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Veronica R. Janssen

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‘De interessantste vragen blijven vragen.
Ze dragen een geheim in zich.
Bij elk antwoord hoort een “misschien”.
Alleen onbelangrijke vragen hebben een duidelijk antwoord.’
‘Bedoelt u dat er geen oplossing is voor het begrip “Leven”?’
‘Ik bedoel dat er voor het begrip “Leven” verschillende oplossingen zijn, dus geen oplossing.’
‘Zo denk ik er ook over, oma Rozerood.
Er is geen oplossing voor het leven,
behalve dan maar gewoon te leven.’

‘Oscar en oma Rozerood’ (2004)
Eric-Emmanuel Schmitt

Effects of a Self-Regulation Lifestyle Program for Post-Cardiac Rehabilitation Patients

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Contents

1.

General Introduction

Coronary Heart Disease

Coronary heart disease (CHD) is the leading fatal illness in most Western countries, claiming more deaths and disability than any other disease. Over the past decades, improvements in diagnosis, treatment and prevention have reduced CHD mortality rates, leaving an increasingly large group of people to live with CHD as a chronic disease (1). In the Netherlands, incidence statistics vary between 6/ 1000 for men and 4 /1000 for women. In 2009, CHD prevalence rates were an estimated 84.000 to 85.000 in the Netherlands (2). As hypertension, abnormal lipids, abdominal obesity, physical inactivity, smoking and consumption of (saturated) fat have been shown to account for most of the risk in both the onset and prognosis of CHD (3,4), adequate disease management requires control of risk factors through medication and lifestyle change.

Cardiac rehabilitation: the lifestyle changes necessary to modify risk factors seem virtually impossible to maintain for life

Cardiac rehabilitation programs focus on restoring a patient to full physical and psychosocial functioning, as well as on limiting further progression of the disease by aiding lifestyle change and adequate risk factor management (5). Next to pharmacological therapies and interventional cardiology, cardiac rehabilitation programs are widely recognized as essential to the care of CHD patients. Traditionally, cardiac rehabilitation programs have placed large emphasis on exercise training, but gradually they have become supplemented with health education components, lifestyle counselling and psychological treatment to better address the full range of modifiable risk factors. While (meta-analytic) evidence for the effectiveness of such comprehensive cardiac rehabilitation programs is abundant (6–10), studies show that 1.5 years after discharge from hospital most beneficial effects of cardiac rehabilitation on risk factor profiles have been lost (11,12). This situation is especially glaring given that evidence is emerging that the mortality-reducing potential of lifestyle changes is at least comparable to that demonstrated for cardiopreventive drug usage (13,14). Seemingly, many cardiac patients adopt healthier lifestyles during cardiac rehabilitation, but relapse into old habits when returning to everyday life (15–17). Research on the maintenance of lifestyle change following cardiac rehabilitation shows relapse rates as high as 60% over the first six months (16,17). Typically, most cardiac rehabilitation programs 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. However, good intentions alone are not sufficient to consolidate behavior change.

Changing for good? The role of self-regulation

Self-regulation theories of behavior extend beyond the strength of a person's intention and presume that health behavior change can be achieved by setting salient goals and regulating behavior, thoughts and emotions across changing circumstances in order to attain these goals (18). Thus, behavior change is viewed as a dynamic goal-guided process, occurring in phases. A central tenet in all self-regulation theories is that human behavior is inherently organized around the pursuit of goals as goals provide meaning to people's lives (19,20). The motivation to change behavior stems from a perceived discrepancy between an individual's actual state (the input value) and an ultimately desired state (the reference value), leading to adoption of a specific goal. Both cognitions and skills help translate this intention into action and maintenance. Self-monitoring, anticipatory coping, emotion regulation and feedback strategies, for instance, guide goal attainment. Adaptive cognitions, such as self-efficacy, realistic outcome expectancies, satisfaction with the new behavior and ownership of the changed behavior, are thought to be important in subsequent maintenance (18,21,22). Trials and meta-analyses in various domains show that lifestyle modification programs based on self-regulation theory have lasting effects, for example in terms of sustenance of weight loss (23,24), physical activity (25–27), or healthy eating (28). However, the theory has not been applied yet to comprehensive lifestyle modification programs in the area of cardiac rehabilitation.

Aim

This thesis focuses on the role of self-regulation cognitions and skills in relation to health behavior change in (post-) cardiac rehabilitation patients. In a first study, we attempted to determine the effects of a comprehensive cardiac rehabilitation program on illness beliefs, as these are closely related to personal (health) goals and disease outcome. In a second study, we conducted a systematic review and meta-analysis of lifestyle modification programs for CHD patients and examined the efficacy of incorporating self-regulation intervention strategies as a means of changing behavior. In a next step, we developed a brief self-regulation program focused on maintenance of lifestyle change and risk factor modification in post-cardiac rehabilitation patients and tested the efficacy in a randomized controlled design. A more specific aim of this thesis was to investigate whether this self-regulation lifestyle program for post-cardiac rehabilitation patients is capable of instigating and maintaining changes in risk factors and related health behaviors at follow-up.

Outline

Chapter 2: Changes in illness perceptions and quality of life during cardiac rehabilitation

When behavior change is viewed in light of dealing with illness, it is likely to be influenced by the beliefs patients hold about their disease and the corresponding treatment. According to self-regulation theories, such disease-related beliefs, or 'illness perceptions', fuel subsequent coping behaviors and underlie adjustment (29). Reviews have acknowledged the link between illness perceptions and outcomes across a range of diseases (30,31). In cardiac patients, illness perceptions have consistently been related to psychosocial adjustment. More specifically, negative illness beliefs in cardiac patients have been related to (onset of) depressive symptomatology (32–34), whereas positive illness beliefs seem to be associated with better health-related quality of life (34,35). However, the beliefs patients hold about their illness are likely to be influenced by changes in disease status or treatment. In the early phase of the illness (i.e., hospital admission and cardiac rehabilitation) patients continuously acquire new experiences and knowledge. Not surprisingly, health-related quality of life in cardiac patients has been shown to change in the year following the cardiac event (36) with improvements being most apparent during the early phase of illness (37-39). It has been argued that illness perceptions also change during this period (40) and that such changes may be responsible for the observed improvements in quality of life, but there is little research investigating this. Thus, the first chapter aims to examine whether illness beliefs change after participation in a comprehensive cardiac rehabilitation program and, if so, whether these changes are related to improvements in health-related quality of life.

Chapter 3: Lifestyle modification programs for patients with coronary heart disease: a systematic review and

meta-analysis of randomized controlled trials

Lifestyle modification programs for coronary heart disease (CHD) patients have been shown to effectively improve risk factors and related health behaviors, quality of life, re-incidence and mortality (6–10). However, several researchers have called attention to the large amount of variation in effectiveness between separate programs and have pointed out that lifestyle modification programs typically comprise a variety of psychological techniques that support behavior change, but that it is unclear which (combination of) techniques is most effective in modifying lifestyle behaviors. Therefore, we undertook a systematic review and meta-analysis of lifestyle modification programs for CHD patients and examined whether programs that incorporate self-regulation techniques (i.e., goal-setting, planning, self-monitoring and feedback) are more effective than programs that do not employ these techniques. Chapter three describes the results.

Chapter 4: Beyond resolutions? A randomized controlled trial of a self-regulation lifestyle program for post-cardiac rehabilitation patients

On the basis of self-regulation theory, we developed a relatively brief intervention focused on maintenance of lifestyle change and risk factor modification in post-cardiac rehabilitation patients. The program started with an individual 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 seven group sessions, which were structured around the self-regulatory phases of goal pursuit 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. We tested this program in a randomized controlled design and describe effects on risk factors and related health behaviors at posttreatment assessment (6 months after termination of cardiac rehabilitation).

Chapter 5: Long-term follow-up of a lifestyle program for post-cardiac rehabilitation patients: are effects maintained?

Most trials investigating lifestyle maintenance programs in cardiac patients show that effects largely waned over time after termination of the program (41–43). Chapter five assesses effects of the self-regulation lifestyle program on risk factors and related health behaviors at long-term follow-up (15 months after termination of cardiac rehabilitation). The time frame of this follow-up is comparable to that used by the EUROASPIRE II and III surveys. These surveys were conducted on a mere 2500 coronary patients from 15 European countries and investigated their lifestyles, risk factors and use of drug therapies ≈ 1.4 years after discharge from hospital. They showed that by that time, most of the cardiac rehabilitation treatment benefits had worn off and the majority of patients failed to meet secondary prevention targets (44–46). Thus, this chapter also investigates the proportion of patients that achieve target goals for secondary prevention at long-term follow-up.

Chapter 6: Changing for good: the role of self-regulation in exercise adherence following cardiac rehabilitation

Several researchers have criticized the single-pointed focus on performance measures at the expense of theory-building in the field of cardiac rehabilitation (47,48). They have pointed out that the efficacy of the various components of lifestyle modification programs is unclear (48–50) and have emphasized the importance of clarifying the factors that moderate or mediate program effectiveness. Meta-analyses have identified specific program characteristics, such as setting, timing and duration, as moderating factors (6,49,51), but less is known about the psychological mechanisms by which lifestyle modification programs bring about change. The aim of this chapter is to investigate the mechanism that might explain any observed treatment effects of the self-regulation lifestyle intervention. It is hypothesized that the self-regulation lifestyle program promotes self-regulation skills, and that self-regulation skills will mediate any observed effects of the program on health behaviors.

Chapter 7

In the concluding chapter, the findings from the different studies are integrated and discussed. Directions for future research and recommendations for clinical implementation of the self-regulation lifestyle program are presented.

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2.

Changes in Illness Perceptions and Quality of Life During Participation in Cardiac Rehabilitation

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Abstract

Background The beliefs patients hold about their disease and corresponding treatment have been shown to predict recovery in cardiac patients. However, it is not known to what extent these beliefs change during participation in cardiac rehabilitation and whether this is related to psychological indicators of outcome.
Method Illness perceptions and health-related quality of life (HRQOL) were measured upon entry to (T0) and completion of (T1) a three-month outpatient cardiac rehabilitation program in 158 cardiac patients.
Results Repeated measures ANOVA revealed that all illness perceptions other than timeline and personal control changed significantly over the course of cardiac rehabilitation. Overall, cardiac rehabilitation patients came to view their illness as more benign. Further analysis revealed that perceiving fewer emotional consequences of the illness, gaining a better understanding, and attributing fewer symptoms to the illness at the end of cardiac rehabilitation, was related to better HRQOL.
Conclusion Illness perceptions change during cardiac rehabilitation and these changes are associated with enhanced quality of life. Clinical trials have shown illness beliefs in cardiac patients to be modifiable during hospital admission; our results suggest that cardiac rehabilitation may provide a second window of opportunity during which illness perceptions can be actively monitored and modified if maladaptive.

Keywords Cardiac rehabilitation; Coronary heart disease; Illness perceptions; Quality of life

Introduction

Next to pharmacological therapies and interventional cardiology, cardiac rehabilitation (CR) programs are widely recognized as essential to the care of cardiac patients. CR programs aim to restore a patient to full physical and psychosocial functioning, and prevent recurrent cardiovascular events (1, 2). Core components of CR therefore include exercise training and psychoeducational programs that focus on education, lifestyle counseling and stress-management. Such programs have shown to be effective in reducing mortality, morbidity and risk factors, and in enhancing (health-related) quality of life (3-7). Quality of life is a broad concept that refers to a patient's subjective perception of the effect of the illness (and corresponding treatment) on physical, emotional and social domains of life (8). Although quality of life is an important construct in the evaluation of treatments, the construct is not derived from theory and, therefore, less attention has been paid to understanding how patients make quality-of-life judgments. Self-regulation theory offers a theoretical framework for understanding the (cognitive) processes underlying these value judgments. It argues that the beliefs patients hold about their illness and treatment are key determinants in how patients evaluate the effect of the illness on their lives (9). Leventhal's self-regulation model (10) classifies such beliefs, or illness perceptions, in seven domains: identity (the label and symptoms associated with the illness), timeline (perceptions about the duration and the course of the illness), consequences (the effects of the illness on the patient's life and daily functioning), the cause of the illness, illness coherence (the extent to which the patient feels he or she understands the illness), the amount of control the patient feels he or she has over the illness and the extent to which the patient perceives the treatment to help, and emotional representation (to what extent the patient is emotionally affected by the illness). Meta-analyses have acknowledged the link between illness perceptions and psychosocial adjustment across a range of diseases (11). In cardiac patients, positive illness perceptions (i.e., attributing fewer symptoms to the illness, perceiving fewer consequences, and experiencing a greater sense of control over the illness) have been associated with better quality of life (12,13). In contrast, pessimistic illness perceptions (i.e., serious consequences, a strong illness identity, and a chronic timeline, poor control) have been related to the onset of depressive symptoms (14-16).

