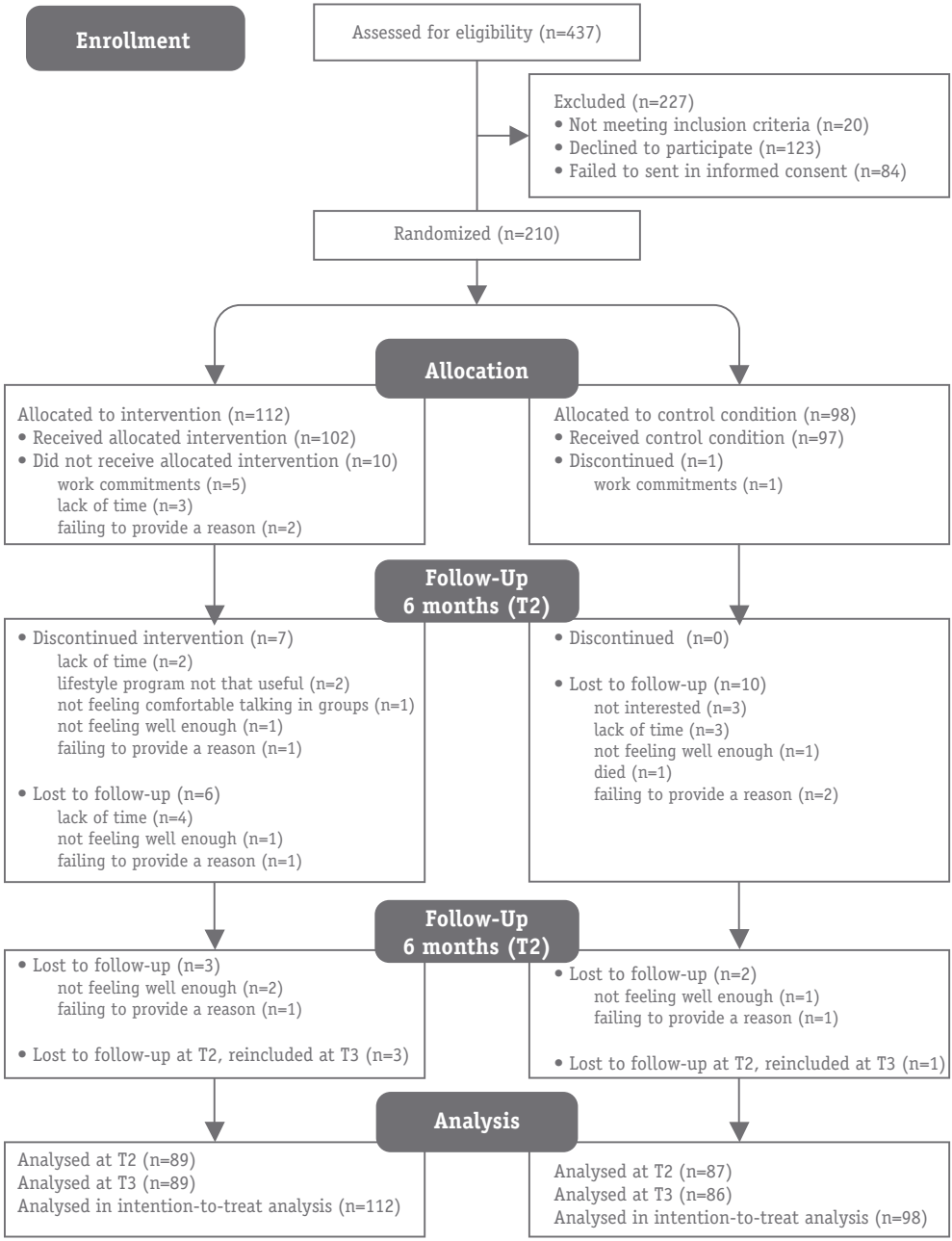
	Baseline (completion of CR)				Posttreatment (6 months post CR)			
	Lifestyle intervention (n=89)	Control group (n=86)			Lifestyle intervention (n=89)	Control group (n=86)		
Obesity†	19 (21.3)	24 (27.9)	1.02	.31	20 (22.5)	27 (31.4)	1.77	.18
Increased waist circumference §	51 (57.3)	44 (51.2)	0.67	.42	45 (50.6)	45 (52.3)	0.05	.82
Raised BP‡	20 (22.5)	22 (25.6)	0.23	.63	12 (13.5)	26 (30.2)	7.22	.01
Raised TC/ HDL-C ratio ∫	16 (18.0)	24 (27.9)	2.45	.12	19 (21.3)	26 (30.2)	1.81	.18
Current smoking #	4 (4.5)	7 (8.2)	0.99	.32	8 (9.3)	5 (5.9)	0.71	.40
Physical inactivity ∞	45 (50.6)	47 (54.7)	0.29	.59	29 (32.6)	53 (61.6)	14.82	.00
No (%) of patients presenting with risk factors	(n=88)	(n=85)			(n=86)	(n=85)		
0 risk factors	17 (19.3)	12 (14.1)			20 (23.3)	11 (12.9)		
1 risk factor	22 (25.0)	23 (27.1)			27 (31.4)	23 (27.1)		
2 risk factors	29 (33.0)	19 (22.4)			25 (29.1)	17 (20.0)		
3 risk factors	9 (10.2)	20 (23.5)			7 (8.1)	17 (20.0)		
4 risk factors	10 (11.4)	10 (11.8)			6 (7.0)	12 (14.1)		
5 risk factors	1 (1.1)	1 (1.2)			1 (1.2)	5 (5.9)		
6 risk factors	-	-			-	-		
Cumulative score 0/1 risk factor 2-6 risk factors	39 (44.3) 49 (55.7)	35 (41.2) 50 (58.8)	0.17	.68	47 (54.7) 39 (45.3)	34 (40.0) 51 (60.0)	3.68	.06

