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

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Citation

Janssen, V. R. (2012, September 25). *Effects of a self-regulation lifestyle program for post-cardiac rehabilitation patients*. Retrieved from <https://hdl.handle.net/1887/19850>

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Issue Date: 2012-09-25

Changing for Good: The Role of Self-Regulation in Exercise Adherence Following Cardiac Rehabilitation

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Submitted for publication

Abstract

Background Secondary prevention programs for cardiac patients have been proven effective, but less is known about the psychological mechanisms by which they bring about change. We investigated whether self-regulation skills might explain the long-term treatment effect of a brief self-regulation lifestyle program for post-CR patients.

Design Randomized-controlled trial.

Methods Following completion of CR 210 patients were randomized to receive either a lifestyle maintenance program (n=112) or standard care (n=98). Risk factors and health behaviors were assessed at baseline (end of CR), 6 months and 15 months thereafter.

Results ANCOVAs showed a significant effect of the lifestyle program on exercise behavior after 15-months. Furthermore, the lifestyle program group reported improved self-regulation skills as compared to the control group and mediation analysis demonstrated that the treatment effect on physical activity could be explained by self-regulation skills.

Conclusion This suggests that long-term health behavior change may be facilitated by self-regulation skills, and that such skills can be successfully trained in an intervention setting. It is suggested that future research may investigate moderators of effectiveness so that intervention programs can be tailored to ‘what works best for whom’.

Trial Registration ISRCTN06198717 Controlled-trials.com

Introduction

In the management of coronary heart disease, lasting lifestyle changes are elementary to survival (1,2). Nonetheless, the majority of patients show large relapse rates and poor risk factor control - even after participation in evidence-based interventions, such as cardiac rehabilitation (3,4). To prevent

relapse, we developed a brief self-regulation program focusing on maintenance of lifestyle change and risk factor modification in post-cardiac rehabilitation (CR) patients. Following a three-month outpatient CR program, patients were randomized to either the lifestyle intervention or the control condition (care as usual). As previously reported, we found the self-regulation program to show effects on blood pressure, waist circumference and physical activity six months later (5). At long-term (15 months) follow-up, a significantly greater proportion of patients in the lifestyle intervention group achieved 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 (6). Several researchers have emphasized the importance of clarifying the factors that mediate program effectiveness (7–9). Behavior change techniques are more likely to mediate treatment effects on health behavior than on risk factors (10). As exercise adherence has been shown to be important in reducing cardiac morbidity and mortality (11), the aim of this report is to investigate the mechanism that might explain the long-term treatment effect on physical activity. As depicted in Figure 1, it is hypothesized that the lifestyle program promotes self-regulation skills, and that self-regulation skills mediate the long-term effect of the program on exercise adherence.

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 centre (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

Details of the intervention have been described elsewhere (5). In brief, patients in the intervention group and the control group both attended a comprehensive three-month outpatient CR program. 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 during which important (life) goals for the patients were explored and a personal health goal was set. 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 centre. Group sessions were structured around the self-regulatory phases of goal pursuit and focused on enhancing the relevant self-regulation skills (10). 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.

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 patients' cardiologist.

Outcome Measures

Full study methods have been reported previously (5).

Health behaviors. Exercise behavior was assessed using Yamax Digiwalker (SW-200) pedometers, which have been validated for accuracy and reliability (12). 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.

Self-Regulation. SR skills were measured using the Self-Regulation Skills Battery (SRSB) (13), which has been shown to have good discriminative and evaluative properties (14).

Using a standardized goal-elicitation procedure, patients specified a personal health goal. Prior to health goal pursuit, goal-cognitions were assessed (T1). At T2, SR skills regarding goal pursuit were assessed using 23 items that measured goal-efficacy, self-monitoring and feedback, self-criticism, self-reward, and anticipation and coping with problems. Items were scored on a 5-point Likert-scale ranging from 1 (totally disagree) to 7 (totally agree). Scores were converted to z-scores in order to calculate a composite self-regulation score. Reliability of the composite score was acceptable with Cronbach's alpha = 0.74.

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

Data were analyzed using SPSS for Windows version 18.0. 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. The mediation model (Figure 1) was tested using the bootstrapping procedure of Preacher & Hayes (15). This method estimates the indirect effect of the mediator, which is assumed to be significant at an alpha level of 0.05 if the corresponding 95% confidence interval (CI) does not include zero. The mediation macro for SPSS developed by Hayes (16) was employed with 1000 bootstrapping samples to conduct the analysis. Data are reported as mean value \pm 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 (17).