Patients' self-evaluation of health and functioning is likely to change over time in response to changes in disease status or treatment. Not surprisingly, health-related quality of life in cardiac patients has been shown to change during the year following the cardiac event (17) with improvements being most apparent during the early phase of illness (i.e., hospital admission and CR) (18-20). Similarly, it has been argued that illness perceptions are also susceptible to change during this period, as patients continuously acquire new experiences and knowledge and will update their beliefs accordingly (21). In contrast, during the chronic phase of illness, illness perceptions are no longer directly challenged by changes in treatment or disease status, and likely to remain fairly stable (22). Nonetheless, there has been a paucity of research examining the changeability of illness perceptions over time. To our knowledge, there have been six such studies, the majority of which found illness perceptions to be relatively stable (22-24) or to show only small changes (25-27). Most of these studies, however, focused on patient groups for whom the acute nature of their illness had abated by the time of their participation in the study. Two studies on patients with myocardial infarction examined illness perceptions in hospital and four or twelve months after. Patients' perceptions of consequences and identity were found to be stable, but perceptions of control had worsened and the perception of duration of the disease had increased (26,27).

Tentative evidence suggests that illness perceptions are – at least in part – malleable during the acute illness phase. Petrie and colleagues showed that illness perceptions can be successfully altered during hospital admission (28,29). After receiving a brief intervention designed to change illness perceptions,

patients viewed their illness as less threatening, i.e., they perceived fewer consequences, experienced greater (treatment) control over the illness and had a better understanding of their illness. Furthermore, patients felt better prepared to leave the hospital and returned to work more quickly (28,29). CR typically takes place soon after discharge from hospital. Moreover, core components of CR, such as physical exercise and psychoeducational programs, target key illness cognitions and erroneous beliefs, suggesting that changes in illness perceptions and outcomes are likely.
Thus, the aims of the present study are to investigate whether illness perceptions change after participation in a comprehensive CR program and, if so, whether these changes are paralleled by changes in health-related quality of life (HRQOL).

Method

Participants

Participants were recruited in between May 2007 and September 2009 from a major cardiac rehabilitation centre in the Netherlands. All Dutch-speaking patients under 75 who had been diagnosed with ischemic coronary heart disease were eligible for participation. Of 316 eligible patients, 158 signed a letter of informed consent and completed measures upon admission to (T0) and completion of cardiac rehabilitation (T1). This represents a response rate of 50%. General sample characteristics are displayed in Table 1. Approval from the relevant Medical Ethics Committee was obtained for the study.

Measures

Clinical data, including disease severity, admitting diagnosis, cardiac history, co-morbidity, and cardiac risk factor profile, were obtained from admission medical records (T0). The New York Heart Association (NYHA) functional capacity was used to index disease severity. Demographic data included age, gender, marital status and education, and were obtained from a self-report questionnaire administered upon entry to cardiac rehabilitation (T0).

Illness perceptions were measured upon entry to (T0) and completion of (T1) cardiac rehabilitation using the Dutch version of the Brief Illness Perception Questionnaire (30, 31). The (single-item) dimensions consequences, timeline, identity, personal control, treatment control and coherence, and the (two-item) dimension emotional representation were administered. Responses were scored on a 10-point Likert-type scale, with higher scores reflecting a greater endorsement of the given belief (e.g., higher scores indicate a longer timeline, more consequences, greater control etc.).

Health-related Quality of Life (HRQOL) was measured at T0 and T1 using the Dutch validated version of the MacNew Heart Disease Health-related Quality of Life Questionnaire (32,33) which has been shown to have good discriminative and evaluative properties (34). This 27-item disease-specific questionnaire assesses the impact of the cardiac condition on several aspects of the patient's life over the last four weeks. Items are scored on a 7-point scale ranging from 1 (poor HRQOL) to 7 (high HRQOL), with a physical function subscale, an emotional function subscale, and a social function subscale, and a total HRQOL scale.

Procedure

Upon admission to (T0) and completion of (T1) CR, patients filled out a self-report questionnaire as part of the routine intake procedure. In accordance with the Dutch Guidelines for Cardiac Rehabilitation (35) the three-month outpatient CR program comprised (a) physical training sessions three times a week, consisting of cycling and weight training at a level of intensity of 70% of initial maximal oxygen consumption (VO^2 max) (supervised by a physical therapist) ; (b) 4 two-hour psychoeducational sessions on the pathophysiology of 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 two-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).

Data analysis

Based on a previous study examining changes in HRQOL outcomes after CR in the Netherlands (34), small to modest effect sizes can be expected. A priori analyses carried out in G*Power (36) showed that a sample of 95 patients would be sufficient to detect an effect size of at least 0.2 with 80% power at the 5% significance level. Data were analyzed using SPSS for Windows version 17.0. Prior to analyses, data were screened for missing values and violations of the assumptions for ANOVA and multiple regression, including the assumption of normality and multicollinearity. The physical, social, and emotional HRQOL scores violated the assumption of normality and showed moderate to severe negative skewness. Inverse square root transformations normalized the quality of life scores. At both measurement points (T0 and T1) some information was missing due to incomplete self-report questionnaires. Missing data were less than 10% for the HRQOL scores at T0 and less than 5% for the scores at T1. No missing data techniques, such as multiple imputation, were applied.

Pearson correlations and t-tests were carried out to examine potential confounding variables. Disease severity (NYHA functional status), but not age and gender, was found to be significantly related to HRQOL scores. In order to test the stability of illness perceptions over time, one-way repeated measures ANOVAs were computed across time points. Subsequently, hierarchical multiple regression analyses controlling for disease severity and illness perceptions at entry to CR (T0) were carried out in order to examine whether illness perceptions at completion of

CR (T1) predicted HRQOL at T1. Even though the bivariate correlations between the individual T0 and T1 illness perceptions did not exceed 0.7, the VIF-values and the tolerance statistics indicated slight multicollinearity between the illness perceptions predictors. For this reason a principal component analysis was carried out to determine the factor structure of the IPQ Brief. As presented below, a two-factor solution with, on the one hand, a control-related dimension and, on the other hand, an impact-related dimension was found. Subsequently, the hierarchical multiple regression analyses were repeated with the two illness perceptions dimensions in order to examine whether the T1 Impact and Control dimensions predicted HRQOL at T1 after controlling for disease severity and the T0 Impact and Control dimensions.

Results

Factor Analysis

Several studies have pointed out the negative relationships between the illness coherence/control-related dimensions and the other illness perceptions, as well as the positive interrelationships between timeline, identity, consequences, and the emotional representation dimensions (1,11). A principal component analysis with a two-factor solution confirmed this pattern in our data (factor loadings are presented in parentheses); timeline (.56), identity (.73), consequences (.87), and the emotional representation items ‘concern’ (.85) and ‘response’ (.82) loaded on one factor, which was interpreted as reflecting ‘Impact’ of the illness. The control-related dimensions personal control (.72), treatment control (.56), and illness coherence (.72) loaded on a second factor, which was considered to represent illness ‘Control’. The total amount of variance explained by the two factors was 55.6%.

Stability of illness perceptions

One-way repeated measures ANOVAs showed that all illness perceptions other than timeline and personal control changed significantly from entry to CR to completion of CR. As is shown in Table 2, patients perceived fewer consequences ($F(1,154) = 36.56$, $p < 0.001$) and fewer symptoms of their cardiac disease (identity: $F(1,152) = 25.86$, $p < 0.001$) over time. The emotional impact of the disease decreased (emotional representation: $F(1,155) = 38.08$, $p < 0.001$) and patients' sense of understanding of the disease increased (coherence: $F(1,153) = 7.91$, $p < 0.01$) Finally, perceptions about the extent to which the treatment could help control their disease also increased significantly (treatment control: $F(1,149) = 5.68$, $p = < 0.05$). In contrast, perceptions of the duration of cardiac disease remained stable over the course of CR. Perceptions about personal control increased slightly, albeit non-significantly. Finally, the overarching 'Impact' and 'Control' dimensions also showed a significant change over time; perceptions of impact decreased ($F(1,155) = 38.08$, $p < 0.001$ and perceptions of control increased $F(1,153) = 11.41$, $p < 0.01$).

Changes in illness perceptions and quality of life

Table 3, displaying the results of the hierarchical multiple regression analyses, shows that illness perceptions at T1 explained a significant amount of variance in emotional, physical, social and total HRQOL-scores ($p < .01$), after controlling for baseline HRQOL scores and disease severity. In particular, illness coherence (the extent to which the patient understands the illness), illness identity (the symptoms associated with the illness) and emotional representation (to what extent the patient is emotionally affected by the illness) were found to be related to HRQOL. The standardized coefficients show that fewer symptoms and a smaller perceived emotional impact of the illness was related to enhanced HRQOL at the end of CR ($p < 0.01$). Furthermore, the better patients' sense of understanding the illness, the higher social, physical and total HRQOL-scores were ($p < 0.05$).

As the VIF-values and the tolerance statistics indicated slight multicollinearity between the illness perceptions predictors, the analyses were repeated using the two overarching 'Impact' and 'Control' dimensions. Table 4 shows that the illness perceptions dimensions explained a significant amount of the variance in emotional, physical, social and total HRQOL ($p < .01$), after controlling for baseline HRQOL scores and disease severity. The standardized coefficients show that low perceptions of impact at the end of CR were related to better HRQOL ($p < .01$), Perceptions of control, however, did not significantly predict HRQOL ($p > .05$).

Discussion

We found that illness perceptions of cardiac patients changed during CR and that these changes were related to changes in HRQOL. Overall, perceptions related to impact of the disease decreased, whereas perceptions of control increased. Patients perceived fewer consequences of their disease, attributed fewer symptoms to their illness, experienced an increased sense of illness coherence, a greater sense of treatment control, and a lessened emotional impact of the disease. Thus, patients came to view their illness as more benign over the course of CR. This is in contrast to earlier studies on cardiac patients, which found that patients came to view their illness as more chronic (i.e., longer timeline) and less controllable (26,27). These patients, however, did not attend CR. CR typically takes place during the more acute phase of coronary heart disease, in which illness perceptions are still being updated as a results of changes in treatment and disease status. For obvious lack of a control condition, it is not possible to draw any conclusions as to whether the reported changes in illness perceptions in our sample were brought about by participation in CR, or whether they are a non-specific effect of adaptation to illness. Nonetheless, our results suggest that during CR illness perceptions are still susceptible to change, thus providing a window of opportunity during which negative illness perceptions that are not in accordance with disease severity can be altered and positive perceptions can be strengthened. Moreover, such interventions may be fitted in the existing infrastructure of CR relatively cost-effectively; a recent systematic review shows that different health practitioners can be trained to adequately deliver interventions aimed at changing maladaptive illness beliefs (37). Other support comes from the field of reattribution theory, which has longstanding experience in training health professionals other than psychologists in rectifying maladaptive illness beliefs (38,39). Future research should investigate whether CR can be used as a vehicle to affect changes in illness perceptions in a direction that is compatible with recovery.