Abbreviations: BP, blood pressure; SBP, systolic blood pressure; DBP: diastolic blood pressure; TC/HDL-C ratio, total cholesterol to high-density lipoprotein cholesterol ratio
† Body Mass Index >=30 kg/m²
§ men >=102 cm, women >= 88 cm
‡ SBP >= 140 mm/Hg and/or DBP >= 90 mm/Hg; in patients with diabetes SBP >=130 mm/Hg and/or DBP >= 80 mm/Hg
∫ TC/HDL-C ratio >= 4.0 mmol/l
 # Current smoking: T1 lifestyle n=88, T1 control n=85; T2 lifestyle n=86 T2 control n=85; T3 lifestyle n=88, T3 control n=85
∞ Daily steps < 8000

Table 5 cont.

	Posttreatment (15 months post CR)			
	Lifestyle intervention (n=89)	Control group (n=86)		
Obesity†	17 (19.1)	29 (33.7)	4.83	.03
Increased waist circumference §	48 (53.9)	51 (59.3)	0.51	.47
Raised BP‡	15 (16.9)	20 (23.3)	1.12	.29
Raised TC/ HDL-C ratio ∫	25 (28.1)	23 (26.7)	0.04	.84
Current smoking #	4 (4.5)	7 (8.3)	1.03	.31
Physical inactivity ∞	35 (39.3)	49 (57.0)	5.46	.02
No (%) of patients presenting with risk factors	(n=88)	(n=84)		
0 risk factors	20 (22.7)	13 (15.5)		
1 risk factor	26 (29.5)	18 (21.4)		
2 risk factors	21 (23.9)	18 (21.4)		
3 risk factors	14 (15.9)	22 (26.2)		
4 risk factors	3 (3.4)	10 (11.9)		
5 risk factors	4 (4.5)	3 (3.6)		
6 risk factors	-	-		
Cumulative score 0/1 risk factor 2-6 risk factors	46 (52.3) 42 (47.7)	31 (36.9) 53 (63.1)	4.11	.04

Figure 1. Participant flow.



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