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. A total of 294 patients indicated that they were willing to participate, of whom 210 sent in an 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 (a diagram showing the flow of the participants through each stage of the trial has been reported previously (5). Demographic and clinical characteristics have been described elsewhere (5), but in brief: the intervention group consisted of 80 men and 22 women versus 81 men and 15 women in the control group. The mean age was 56.6 (SD = 9.2) in the intervention group and 58.8 (SD = 9.3) in the control group. Main diagnoses included myocardial infarction, coronary artery bypass surgery and percutaneous coronary intervention. The majority of patients scored I or II on the NYHA functional capacity index.

Mediation analysis

The effect of the independent variable on the mediating variable (path a, Figure 1) was found to be significant, in that participation in the lifestyle intervention group predicted higher self-regulation scores at T2, after controlling for age, gender, cardiac history and NYHA-classification (B=.52, t=1.95, p=0.05). The effect of the mediating variable on the dependent variable (path b) was found to be significant, in that higher self-regulation scores at T2 were associated with greater physical activity at T3, controlling for physical activity

at T1, participation in the lifestyle/control group, and the aforementioned control variables ($B=278.44$, $t=2.17$, $p=0.03$). The indirect effect ($a \times b$) of the independent variable on the dependent variable through the mediator was also found to be significant; after adjusting for physical activity at T1 and age, gender, cardiac history and NYHA-classification, the lifestyle intervention program had a significant indirect effect on physical activity at T3 through self-regulation at T2 (point estimate = 144.22, 95% CI 8.42 to 329.32). Repeating the analyses without the covariates confirmed these results.

Discussion

At long-term follow-up, participation in the self-regulation lifestyle intervention was associated with higher levels of physical activity in post-CR patients. Furthermore, the lifestyle group reported improved SR skills as compared to the control group and mediation analysis demonstrated that the effect on physical activity could be explained by self-regulation skills. This suggests that SR-skills are at least partly responsible for the change brought about in exercise behavior. Despite the demonstrated benefit of exercise training on cardiac mortality (11,18), long-term adherence to recommended levels of physical activity remains problematic (19,20). It is promising that by training self-regulation skills maintenance of this behavior seems to be facilitated. Future research might assess whether self-regulation skills and cognitions also act as moderators of treatment effects. This would shed light on 'what works for whom', i.e., which people profit most from what type of intervention. In primary prevention, it has been shown that tailoring interventions to psychological constructs improves effectiveness (21). Similarly, in secondary prevention, patients could be screened upon entry to a program and matched to different forms of interventions tailored to the relevant self-regulation skills and/or cognitions.

Table 1.

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)
Physical activity (steps per day)	8047 ± 3328	8061 ± 3971

Note: Values are shown as n(%) or mean ± SD where appropriate.

CABG, Coronary Artery Bypass Surgery

† PCI, Percutaneous Coronary Intervention

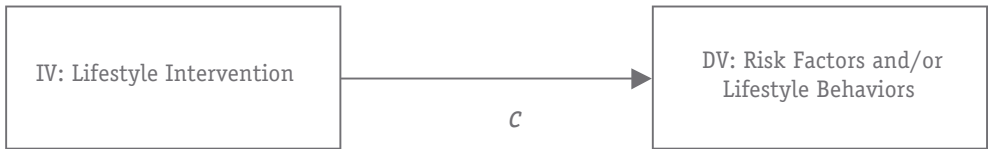
§ Prosthetic valve or valve repair surgery (Intervention n=3, Control n=2), angina pectoris (Intervention n=2, Control n=3)

‡ Includes antecedent cardiac events such as myocardial infarction, CABG, PCI or arrhythmias

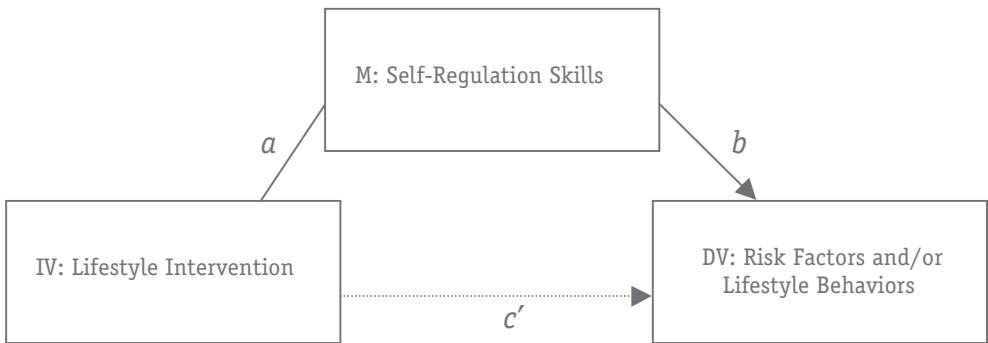
Figure 1.

The effect of the lifestyle intervention program on outcomes with (II) and without (I) the hypothesized mediator.

(I) Direct treatment effect:



(II) Indirect treatment effect via self-regulation:



Note. Abbreviations: IV, Independent Variable; M, Mediator; DV, Dependent Variable

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