The second aim of the study was to investigate whether the reported changes in illness perceptions were related to quality of life in cardiac patients. Overall, patients perceived a lessened impact of their disease after CR and this was associated with enhanced emotional, social, physical and total HRQOL. In particular, perceiving fewer emotional consequences of the illness, gaining a better understanding, and attributing fewer symptoms to the illness at the end of CR, was related to better HRQOL. Perceptions of control did not appear to be related to wellbeing. Previous studies in cardiac patients have also found optimistic impact-related illness perceptions to be predictive of wellbeing (40) and pessimistic impact-related perceptions to predict distress (41). This is in line with self-regulation theory, which suggests that quality of life is likely to be enhanced when reminders of the disease (i.e., attributed symptoms and associated worry) are moderated and patients come to view the disease as less threatening (9). Our finding that control-related perceptions were not associated with HRQOL has been reported before by French and colleagues (13).

Limitations

We used Kaptein and colleagues' adaptation of the IPQ Brief. This Dutch version has been shown to have relatively good reliability and moderate validity (31). Yet, concern has been raised with regards to the phrasing of items and the wording of the control-related items in Dutch (42, 43). In view of this recent debate about the psychometrical qualities of the IPQ Brief and, in particular, the validity of the Dutch version (42-44), future research may prefer to use the IPQ-Revised, which shows good reliability and validity (45). Furthermore, as this version of the IPQ is more commonly used in cardiac research (e.g., 27-29), this would allow for better comparison between samples on a subscale level.

In conclusion, we found that illness perceptions of cardiac patients changed over the course of CR and these changes were associated with enhanced HRQOL. Clinical trials have shown illness perceptions in cardiac patients to be modifiable during the acute phase of the disease (28,29). Evidently, CR provides a very suitable setting in which the evolution of illness perceptions over time can be monitored and maladaptive beliefs can be modified.

Table 1.
Sample characteristics.

	Patients (N=158)
Gender	
Men	127 (80.4)
Women	31 (19.6)
Age	58.0 ± 9.2
Marital status	
Single	11 (7.0)
Married/partnered	131 (82.9)
Divorced/separated	10 (6.3)
Widowed	5 (3.2)
Education	
Primary education	8 (5.1)
Secondary education	9 (5.7)
Vocational education	97 (61.4)
Tertiary education (college/university)	44 (27.2)
Type of work	
Full-time	82 (51.9)
Part-time	27 (17.1)
Home/retired	48 (30.4)
Diagnosis	
Myocardial Infarction	60 (38.0)
Coronary Artery Bypass Surgery (CABG)	45 (28.4)
Percutaneus Coronary Intervention (PCI)	41 (25.9)
Arrhythmias	9 (5.7)
Other †	3 (1.9)
Cardiac History §	
Yes	53 (33.8)
No	104 (66.2)
NYHA	
I	90 (57.6)
II	48 (30.9)
III	17 (10.9)
IV	1 (0.6)

Note: Values are shown as n(%) or mean ± SD where appropriate.
† Prosthetic valve or valve repair surgery (n=2), angina pectoris (n=1)
§ Includes antecedent cardiac events such as myocardial infarction, CABG, PCI or arrhythmias

Table 2.
Descriptive statistics and change in illness perceptions at entry to CR (T0) and completion of CR (T1).

	T0	T1	df	F	p
Illness Perceptions					
Consequences	5.44 ± 2.62	4.27 ± 2.68	1,154	36.56	0.00
Timeline	6.95 ± 3.32	7.11 ± 3.59	1,150	0.52	0.47
Control (self)	6.06 ± 2.38	6.40 ± 1.86	1,148	1.84	0.18
Control (treatment)	7.71 ± 1.86	8.14 ± 1.56	1,149	5.68	0.02
Identity	4.12 ± 2.57	3.10 ± 2.37	1,152	25.86	0.00
Coherence	6.61 ± 2.82	7.31± 2.44	1,153	7.91	0.01
Emotional Representation	4.56 ± 2.53	3.47 ± 2.52	1,155	38.08	0.00
Impact dimension	5.10 ± 2.20	4.26 ± 2.19	1,155	39.55	0.00
Control dimension	6.78 ± 1.64	7.28 ± 1.45	1,153	11.41	0.00
HRQOL					
Emo HRQOL	5.34 ± 1.16	4.89 ± 0.56			
Social HRQOL	5.61 ± 1.05	5.63 ± 0.89			
Physical HRQOL	5.19 ± 1.03	5.90 ± 0.84			
Total HRQOL	5.37 ± 0.96	5.36 ± 0.63			

Note: Data are presented as mean ± SD

Table 3

Hierarchical Multiple Regression Results: explained variance (R^2), standardized coefficients (βs), and total model adjusted R^2 with HRQOL regressed on illness perceptions at T1.

Variable	Total Quality of Life (T1)	Emotional Quality of Life (T1)	Physical Quality of Life (T1)	Social Quality of Life (T1)
Block 1: Control Variables				
T0 measure per outcome variable	.41**	.32**	.26**	.46**
Disease severity †	-.02	.09	-.09	-.09
R^2	28.8%**	17.2%**	25.4%**	38.4%**
Block 2: Illness Perceptions T0				
Consequences	.05	.14	-.06	.12
Timeline	-.09	-.05	-.10	-.15
Control (self)	-.01	.01	-.01	.02
Control (treatment)	.16*	.15	.15*	.11
Identity	.07	.15	-.01	.07
Coherence	-.15*	-.08	-.12	-.14*
Emotional Consequences	.08	-.13	.16	-.01
R^2	34.4%	24.4%	33.4%*	44.4%**
Block 3: Illness Perceptions T1				
Consequences	.06	.06	.04	.04
Timeline	.12	.06	.13	.12
Control (self)	-.06	-.07	-.01	-.10
Control (treatment)	-.05	-.07	-.04	.03
Identity	-.43**	-.21	-.49**	-.36**
Coherence	.16*	.12	.13*	.13*
Emotional Consequences	-.30**	-.36**	-.25*	-.27**
	59.8%**	39.2%**	60.3**	63.7**
Total Adjusted R^2	54.5%	31.4%	55.0%	58.8%
Total Model F(df)	11.18(16, 136)**	5.07(16, 142)**	11.40(16, 136)**	13.15(16, 136)**

*Note: * $p < .05$; ** $p < .01$ †NYHA Functional Status*

Table 4.
Hierarchical Multiple Regression Results: explained variance (R^2), standardized coefficients (βs), and total model adjusted R^2 with HRQOL regressed on Impact and Control dimensions at T1.

Variable	Total Quality of Life (T1)	Emotional Quality of Life (T1)	Physical Quality of Life (T1)	Social Quality of Life (T1)
Block 1: Control Variables				
T0 measure per outcome variable	.38**	.36**	.25**	.44**
Disease severity †	- .07	.10	-.15*	-.12
R^2	28.8%**	17.2%**	25.4%**	38.4%**
Block 2: Illness Perceptions T0				
Impact dimension	.15	.12	.10	.09
Control dimension	- .01	.05	.01	-.03
R^2	31.1%	19.2%	29.5%*	41.3%*
Block 3: Illness Perceptions T1				
Impact dimension	-.48**	-.41**	-.50**	-.43**
Control dimension	.05	.01	.07	.05
R^2	43.5%**	27.8%**	43.1%**	51.4%**
Total Adjusted R^2	41.0%	24.6%	40.5%	49.2%
Total Model F(df)	16.97(6, 138)**	8.84(6, 144)**	16.66(6, 138)**	23.24(6, 138)**

*Note: * $p < .05$; ** $p < .01$ †NYHA Functional Status*

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3.

Lifestyle Modification Programs for Patients with Coronary Heart Disease: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Abstract

Background Lifestyle modification programs for coronary heart disease patients have been shown to effectively improve risk factors and related health behaviors, quality of life, re-incidence and mortality. However, improvements in routine cardiac care over the recent years may offset the incremental benefit associated with older programs.
Purpose To determine the efficacy of lifestyle modification programs for coronary heart disease patients developed over the last decade (1999-2009) by means of a systematic review and meta-analysis.
Results 23 trials (involving 11085 randomized patients) were included. Lifestyle modification programs were associated with reduced all-cause mortality (summary OR = 1.34; 95% CI: 1.10 to 1.64), cardiac mortality (summary OR = 1.48; 95% CI: 1.17 to 1.88), cardiac readmissions and non-fatal reinfarctions (summary OR = 1.35; 95% CI: 1.17 to 1.55). Furthermore, lifestyle modification programs positively affected risk factors and related lifestyle behaviors at posttreatment (M =10.2 months), and some of these benefits were maintained at long-term follow-up (M =33.7 months). Improvements in dietary and exercise behavior were greater for programs incorporating all four self-regulation techniques (i.e., goal-setting, self-monitoring, planning and feedback techniques) compared to interventions that included none of these techniques.
Conclusion The evidence summarized in this meta-analysis confirms the benefits of lifestyle modification programs - over and above benefits achieved by routine clinical care alone.

Keywords: cardiac rehabilitation, secondary prevention, lifestyle modification, self-regulation, coronary heart disease, meta-analysis.

Introduction

Mortality rates for coronary heart disease (CHD) have been declining due to improvements in diagnosis, treatment and prevention, leaving a greater number of patients in need of optimal secondary prevention (1,2). The benefits of cardiac rehabilitation (CR) programs have long been recognized, and CR programs have become widely available (3). CR programs aim to return patients to physical and psychosocial functioning and to reduce the risk of recurrent cardiovascular events (4). Once, CR programs were almost exclusively exercise-based, but gradually they have become supplemented with health education, lifestyle counseling and psychological treatment components, which better address the full range of modifiable risk factors. Such comprehensive lifestyle modification programs have received increasing attention as evidence is emerging that the mortality-reduction potential of lifestyle changes in CHD patients is at least comparable to that demonstrated for cardiopreventive drug usage (5,6). There is a large body of evidence showing that lifestyle modification programs effectively improve risk factors and related health behaviors, quality of life, morbidity and mortality (e.g., 7-11).

Contemporary lifestyle modification programs often comprise a variety of psychological methods to support behavior change. Several researchers have called attention to the large differences in efficacy between such programs, emphasizing the importance of clarifying factors that impact upon program effectiveness (11-13). Research has identified specific program characteristics which moderate treatment effectiveness, such as setting, timing, and duration (7,11,12), but these have provided little insight into the psychological mechanisms of change. Several meta-analyses and reviews have attempted to isolate effective behavior-change techniques. Self-monitoring, for instance, has been found to be effective across populations and behaviors

(14-17). However, breaking up interventions into separate techniques and assessing the effectiveness of such techniques individually does not take into account the synergistic effects of combining sets of techniques (14,17). Self-regulation (SR) theories of behavior change (18,19) assume that all behavior is goal-directed and that the motivation for behavior change stems from the wish to reduce a discrepancy between one's current state and a desired state (i.e., goal-setting). Intent is then translated into action using implementation and planning techniques. Action is governed by self-monitoring and feedback strategies regarding goal-related progress. Thus, lifestyle modification programs that incorporate this set of techniques (i.e., goal-setting, planning, self-monitoring and feedback) may be more effective than programs that do not employ such SR techniques (14,20).

A further impetus for an update of existing meta-analyses is the observation that in more recent lifestyle modification trials, control patients tend to show improved risk factor management as well (12,21). In most non-pharmacological studies, routine clinical care serves as control condition, and several researchers have pointed out that older trials may pre-date improvements in routine cardiac care, such as added exercise and/or lifestyle modification components (21,22). A recent meta-analysis in the area of HIV by De Bruin and colleagues (23) showed that the quality of standard care offered to the control condition affected the incremental benefit of behavior change intervention programs. Within cardiac rehabilitation research, Linden and colleagues (11) commenced to investigate the differential effect of quality of care (high versus low) offered to the control condition, but they had to abandon their attempt because of a lack of studies in the separate types of control conditions.

The aim of this meta-analysis is to examine whether lifestyle modification programs in CHD patients tested over the last ten years (1999-2009) improve risk factors and related health behaviors, reduce mortality and cardiac recurrences, and whether the effects on these clinical outcomes are moderated by the type of care offered to the control condition. In addition, the efficacy of programs incorporating all four SR techniques of behavior change (i.e., goal-setting, planning, self-monitoring and feedback) compared to programs that utilized none of these techniques will be examined. As current guidelines place large emphasis on addressing the full range of modifiable risk factors (24), only programs focusing on multiple risk factors and related lifestyle behaviors will be included.

Method

Search strategy and eligibility criteria.

This meta-analysis included only randomized controlled trials (RCTs) published in English in peer-reviewed journals between 1999 and 2009, which tested face-to-face lifestyle modification programs for CHD patients. We included studies with patients that were eligible for CR and/or belonged to one of the following diagnostic groups (25): myocardial infarction with and without percutaneous intervention, angina pectoris with and without percutaneous intervention, heart surgery (including patients with prosthetic valve or valve repair surgery and coronary bypass artery grafting), implantable cardioverter defibrillator patients, and heart failure patients. Furthermore, studies were included only if: (a) the modification of lifestyle formed the main focus of the intervention; (b) the efficacy of the lifestyle modification program formed the main target of evaluation; (c) at least one face-to-face session between the health care provider and the patient took place; (d) the outcomes reported included one or more modifiable risk factors (i.e., cholesterol levels, blood pressure, body mass index, waist/hip ratio, or smoking) as well as one or more health behaviors (i.e., dietary habits or exercise) (26). In case data reported did not allow calculation of effect sizes, or data were presented for mixed

populations only (i.e., stroke/ ischemic attack patients and CHD patients), we contacted the principle author in an attempt to obtain the missing data, or request CHD specific information. We excluded studies that evaluated single-modality interventions (i.e., focused on the modification of a single risk factor only), or used selective populations (i.e., CR non-attenders).
We searched Web of Science, PubMed, Medline, PsychINFO, and the Cochrane Library for relevant articles published between 1999-2009 using an updated version of Dusseldorp and colleagues' (7) search algorithm "cardiovascular disease, coronary heart disease, coronary artery disease, percutaneous angioplasty, PTCA, PCI, myocardial infarction, coronary bypass surgery, coronary artery bypass graft, CABG, health education, psychological intervention(s), psychoeducational intervention(s), behavio(u)r modification, cognitive behavio(u)ral intervention(s), cardiac rehabilitation, secondary prevention, self-management, risk factor(s), smoking, cholesterol, triglycerides, blood pressure, body mass index, overweight, weight, obesity, diet, dietary behavio(u)r, exercise, physical activity". The detailed search strategy is available from the authors. In addition, reference lists from existing reviews and meta-analyses were hand-searched to locate additional studies.

Study selection and quality assessment

Two investigators (VJ and IB) independently reviewed potentially eligible titles and abstracts using a pilot-tested standardized form with written instructions. All articles published within the relevant time period (1999-2009) were considered for inclusion. Disagreements were resolved by consensus. The methodological quality of each eligible study was assessed using the Jadad quality criteria (27) and sample size. Following previous meta-analyses (12,28) we did not include allocation concealment in the Jadad scoring procedure, as blinding of assessors and participants is difficult to accomplish in the study of lifestyle interventions. Thus, the

Jadad score consisted of two items assessing randomization and one item assessing losses to follow-up, leading to a maximum score of 3 points. It is known that meta-analyses incorporating a relatively high number of small positive trials tend to overestimate the magnitude of effect sizes. Several authors have suggested that studies with less than 35 patients per condition should be considered too small (29,30). Therefore, study size was coded as a means of quality control.

Coding and data extraction

Two coders (VJ and IB) independently extracted all relevant information from each eligible article by using a standardized data extraction form based on Dusseldorp and colleagues' (7) coding scheme. For the complete coding form, see Appendix 1. Articles were coded for the following study features: (a) bibliographic information; (b) location (country, setting [primary vs. secondary care]); (c) characteristics of trial patients (mean age, gender, diagnosis) and the trial's inclusion and exclusion criteria; (d) quality criteria; (e) content information for the intervention (intensity [duration of the program in months x number of sessions], participation of partners, and type of behavior change technique used [goal-setting, self-monitoring, planning, feedback]); (f) type of care offered to the control condition (content of standard care and additional services, such as structured exercise, lifestyle modification or stress- management); (g) type of outcome (systolic blood pressure, diastolic blood pressure, body mass index, total cholesterol, smoking, exercise [min/wk], dietary habits [saturated fat intake, energy in kJ/kcal], cardiac readmission and reinfarction, cardiac mortality, all-cause mortality); (h) effect size data for pre-, posttest and follow-up measurements (short-term < 12 months, medium term ≥ 1 year < 2 years, long-term ≥ 2 years). Finally, each intervention was assessed for the presence of SR techniques of behavior change (goal-setting, self-monitoring, planning, feedback). Behavior change techniques were assigned a score of 0 ('not present'), 1 ('somewhat present) or 2 ('present') based on the extent to which the technique was used in the intervention (see Appendix 1, p 3 and 4 for coding form). Subsequently, interventions that included all four SR techniques were classified as 'high SR-interventions' (score of 2 on at least three constructs, score of 0 on none of the constructs). Interventions that did not employ these techniques were classified as 'low SR-interventions' (score of 0 or 1 on all four constructs). Interventions scoring high on some of the SR techniques and low on others were categorized as 'neither high nor low'. We carried out calibration exercises to enhance consistency among the review team before using the data extraction form. Discrepancies were resolved by consensus or third party arbitration (SM, VDG). The average agreement between the two coders (VJ and IB) was satisfactory (Cohen's $\kappa = 0.74$).

Data analysis

Comprehensive Meta-Analysis Software version 2.2 (31) was used to calculate standardized difference effect size estimates (Hedges'g) for continuous data and odds ratios for categorical data. Summary effect sizes were computed as the weighted mean of the study effect sizes. We tested for statistical heterogeneity using the I^2 statistic. For a heterogeneous set of effect sizes, the random summary effect estimates with 95% confidence intervals were reported, while for a homogeneous set the fixed estimates with 95% confidence intervals were reported. We differentiated between outcomes assessed at baseline (immediately preceding start of the program), posttreatment (immediately following termination of the program) and at follow-up. Following Dusseldorp and colleagues (7), we categorized follow-up outcome assessment time into three measurement periods: short-term (< 12 months), medium-term (≥ 1 year < 2 years), and long-term (≥ 2 years). If a study reported several posttests within a measurement period, the last posttest within that period was chosen. For risk factor and health behavior outcomes, separate meta-analyses were conducted at both posttreatment and follow-up. For mortality, readmission and reinfarction rates, meta-analyses were conducted at outcome assessment time ≥ 12 months and ≤ 5 years (there was only one study (32) that reported mortality data at 6 months and one study (33) that reported 10-year follow-up data in addition to the 5-year follow-up). In all other cases, if a study reported mortality data at both medium- and long-term follow-up, the longest follow-up duration was chosen.

Additional analyses

In case of heterogeneity, comparative subgroup analyses were carried out to examine if the treatment effects varied in relation to the following moderators: (a) setting (primary versus secondary care) (b) exclusion criteria (on the basis of cardiac diagnosis yes/no, on the basis of disease severity yes/no) (c) presence of SR strategies (goal-setting, self-monitoring, planning, feedback) in the intervention ('high SR' [score of 2 on at least three out of four constructs, score of 0 on none of the constructs] versus 'low SR' [score of 0 or 1 on all four constructs]. Interventions scoring high on some of the constructs and low on others were categorized as 'neither high nor low' and not used in the comparative subgroup analyses.) (d) type of care offered to control group (usual care without [=0] or with [=1] exercise and/or lifestyle modification). Subsequently, meta-regression was used to examine the effects of the continuous study variable intensity (no of sessions x duration in months) on treatment effects.

Sensitivity analyses were pre-specified and carried out to explore whether treatment effects were affected by methodological quality ('high risk of bias' [Jadad score ≤ 2 and/or sample size < 35 per condition] versus 'low risk of bias' [Jadad score > 2 and sample size ≥ 35 per condition]) (29,30). In order to ascertain the validity of the results obtained, analyses were repeated excluding these high risk of bias (i.e., low quality or small sample size) studies.

Results

Study Characteristics and Quality

Of 106 eligible randomized controlled articles, 68 were excluded; leaving a total of 38 articles evaluating 23 trials (see Figure 1). The number of articles exceeded the number of trials as 8 trials reported short-term and long-term data separately or reported different outcomes in different articles (34-41). In total, 5537 participants were included in the intervention groups and 5548 in the control groups. Table 1 shows characteristics of the included studies and a brief description of the content of both the intervention and the control condition.

The content of the control conditions differed across trials. In 14 trials, control groups received 'usual care'. This mostly consisted of standard care by the family physician or cardiologist. In six trials, control groups received some form of lifestyle modification. In most cases, this involved information on risk factors and lifestyle change, sometimes coupled with follow-up contact. This was coded as 'lifestyle modification'. In 3 trials, control groups received full cardiac rehabilitation, including structured exercise sessions, education and lifestyle counseling. This was coded as 'lifestyle modification plus exercise'. None of the patients in control conditions received stress-management training.

As regards intervention content (Table 2), 9 trials included all four SR techniques in their intervention ('high SR'). Six 6 trials used some of these techniques, but not all ('neither high, nor low SR') and 8 trials incorporated none of these techniques ('low SR'). Furthermore, Table 2 and appendix 2 show that trial quality was moderate with Jadad scores between 2 and 3. Nevertheless, 9 trials failed to specify the method of randomization or did not adequately describe this (see appendix 2). All trials reported on losses to follow-up, and 11 trials carried out intention-to-treat analyses. Table 2 also shows that 3 studies (39,42,43) included fewer than 35 patients per condition.

Synthesis of Results

Mortality

All-cause mortality data with outcome assessment times between 12 and 60 months (M = 34.4 months) were available for 6 trials (32,34,35,44-46) reporting data for 6270 patients. Cardiac mortality data with this follow up period were available for 5 trials (34,44,47-49) reporting on 5237 patients with outcome periods ranging from 36 to 60 months (M = 54.5 months). Lifestyle modification programs were associated with a significant reduction in all-cause mortality (summary OR = 1.34 [$p < 0.00$; 95% CI: 1.10 to 1.64]) and cardiac mortality (summary OR = 1.48 [$p < 0.00$; 95% CI: 1.17 to 1.88]). There was no evidence of heterogeneity between the trials for both analyses ($p = 0.8$, $I^2 = 0\%$) and ($p = 0.5$, $I^2 = 0\%$). Figure 2 shows forest plots for both outcomes.

Reinfarction and readmission

Reinfarction rates were available for 6 trials (34,43-45,48,49) at assessment time ≥ 12 months. Two trials (46,50) reported cardiac readmissions instead of reinfarction rates. We considered the combined outcomes of cardiac readmission and reinfarction such that outcome data were available for 8 trials (34,43-46,48-50) reporting on 6479 patients with outcome assessments ranging between 12 and 60 months (M = 31.8 months). Lifestyle modification programs were associated with a significant reduction in reinfarction and readmission (summary OR = 1.35 [$p < 0.00$; 95% CI: 1.17 to 1.55]) and there was no evidence of heterogeneity between the trials ($p = 0.24$, $I^2 = 23\%$). Figure 3 shows forest plots.

Risk factors and lifestyle behaviors
Table 3 presents summary effects and heterogeneity statistics for the separate risk factors and related lifestyle behaviors for posttreatment and follow-up data. At posttreatment, small but significant summary effects were found for nearly all risk factors (systolic and diastolic blood pressure, total cholesterol, and smoking) and lifestyle behaviors (exercise, dietary habits). However, data showed evidence of significant heterogeneity. At follow-up assessment, significant summary effects were found for diastolic blood pressure, body mass index, exercise and dietary habits. Risk factor data appeared mostly homogenous, but the dietary outcomes showed evidence of heterogeneity. Forest plots for all outcomes are displayed in Appendix 3.

Additional analyses
Sensitivity analyses were carried out in order to examine if treatment effects differed according to methodological quality. High risk of bias trials (low quality and/or small sample size) showed greater effect sizes for reinfarction and readmission rates, and smoking, total cholesterol, and dietary behavior (fat intake) outcomes than low risk of bias trials (high quality and adequate sample size). Repeating the analyses excluding high risk of bias studies reduced the magnitude of effect sizes, but the treatment effects remained significant. For reinfarction and readmission rates, excluding high risk of bias studies ($k = 3$) decreased the summary effect from OR equals 1.35 [$p < 0.00$; 95% CI: 1.16 to 1.57, $k = 8$] to 1.30 [$p < 0.00$; 95% CI: 1.12 to 1.50, $k = 5$]). For smoking, the summary effect decreased from OR equals 1.21 ($p = 0.05$; 95% CI: 1.00 to 1.47, $k = 18$) to 1.18 ($p < 0.00$; 95% CI: 1.06 to 1.31, $k = 12$). For total cholesterol, the summary effect decreased from g equals 0.20 ($p < 0.00$; 95% CI: 0.10 to 0.32, $k = 17$) to 0.08 ($p < 0.00$; 95% CI: 0.04 to 0.13, $k = 10$). For dietary behavior, the summary effect decreased from g equals 0.41 ($p < 0.00$; 95% CI: 0.01 to 0.60, $k = 16$) to 0.25 ($p < 0.00$; 95% CI: 0.11 to 0.40, $k = 9$)

Subgroup analyses were carried out in order to examine if treatment effects varied in relation to the following characteristics: (a) setting (primary versus secondary care) involvement of partners (yes/no) (b) exclusion criteria (on the basis of cardiac diagnosis yes/no, on the basis of disease severity yes/no) (c) extent to which each of the SR behavior change techniques (goal-setting, self-monitoring, planning, feedback) was present in the intervention ('low SR' versus 'high SR') and (d) type of care offered to control group, where standard care was coded as 'UC' (k=14). Standard care plus lifestyle modification (k=6) and standard care plus lifestyle modification and exercise (k=3) were coded as 'UC plus'.
For the risk factors (i.e., systolic blood pressure, diastolic blood pressure, BMI and total cholesterol) effect sizes did not vary in relation to any of these characteristics.
For the lifestyle behaviors, however, the variation in effect sizes could be accounted for by several moderators. The results are presented in Table 4. First, studies set in secondary care were associated with greater improvements in non-smoking, physical exercise, and dietary habits. Second, interventions involving partners of patients were associated with greater benefits in smoking cessation rates and dietary behavior (fat intake).
Third, the magnitude of effect sizes appeared to be greater in trials where the control condition was standard cardiac care versus trials where the control condition consisted of 'usual care plus', i.e., offering lifestyle modification with/without exercise components, on top of standard cardiac care. Thus, the additional benefits of lifestyle modification programs were smaller in terms of improved diet (fat intake), exercise behavior and smoking in trials that offered 'usual care plus'. Finally, interventions incorporating all four SR psychological techniques were associated with greater lifestyle benefits. More specifically, programs that included this set of techniques (i.e., goal-setting, planning, self-monitoring and feedback) were more successful in changing exercise behavior and dietary habits (fat intake) than

programs that used none of these techniques. These differences did not seem to persist in the long-term. Because of the limited number of studies providing follow-up outcome data, however, the long-term results should be interpreted with caution. Meta-regression analysis revealed no significant association between the continuous study variable 'program intensity' (no of sessions x duration in months) and treatment effects (data not shown).

Publication Bias

Visual inspection of funnel plots revealed some asymmetry for smoking, exercise, and dietary habits outcomes. Fail-safe numbers for these outcomes were n = 56 for smoking, n= 506 for exercise, n = 502 for fat intake and n = 83 for energy intake. As a rule of thumb, Rosenthal (51) suggests that the fail-safe number should not be smaller than 5n + 10, where n is the number of studies excluded in the meta-analysis. Correcting for publication bias using the 'trim and fill' method (52) led to slightly revised summary effects for smoking, exercise, and energy intake, but the treatment effects remained significant. There was no evidence of publication bias for all-cause mortality, cardiac mortality, reinfarction and readmission, blood pressure, BMI and total cholesterol outcomes as evidenced by symmetrical funnel plots and the 'trim and fill' method.

Discussion

The evidence summarized in this meta-analysis suggests that comprehensive lifestyle modification programs for CHD patients reduce mortality, re-incidence and readmission rates. Overall, lifestyle modification programs included in this meta-analysis reduced mortality by 34% and cardiac re-incidence and readmissions by 35% over a follow-up period ranging from one to five years. This is consistent with reductions in mortality and cardiac recurrence observed by previous meta-analyses and systematic reviews (7,15,28,53,54).

Comprehensive lifestyle modification programs were also shown to positively affect risk factors and related lifestyle behaviors both at posttreatment (M =10.2 months) and at follow-up (M =33.7 months). At posttreatment, lifestyle modification programs were associated with significant reductions in blood pressure (both systolic and diastolic), total cholesterol and smoking, and significant improvements in exercise behavior and dietary habits - even though the summative effect sizes were only small to moderate. Nevertheless, these findings are largely consistent with previous meta-analyses which have also reported very small effect sizes for blood pressure and small-to-moderate effect sizes for changes in cholesterol levels, smoking, and exercise behavior (11,12). Evidence from large population studies suggests that, jointly, such small individual reductions lead to clinically important improvements in risk factor profile (55).

At follow-up, treatment benefits were maintained for exercise behavior and dietary habits, but not for smoking. Furthermore, improvements had become evident for BMI, which may be a reflection of the time-lag between improved dietary habits and exercise behavior, and a subsequent healthier BMI. Surprisingly, effects did not persist in the long term for systolic blood pressure and cholesterol levels – although it should be noted that only a limited number of studies provided follow-up data for these end-points. As a result, these findings should be interpreted with caution.

As regards the factors that impact upon program effectiveness, we found changes in lifestyle to vary dependent upon whether or not SR techniques of behavior change were utilized in the lifestyle modification program. More specifically, programs that included all four SR techniques were more successful in changing exercise behavior and dietary habits (fat intake) compared to interventions that included none of these techniques. However, at long-term follow-up we found these differences to dissipate, implying that the beneficial effects of such psychological strategies seem to wear off once the program has terminated. Research on long-term adherence typically shows that maintenance of lifestyle change is problematic as many cardiac patients relapse into old habits (56, 57). Future lifestyle modification programs might maintain these benefits by offering some form of continuation, for example by offering booster sessions that reinforce the continuous use of goal-setting, self-monitoring, and feedback strategies. Evidence from a recent large-scale trial suggests that such strategies may indeed be effective (44).

As speculated, we found the incremental benefit of lifestyle modification programs to be smaller in terms of non-smoking, improved diet and exercise behavior in settings where standard care was elaborate. This accords with the meta-analysis by De Bruin and colleagues (23), which demonstrated that quality of standard care determined treatment outcomes in HIV behavior-change interventions. These findings suggest that future meta-analyses on comprehensive CR programs should take into consideration the type of care offered to the control condition, thus accrediting ongoing developments in the routine management of CHD.

Limitations and future research

The interpretation of our results may be challenged by the heterogeneity observed, in particular with regards to the lifestyle outcomes. Sensitivity and subgroup analyses revealed some sources of heterogeneity, but were unable to account for all of the systematic variation in effect sizes. Future research should continue exploring factors that may moderate program effectiveness, such as intensity of the program, provision of booster sessions and relapse prevention, modes of intervention delivery (e.g., face-to-face, internet- or telephone-based) used, and type of participants included. Increasingly, trials have

been investigating the efficacy of CR programs in selective populations, such as women, the elderly, ethnic minorities, and high-risk patients. Future meta-analyses might identify subgroups that benefit most/least from CR programs.
Secondly, several authors have expressed serious concerns over the inclusion of lesser quality studies in systematic reviews and meta-analyses (58-60). In an attempt to address this, we controlled for study quality by independently analyzing low risk of bias trials. Re-analysis of our data thus decreased the magnitude of the summative effect sizes but did not alter results, rendering it less likely that our results are inconclusive or confounded. Nevertheless, it has been suggested that future meta-analyses should apply even stricter quality controls, for example by including only RCTs that adhere to the CONSORT guidelines (59).
Thirdly, several authors have voiced concern over the inadequate way in which the content of behavioral interventions tends to be reported in the literature (14,61,62). Not only do intervention descriptions often fall short of describing exactly which behavior change techniques were used, certain labels (e.g., 'lifestyle modification' or 'stress-management') may mean different things to different practitioners. Thus, future research should report the content of both intervention and control condition according to a taxonomy, for example as developed by Michie and colleagues (61) or Schulz and colleagues (63).
Finally, this meta-analysis used summary data from published studies – as is common in this field. Recently, however, it has been suggested that meta-analytic research should move from aggregating study-level data to the synthesis of individual patient data (64), which involves combining raw patient data from each study, in order to allow analysis as if it were one large dataset. Using individual patient data would reduce confirmatory publication bias and selective outcome reporting and aid meta-analyses and systematic reviews in reaching conclusions based on objective and compelling

evidence (65). However, the extra time, effort and complexity involved in obtaining and analyzing raw patient data requires a new infrastructure and, most probably, a shift in scientific mentality.

In conclusion, the evidence summarized in this meta-analysis suggests benefit from recent lifestyle modification programs (1999 – 2009) for multiple outcomes, over and above improvements achieved by routine clinical care alone. Furthermore, our findings suggest that programs using all four SR techniques of behavior change (i.e., goal-setting, self-monitoring, planning and feedback) were more successful in changing lifestyle behaviors than programs that did not use such techniques. Nevertheless, results also show that long-term lifestyle change and risk factor reduction pose a challenge. Future lifestyle modification programs should therefore incorporate psychological techniques and strategies that specifically target relapse prevention and maintenance of behavior change.

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Table 1.
Characteristics of included studies

Author, year (ref.)	**Sample size, N**	**Mean age**	**Population a**	**Measurement period b**
Aldana et al., 2007 (66)	93	62	CHD	PT= 6 mths FU= 12 mths
Allison et al., 2000 (67)	326	58	AP	PT= 6 mths
Brugemann et al., 2007 (68)	137	57	CABG PCI	PT= 3 mths FU= 9 mths
Campbell et al., 1998 (69) Campbell et al., 1998 (70) Murchie et al., 2003 (34) Murchie et al., 2004 (71) Delaney et al., 2008 (33)	1173	66	CHD	PT= 12 mths FU= 24 mths FU= 48 mths FU= 56 mths
Cupples et al., 1994 (47) Cupples et al., 1999 (35)	688	63	AP	PT= 24 mths FU= 60 mths
Giannuzzi et al., 2008 (44)	3241	58	MI	PT= 6 mths FU= 24 mths FU= 36 mths
Higgins et al., 2001(72)	99	48	PCI	PT= 2 mths FU= 12 mths
Jeong et al., 2002 (42)	45	53	MI	PT= 3 mths
Jiang et al., 2007 (73)	167	62	CHD	PT= 3 mths FU= 6 mths

Intervention Content (Intensity: no of session/ duration in months)	Control Condition Content
Intense cardiovascular disease risk factor program based on the Ornish Program for Reversing Heart Disease. The program involveda 10% fat vegetarian diet, supervisedexercise, stress management training, smoking cessation, andgroup psychological support.(72 sessions/12 months)	Standard cardiac rehabilitation (structured exercise program 3x a week, dietary and smoking cessation counselling).
Nurse-run risk factor management program. Intervention strategies included: institutingpharmacologic lipid management, making appropriate referrals (f.i.to the diabetic clinic, social work, or psychology);counseling on exercise, diet, and smoking cessation; and reporting abnormal results to the patient's primary care physician. (3 sessions/6 months)	Usual care by physician + follow-up appointment with a cardiologist
Comprehensive cardiac rehabilitation program, which included one risk factor management teaching session and physical training thrice a week for 8weeks.In addition, relaxation therapy and weekly psycho-education sessions.(27 sessions/2 months)	Standard cardiac rehabilitation (onerisk factor management teaching session and physical training thrice a week for 6 weeks).
Nurse-run clinics in general practice promotingmedical and life-style aspects of secondary prevention. Regular follow-ups offered over one year. Risk factors and symptoms were assessed and clinic visits includedfeedback, goal planning, and an agreed action plan.(6 sessions/12 months	Usual care by own GP
Practical advice regarding cardiovascular risk factors given by a health visitor. Patients were reviewed at four monthly intervals and given appropriate health education (7 sessions/24 months)	Usual NHS care.
Long-lasting multifactorial educational and behavioural program following completion of initial cardiac rehabilitation. Sessions consisted of aerobic exercise, comprehensive lifestyle and risk factor counselling, clinical assessment, and reinforcement of preventive interventions. (11 sessions/36 months)	Usual care by family physician. Letter to own family physician recommending secondary prevention goals. Annual scheduled assessments with feedback to family physician.
Two in-hospital education sessions and an individualized, comprehensive, home-based cardiac rehabilitation program combining risk factor modification with exercise and psychological counseling. The program was based on Social Cognitive Theory and included goal-setting, detailed action plans, self-monitoring and feedback, skills training. (5 sessions/2 months)	Two in-hospital education sessions + 3-monthly post-discharge telephone calls focused on providing CHD information.
Individualized teaching program in hospital, supportive care via telephone contact or mail for 12 weeks post-discharge (3 sessions/ 3 months)	Routine care (verbal instruction)
Nurse-led home-based cardiac rehabilitation program. In-hospital education aimed at self-managed cardiac rehabilitative care after discharge. After discharge, 12-week nurse-led home-based program focused on lifestyle and treatment adherence. Follow-up visits and telephone calls. 19 sessions/ 3 months)	Routine care

Author, year (ref.)	Sample size, N	Mean age	Population a	Measurement period b
Lear et al., 2002 (36) Lear et al., 2003 (74) Lear et al., 2005 (75) Lear et al., 2006 (76)	302	64	CHD	PT= 12 mths FU= 24 mths FU= 36 mths FU= 48 mths
Lisspers et al., 1999 (77) Hofman-Bang et al., 1999 (85) Lisspers et al., 2005 (48)	87	53	PCI	PT= 12 mths FU= 24 mths FU= 36 mths FU= 60 mths
McHugh et al., 2001 (78)	98	62	Pts on CABG waiting list	PT= 15 mths
Mildestvedt et al., 2007 (38) Mildestvedt et al., 2008 (79)	176	56	CHD	PT= 6 mths FU= 24 mths
Murphy et al., 2009 (50)	903	68	CHD	PT= 18 mths
Nordmann et al., 2001 (32)	201	62	CHD	PT= 9 mths FU= 18 mths
Ornish et al., 1990 (80) Ornish et al., 1998 (49) Pischke et al., 2008 (39)	48	58	CHD	PT= 12 mths FU= 60 mths
Salminen et al., 2006 (81)	112	74	CHD	PT= 16 mths

Intervention Content (Intensity: no of session/ duration in months)	**Control Condition Content**
Extensive Lifestyle Management Intervention (ELMI) based on the principles of behavioral change and aimed at individualizing risk factor and lifestyle management. It consisted of cardiac rehabilitation sessions (exercise program), and risk factor and lifestyle counseling sessions and telephone follow-up. (39 sessions/ 12 months)	Annual risk factor assessment visit + usual care by family physician
Comprehensive behaviorally oriented program aimed at longterm changes in risk factor-related lifestyle behavior. The program started with a 4-week residential stay focused on health education, practical skills training and habit rehearsal. Follow-up consisted of an 11-month structured maintenance program involving self-monitoring, feedback, and regular contacts with a nurse during one year. (>100? sessions/ 12 months)	Standard care by own physician.
A nurse-led shared care program consisting of health education and motivational interviews, according to individual need, carried out monthly. Interventions addressed behavioral risk factors and were focused on tracking progress. (15 sessions/ 15 months)	Usual care.
Standard cardiac rehabilitation program including daily exercise groups, dietary and smoking cessation counseling. In addition, patients received an individualized self-efficacy and autonomy supportive intervention consisting of two individual sessions and two follow-up telephone calls. (4 sessions/ 24 months)	Standard cardiac rehabilitation (daily physical training, dietary and smoking cessation counseling).
Tailored care plans for practices (practice based training in prescribing and behavior change, administrative support, quarterly newsletter) and tailored care plans for patients based on Social Cognitive Theory (motivational interviewing, goal identification, and target setting for lifestyle change) with reviews every four months at the practices. (9 sessions/ 18 months)	Usual care in control general practices. Not organized in a formal manner, in some practices this included monitoring of risk factors and providing advice on lifestyle.
Risk factor case management program during hospitalization consisting of structured counseling about treatable cardiovascular risk factors. After hospital discharge, patients received two follow-up sessions where goals and progress were reviewed. (3 sessions/ 6 months)	Assessment + information about cardiovascular risk factors by treating physicians. No structured counseling.
Intensive lifestyle changing program: 10% fat vegetarian diet, aerobic exercise, stress management training, smoking cessation, group psychological support. (> 100 sessions?/ 12 months)	Usual care (following advice of personal physician).
A health advocacy, counseling and activation program aimed at giving information on risk factors. The program consisted of lectures, group discussions, light exercises and social activities. (33 sessions/ 16 months)	Usual care.

Author, year (ref.)	Sample size, N	Mean age	Population a	Measurement period b
Smeulders et al., 2009 (82)	317	67	HF	PT= 1.5 mths FU= 6 mths FU= 12 mths
The Vestfold Heartcare Study Group (2003) (46)	197	55	CHD	PT= 6 mths FU= 24 mths
Toobert et al., 1998 (83) Toobert et al., 2000 (40)	28	63	CHD	PT= 4 mths FU= 12 mths FU= 24 mths
Wallner et al., 1999 (43)	60	59	PCI	PT= 12 mths
Wood et al., 2008 (84)	3088	63	CHD	PT= 12 mths
Zwisler et al., 2005 (41) Zwisler et al., 2008 (45)	770	66	Cardiac Rehabilitation patients	PT= 12 mths

Intervention Content (Intensity: no of session/ duration in months)	**Control Condition Content**
Structured self-management program focused on learning patients how to take responsibility for the day-to-day management of their disease. The program enhances self-efficacy and incorporates skills mastery, reinterpretation of symptoms, modelling, and social persuasion. (6 sessions/ 6 weeks)	Usual care, consisting of regular check-ups at an outpatient clinic.
Nurse-delivered lifestyle intervention: six-week period of ‘heart school’ consisting of supervised exercise sessions and semiweekly group sessions focused on low fat diet, regular exercise, smoking cessation, stress reduction, psychosocial support and education. Follow-up consisted of another nine weeks of organized physical exercise sessions and group meetings every three months for two years. (> 50 sessions, 24 months)	Standardized nurse-based information on CHD & lifestyle measures. Follow-up in routine outpatient cardiology clinics and subsequently by patients’ own GPs.
Intensive lifestyle self-management program consisting of a very-low fat vegetarian diet, exercise, smoking cessation, breathing and relaxation exercises, and group support based on the Ornish program for Reversing Heart Disease. (>100 sessions/ 15 months)	Usual care.
Intensive lifestyle intervention including lifestyle advice, physical activity training programs, food diaries and 1-h sessions with a nutritionist in order to adopt a healthy diet. Follow-up by regular telephone contact. (17 sessions/ 12 months)	Conventional treatment by cardiologists and general practitioners.
Nurse-coordinated, multi-disciplinary family-based cardiovascular disease prevention program consisting of workshops, tailored advice, and a supervised-exercise class. Sessions also included partners and families (16 sessions/ 4 months)	UC hospitals
Individually tailored multidisciplinary program; patient education, exercise training, dietary counseling, smoking cessation, psychosocial support and group workshops. Multidisciplinary advice, monitoring and assessment of risk factors. (>25 sessions?/ 12 months)	Usual care

[a] *Population: AP= Angina Pectoris; CABG= Coronary Artery Bypass Surgery; CHD=Coronary Heart Disease; HF= Heart Failure; MI= Myocardial Infarction; PCI= Percutaneous Coronary Intervention*

[b] *PT= Posttreatment; FU= Follow-up*

Table 2.
Description of moderators

Author, year (ref.)	Setting: primary vs secondary care	Partners involved?	Exclusion on basis of diagnosis iii	Exclusion on basis of disease severity iv	Methodological Quality			Jadad Score
					Risk of Bias	Sample Size viii		
						Tr *n*	Ctr *n*	
Aldana et al., 2007 (66)	Secondary care	No	No	No	High	46	47	2
Allison et al., 2000 (67)	Secondary care	No	Yes (MI, CABG)	No	Low	158	168	3
Brugemann et al., 2007 (68)	Secondary care	No	Yes (HF NYHA III/ IV)	Yes (NYHA III/ IV)	Low	60	62	3
Campbell et al., 1998 (69) Campbell et al., 1998 (70) Murchie et al., 2003 (34) Murchie et al., 2004 (71) Delaney et al., 2008 (33)	Primary care	No	No	No	Low	670	667	3
Cupples et al., 1994 (47) Cupples et al., 1999 (35)	Primary care	No	No	No	Low	317	300	3
Giannuzzi et al., 2008 (44)	Secondary care	Yes	No	No	Low	1620	1621	3
Higgins et al., 2001(72)	Secondary care	Yes	No	No	High	50	49	2
Jeong et al., 2002 (42)	Secondary care	No	No	No	High	22	23	3
Jiang et al., 2007 (73)	Secondary care	Yes	No	No	Low	83	84	3
Lear et al., 2002 (36) Lear et al., 2003 (74) Lear et al., 2005 (75) Lear et al., 2006 (76)	Secondary care	No	No	No	Low	142	136	3
Lisspers et al., 1999 (77) Hofman-Bang et al., 1999 (85) Lisspers et al., 2005 (48)	Secondary care	Yes	No	Yes (maximal exercise capacity < 70 Watt)	High	46	41	2
McHugh et al., 2001 (78)	Primary care	No	No	No	High	49	49	2
Mildestvedt et al., 2007 (38) Mildestvedt et al., 2008 (79)	Secondary care	Yes	No	No	High	84	75	2
Murphy et al., 2009 (50)	Primary Care	No	No	No	Low	360	405	3

Author, year (ref.)	No of sessions/ Program Duration	Psychological Techniques Intervention used in vi					Control Condition vii
		GS	SM	PL	FB	High/ Low SR	
Aldana et al., 2007 (66)	High/ Long-term	0	0	0	1	low SR	LM + E
Allison et al., 2000 (67)	Low/ Short-term	0	0	1	0	low SR	UC
Brugemann et al., 2007 (68)	High/ Long-term	0	0	0	0	low SR	LM + E
Campbell et al., 1998 (69) Campbell et al., 1998 (70) Murchie et al., 2003 (34) Murchie et al., 2004 (71) Delaney et al., 2008 (33)	Low/ Long-term	2	2	2	2	high SR	UC
Cupples et al., 1994 (47) Cupples et al., 1999 (35)	Low/ Long-term	0	0	0	0	low SR	UC
Giannuzzi et al., 2008 (44)	Low/ Long-term	1	1	1	1	low SR	LM
Higgins et al., 2001(72)	Low/ Short-term	2	2	2	2	high SR	LM
Jeong et al., 2002 (42)	Low/ Short-term	0	0	0	0	low SR	UC
Jiang et al., 2007 (73)	High/ Short-term	2	2	1	2	high SR	UC
Lear et al., 2002 (36) Lear et al., 2003 (74) Lear et al., 2005 (75) Lear et al., 2006 (76)	High/ Long-term	2	2	1	2	high SR	LM
Lisspers et al., 1999 (77) Hofman-Bang et al., 1999 (85) Lisspers et al., 2005 (48)	High/ Long-term	2	2	2	2	high SR	UC
McHugh et al., 2001 (78)	Low/ Long-term	1	1	0	2	neither high nor low	UC
Mildestvedt et al., 2007 (38) Mildestvedt et al., 2008 (79)	Low/ Long-term	2	0	1	0	neither high nor low	LM + E
Murphy et al., 2009 (50)	Low/ Long-term	2	2	2	1	high SR	LM

Author, year (ref.)	Setting: primary vs secondary care	Partners involved?	Exclusion on basis of diagnosis iii	Exclusion on basis of disease severity iv	Methodological Quality			Jadad Score
					Risk of Bias	Sample Size viii		
						Tr *n*	Ctr *n*	
Nordmann et al., 2001 (32)	Secondary Care	No	Yes (HF NYHA III/IV)	Yes (NYHA III/ IV)	Low	99	102	3
Ornish et al., 1990 (80) Ornish et al., 1998 (49) Pischke et al., 2008 (39)	Secondary Care	Yes	Yes (no MI in preceding 6 wks, not on lipid-lowering drugs, not scheduled to have CABG)	Yes (ejection fraction > 25%)	High	20	15	2
Salminen et al., 2006 (81)	Primary care	No	No	No	High	58	54	2
Smeulders et al., 2009 (82)	Secondary care	No	No	No	Low	186	131	3
The Vestfold Heartcare Study Group (2003) (46)	Secondary care	Yes	No	No	Low	98	99	3
Toobert et al., 1998 (83) Toobert et al., 2000 (40)	Secondary care	Yes	Yes (no MI in preceding 6 wks, not on lipid-lowering drugs, not scheduled to have CABG)	Yes (ejection fraction <25%)	High	95	96	2
Wallner et al., 1999 (43)	Secondary care	No	No	Yes (ejection fraction <30%)	High	32	28	2
Wood et al., 2008 (84)	Secondary care	Yes	Yes (severe HF)	Yes (severe HF)	Low	946	994	3
Zwisler et al., 2005 (41) Zwisler et al., 2008 (45)	Secondary care	Yes	No	No	Low	380	390	3

iii AP = Angina Pectoris; CABG = Coronary Artery Bypass Surgery; CHD = Coronary Heart Disease; HF = Heart Failure; MI = Myocardial Infarction; PCI = Percutaneous Coronary Intervention

iv NYHA = New York Heart Association functional classification system

v No of sessions: High= > 15 Low= ≤15; Program duration: Long-term= >12 months, Short-term = ≤12 months

vi Psychological Techniques: GS= goal-setting; SM= self-monitoring; PL= planning; FB= feedback. 'low' = 0/1 'high' = 2
High/Low SR: 'low' = score of 1 or 0 on all individual constructs, 'high' = score of 2 on at least three constructs, score of 0 on none of the constructs

vii Control Condition: UC= usual care; LM= lifestyle modification; LM + E= lifestyle modification + exercise

viii Sample Size: Tr N = treatment sample size used in analyses posttreatment; Ctr N = control sample size used in analyses posttreatment

Author, year (ref.)	No of sessions/ Program Duration	Psychological Techniques Intervention used in vi					Control Condition vii
		GS	SM	PL	FB	High/ Low SR	
Nordmann et al., 2001 (32)	Low/ Short-term	2	1	2	2	high SR	LM
Ornish et al., 1990 (80) Ornish et al., 1998 (49) Pischke et al., 2008 (39)	High/ Long-term	2	0	0	0	neither high nor low	UC
Salminen et al., 2006 (81)	High/ Long-term	0	0	0	0	low	UC
Smeulders et al., 2009 (82)	Low/ Short-term	1	0	2	0	neither high nor low	UC
The Vestfold Heartcare Study Group (2003) (46)	High/ Long-term	2	2	1	2	high	LM
Toobert et al., 1998 (83) Toobert et al., 2000 (40)	High/ Long-term	1	0	2	1	neither high nor low	UC
Wallner et al., 1999 (43)	High/ Long-term	2	2	1	2	high	UC
Wood et al., 2008 (84)	High/ Short-term	1	2	1	1	neither high nor low	UC
Zwisler et al., 2005 (41) Zwisler et al., 2008 (45)	High/ Long-term	1	0	1	1	low	UC

Table 3.
Effects of lifestyle modification programs on risk factors and lifestyle behaviours. Values are Hedges'g unless stated otherwise.

Outcome	Trials (ref.)	Assessment period	Mean (range) follow-up (months)	No of randomised participants	Hedges'g	(95% CI)	Homogeneity of variance I^2
Systolic blood pressure	16 (32,39,40,43,44-47,49,50, 66,67,73,74,78,81,84)	posttreatment	10.8 (3–24)	10322	0.09*	(0.02 – 0.17)	46.39*
	9 (32,35,39,40,41,44,46,47,49, 66,74,76,77,85)	follow-up	34.0 (12–60)	4885	0.01	(-0.19 - 0.20)	79.33**
Diastolic blood pressure	16 (32,39,40,43,44-47,49,50, 66,67,73,74,78,81,84)	posttreatment	10.8 (3–24)	10322	0.07*	(0.01 – 0.14)	36.75
	9 (32,35,39,40,41,44,46,47,49, 66,74,76,77,85)	follow-up	34.0 (12–60)	4885	0.08**	(0.02 – 0.15)	0.00
Body mass index	15 (32,35,40,42-45,47,50,66, 72,74,77,78,82,84,85)	posttreatment	10.3 (1.5–24)	10020	0.07	(-0.01 - 0.14)	43.48*
	9 (32,35,66,40,44,72,74,76,77 ,82,85)	follow-up	27.3 (12–60)	5056	0.07**	(0.02 – 0.13)	0.00
Total cholesterol	17 (32,39,40-45,47,49,50,66, 67,68,73,74,78,81,84)	posttreatment	10.7 (3–24)	10307	0.20**	(0.08 – 0.32)	80.01**
	8 (32,35,39,40,44,47,49,66,74 ,76,77,85)	follow-up	35.3 (12–60)	4688	0.03	(-0.03 - 0.09)	42.62
Smoking	18 (32,34,42-47,50,67,69,72, 73,74,77,78,81,82,84,85)	posttreatment	10.1 (1.5–24)	11874	OR=1.21*	(1.00 – 1.47)	52.40**
	11 (32,34,35,38,40,44,46,69, 72,74,76,77,82,85)	follow-up	30.8 (12–60)	6509	OR=1.19	(0.84 – 1.68)	58.51*
Exercise	20 (34,39,40,42-47,49,50,67, 69,72-74,77-79,81,82,84,85)	posttreatment	9.73 (1.5 –24)	11925	0.32**	(0.20 – 0.44)	83.67**
	11 (34,35,39,40,44,46,47,49, 69,72,74,76,77,79,82,85)	follow-up	33.5 (12–60)	6356	0.11**	(0.06 – 0.17)	41.43
Dietary behavior Fat intake	17 (32,34,38-40,43,44,46,47,49, 50,66,67,69,73,74,77,84,85)	posttreatment	9.71 (3–24)	10915	0.38**	(0.21 – 0.56)	90.23**
	11 (32,34,35,38,39,40,44,46, 47,49,66,69,74,76,77,85)	follow-up	35.13 (12–60)	6234	0.27*	(0.05 – 0.50)	90.04**
Dietary behavior Energy intake	10 (32,39,40,43,44,46,47,49, 68,73,77,85)	posttreatment	9.3 (3–24)	4854	0.28**	(0.12 – 0.44)	69.43**
	7 (32,35,39,40,44,46,47,49,77, 85)	follow-up	35.14 (18–60)	4490	12*	(0.01 – 0.24)	32.69

*Note:**≤p0.01; * p≤0.05*
I:For a heterogeneous set of effect sizes, the random summary effect estimates with 95% confidence intervals were reported, while for a homogeneous set the fixed estimates with 95% confidence intervals were reported. For Cupples and colleagues(35), the confidence intervals were used to calculate the standard deviation of change. For Nordmann and colleagues (32)the between-group pvalues were converted to F values assuming a pretest/ posttest correlation of 0.50.

Table 4.
Comparative subgroup analyses assessing the effect of study and treatment characteristics upon effect size, separated by outcome posttreatment

POSTTREATMENT		Smoking			Exercise			Dietary Behaviour: Fat intake			Dietary behaviour: Energy intake		
		k	OR	p	k	g	p	k	g	p	k	g	p
Care Setting:	Primary Secondary	7 11	0.96 1.40	≤ 0.05	6 14	0.14 0.45	≤ 0.01	4 1 3	0 .08 0. 58	≤ 0.01	2 8	0 .06 0.39	≤ 0.05
Partners involved:	no yes	11 7	1.01 1.45	≤ 0.05	10 10	0.23 0.42	ns	9 8	0.17 0.71	ns	4 6	0 .05 0.51	≤ 0.01
Exclusion diagnosis:	no yes	15 3	1.29 1.14	ns	17 3	0.34 0.27	ns	12 5	0.40 0. 55	ns	7 3	0.34 0 .15	ns
Exclusion severity:	no yes	13 5	1.19 1.33	ns	15 5	0.30 0.39	ns	10 7	0.34 0. 55	ns	4 6	0.43 0 .18	ns
Control condition #:	UC UC plus	12 6	1.19 1.28	ns	14 6	0 .42 0.14	≤ 0.05	9 8	0.71 0 .19	≤ 0.01	6 4	0.47 0 .13	ns
SR techniques high vs. low ^	low high	6 9	1.17 1.33	ns	6 8	0.17 0.60	≤ 0.05	5 8	0.14 0.46	≤ 0.05	3 5	0.11 0.38	ns

Note: p-values concern subgroup effects k = number of studies included per subgroup per outcome; OR= Odds Ratio; g = Hedges' g effect size; ns = not significant (p> 0.05); n/a = too few studies in cell to allow meaningful comparison; # Control Condition: UC= usual care; LM= lifestyle modification; LM + E= lifestyle modification + exercise^SRtechniques high versus low; 'low' = score of1 or 0 on all individual constructs,'high'= score of 2 on at least threeout of fourconstructs,score of 0 on none of the constructs

Table 4 cont.

Comparative subgroup analyses assessing the effect of study and treatment characteristics upon effect size, separated by outcome at follow-up

FOLLOW-UP		Smoking			Exercise			Dietary Behaviour: Fat intake			Dietary behaviour: Energy intake		
		k	OR	p	k	g	p	k	g	p	k	g	p
Care Setting:	Primary Secondary	3 8	0.67 1.58	≤ 0.01	2 9	0.12 0.11	ns	3 8	-0.01 0.55	≤ 0.01	2 5	0 .03 0.19	ns
Partners involved:	no yes	5 6	0.76 1.92	≤ 0.01	4 7	0.10 0.12	ns	5 6	0.04 0.80	≤ 0.05	2 5	0 .03 0.15	ns
Exclusion diagnosis:	no yes	10 1	1.29 0.64	n/a	10 1	0.13 0.53	n/a	9 2	0.16 3.40	ns	5 2	0.14 -0.04	ns
Exclusion severity:	no yes	8 3	1.37 1.10	ns	8 3	0.12 0.11	ns	7 4	0.21 0.80	ns	3 4	0.15 0.12	ns
Control condition #:	UC UC plus	5 6	0.82 1.62	≤ 0.05	6 5	0 .18 0.10	ns	5 6	0.83 0.16	≤ 0.05	4 3	0.09 0.15	ns
SR techniques high vs. low ^	low high	2 6	1.04 1.50	ns	2 5	0.09 0.19	ns	3 5	0.16 0.21	ns	2 3	0.13 0.14	ns

Note: p-values concern subgroup effects k = number of studies included per subgroup per outcome; OR= Odds Ratio; g = Hedges' g effect size; ns = not significant (p> 0.05); n/a = too few studies in cell to allow meaningful comparison; # Control Condition: UC= usual care; LM= lifestyle modification; LM + E= lifestyle modification + exercise^SRtechniques high versus low; 'low' = score of1 or 0 on all individual constructs,'high'= score of 2 on at least threeout of fourconstructs,score of 0 on none of the constructs

Figure 1.
Flowchart of selection of trials.

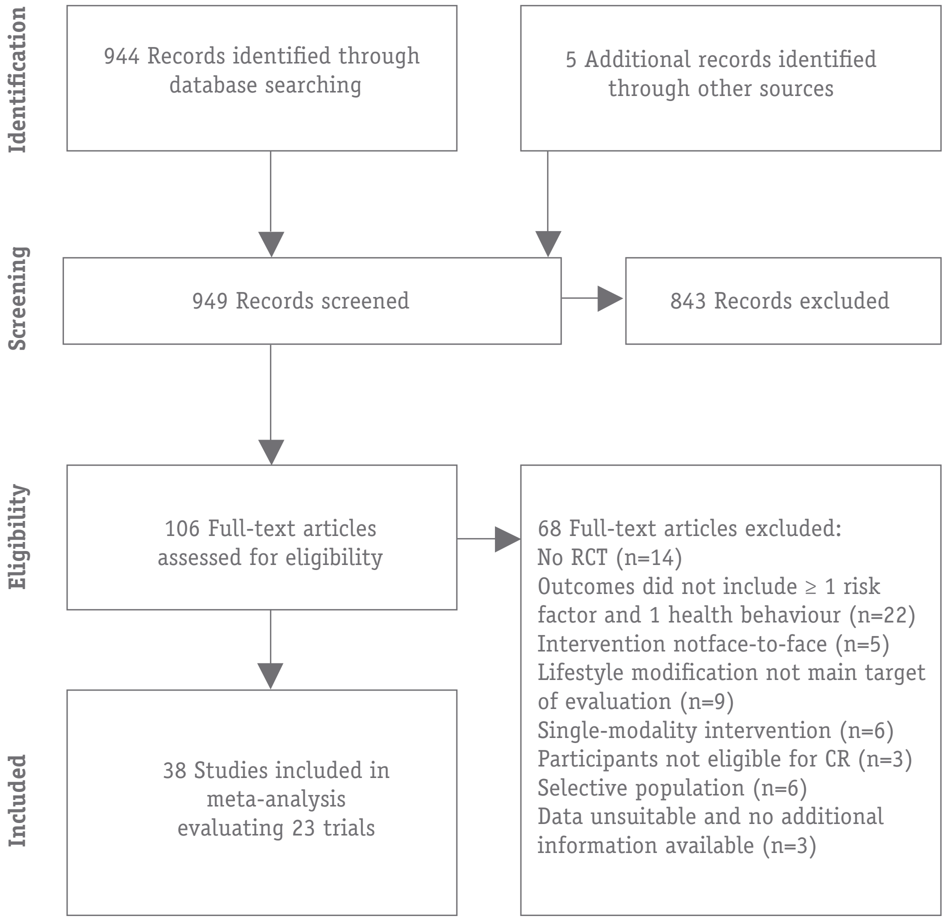
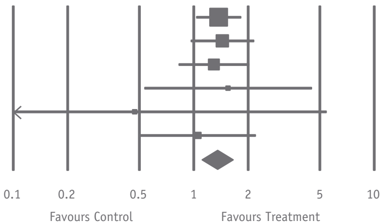


Figure 2.
Forest plots for all-cause mortality and cardiac mortality.

Effect sizes for all-cause mortality

Study name	Outcome	Time point	Odds ratio	Lower limit	Upper limit	p-Value
Campbelll (1998) Murchie (2003)	Mortality	FU long-term	1.374	1.029	1.836	0.031
Cupples (1999)	Mortality	FU long-term	1.441	0.959	2.164	0.078
Gianuzzi (2008)	Mortality	FU long-term	1.294	0.822	2.036	0.266
Nordmann (2001)	Mortality	FU medium-term	1.549	0.531	4.523	0.423
Vestfold Heartcare Study Group (2003)	Mortality	FU medium-term	0.471	0.041	5.464	0.547
Zwisler (2008)	Mortality	FU medium-term	1.056	0.504	2.212	0.885
			1.344	1.104	1.638	0.003

Odds ratio and 95% CI



Effect sizes for cardiac mortality

Study name	Outcome	Time point	Odds ratio	Lower limit	Upper limit	p-Value
Gianuzzi (2008)	Cardiac Mortality	FU long-term	1.369	0.740	2.533	0.317
Campbelll (1998) Murchie (2003)	Cardiac Mortality	FU long-term	1.344	1.003	1.802	0.048
Cupples (1994)	Cardiac Mortality	FU medium-term	2.200	1.060	4.568	0.034
Lisspers (1999) Lisspers (2005)	Cardiac Mortality	FU long-term	2.345	1.057	5.202	0.036
Ornish (1998)	Cardiac Mortality	FU long-term	0.689	0.058	8.179	0.768
			1.481	1.170	1.876	0.001

Odds ratio and 95% CI

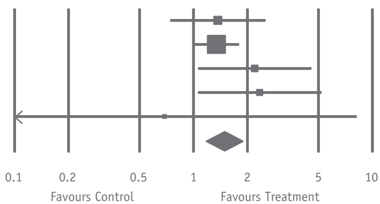
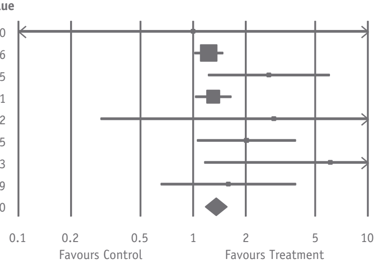


Figure 3.
Forest plot for non-fatal reinfarction and cardiac readmissions to hospital.

Effect sizes for reinfarction and readmission

Study name	Outcome	Time point	Odds ratio	Lower limit	Upper limit	p-Value
Campbelll (1998) Murchie (2003)	Reinfarction	FU long-term	1.000	0.067	14.851	1.000
Gianuzzi (2008)	Reinfarction	FU long-term	1.229	1.014	1.491	0.036
Lisspers (1999) Lisspers (2005)	Reinfarction	FU long-term	2.715	1.214	6.070	0.015
Murphy (2009)	Cardiac readmissions	FU medium-term	1.304	1.024	1.661	0.031
Ornish (1998)	Reinfarction	FU long-term	2.899	0.295	28.531	0.362
Vestfold Heartcare Study Group (2003)	Cardiac readmissions	FU medium-term	2.020	1.050	3.888	0.035
Wallner (1999)	Reinfarction	FU medium-term	6.104	1.154	32.290	0.033
Zwisler (2008)	Reinfarction	FU medium-term	1.591	0.650	3.892	0.309
			1.344	1.166	1.548	0.000

Odds ratio and 95% CI



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Appendix 1.

LIFESTYLE MODIFICATION PROGRAMS FOR CHD PATIENTS CODING FORM

Coder name:

Study identification number:

First Author et al. (Year):

Which type of evaluation(s) is/ are made in the study? (between treatment and control/ comparison groups?

Code		Treatment Group	Control Group
1	☐	Behaviour Modification	Standard Care
2	☐	Behaviour Modification + Physical Training	Standard Care
3	☐	Behaviour Modification + Physical Training	Standard Care + Physical Training
4	☐	Behaviour Modification + Physical Training + Stress Management	Standard Care
5	☐	Behaviour Modification + Physical Training + Stress Management	Standard Care + Physical Training
6	☐	Behaviour Modification + Stress Management	Standard Care
7	☐	Behaviour Modification + Stress Management	Standard Care + Physical Training

What is (are) the name(s) of the psychosocial program(s)?
What is reported as being the goal of the treatment? (in words)

Evaluation / general remarks:

DATA ON SAMPLE CHARACTERISTICS

NO __ Number of total participants in study

TYP __ Type of patients included in the study:

- ☐ (1) Coronair bypass/CABG
- ☐ (2) Myocardical Infarct/MI
- ☐ (3) PTCA / PCI / Dotter
- ☐ (4) Cardiac Valve Surgery
- ☐ (5) ICD
- ☐ (6) Heartfailure
- ☐ (7) Angina Pectoris
- ☐ (8) Coronary Heart Disease
- ☐ (9) Other (specify)......

CO __ Demographic feature of patients: nationality

- ☐ (1) American
- ☐ (2) European
- ☐ (3) Australian
- ☐ (4) Canadian
- ☐ (5) Asian
- ☐ (9) Other (specified) ....

GEN __ at pretest (1) only male (2) only female (3) both male and female

FEM __% percentage female

AGE __ Mean age (rounded) of total group of patients included in study

AGE_TR __ Mean age (rounded) of treatment group patients included in study

AGE_CG __ Mean age (rounded) of control group patients included in study

EXC __ Patient exclusion criteria used? (1) yes (2) no (9) Unknown

KINDEXC __ Specific Kinds of Patients **Excluded:**

- ☐ (1) prior or future hospitalisation for cardiac reasons
- ☐ (2) other cardiac complications
- ☐ (3) specific cardiac diagnoses;.................................
- ☐ (4) age-criterium:....................................
- ☐ (5) gender-criterium:................................
- ☐ (6) somatic comorbidity
- ☐ (7) psychological problems/ mental illness
- ☐ (8) practical reasons (specified)..................
- ☐ (9) other (specified):........................ ....

CODING FOR TREATMENT GROUP

TRPAR	___	Were partners involved in the treatment? (1) yes (2) no (9) unknown
P_EXT	___	To what extent were partners in volved in the treatment? (1) participation in one session ,(2) participation in two sessions, (3) participation in multiple sessions
TRPROF	___	The treatment was carried out by a (1) psychologist/psychotherapist/psychiatrist (2) physician (3) other specialist (e.g. physiotherapist, social worker, nurse ...) (4) multi disciplinary team, including a psychologist / psychotherapist / psychiatrist specified (5) multi disciplinary without a psychologist / psychotherapist / psychiatrist specified or unspecified (6) other, specified...
TRTARG	___	Target group of intervention was (1) individual patient or couples separately (2) group of patients or group of couples (3) both 1 and 2

GUIDELINES FOR CLASSIFICATION OF TREATMENT

Behaviour Modification is defined as: instructional activities focused on health education and/or health behavior change. This involves personal contacts between a health professional and coronary heart patients (and partners) in order to facilitate positive changes in risk factors for coronary heart disease and/ or unhealthy behaviours and must include at least one face-to-face session.
Physical Training means not information about physical activities or physiotherapy, but actual exercise training (this training can also be directed by a manual).

TRTYPE	___	The program included: (more than one box may be ticked) ☐ (1) Behaviour modification directed at modification of at least one risk factor and one health behaviour ☐ (2) Stress Management ☐ (3) Physical Training ☐ (4) Information supply (by leaflets or education) ☐ (5) Standard care

TRSET __ Setting of the treatment
(1) primary care (2) secondary care

TRSES# __ Total number of sessions

TRFOL# __ Number of follow up sessions

TRDUR __ Duration of total program............months...................weeks

TRDUR_O __ Other information on treatment duration

CODING FOR SELF-REGULATION CONSTRUCTS

SRGOAL __ Goal-setting

- ☐ (0) – No mention of goal-setting
- ☐ (1) – Goal-setting mentioned explicitly, but no description of actual goals
- ☐ (2) – Goal-setting mentioned explicitly, and content of goals is specified
  For Example: “realistic goals,” or specification with regard to time

SRPLAN __ Planning

- ☐ (0) – No mention of planning
- ☐ (1) – Mentioned simply as planning, OR by use of one of the terms ‘sub-goals’ ‘steps’ ‘laddering’ or breaking large goals down into smaller goals.
- ☐ (2) – Planning mentioned specifically in regard to either where, when, how, or with whom a specific action is to take place. May also be termed “action planning” or “implementation intention”

SRMON __ Self-monitoring

- ☐ (0) – No mention of self-monitoring OR mentioned in the form of an emotional diary”
- ☐ (1) – Self-monitoring mentioned explicitly mentioned, but unspecified.
- ☐ (2) – Self-monitoring mentioned in regard to a specific behavior.

SRPROG __ Progress Evaluation/Feedback

- ☐ (0) – Not mentioned; Self-monitoring diaries not reviewed
- ☐ (1) – Feedback is provided to patients regularly
- ☐ (2) – Feedback is provided regularly regarding goal-related progress

CODING FOR CONTROL / COMPARISON GROUP

CONPROF __ The treatment was done by a
(1) psychologist/psychotherapist/psychiatrist
(2) other specialist (e.g. physiotherapist, social worker, nurse ...)
(3) multi disciplinary team, including a psychologist / psychotherapist/ psychiatrist specified
(4) multi disciplinary without a psychologist / psychotherapist/ psychiatrist specified or unspecified
(5) not applicable

CONTARG __ Target group of intervention was:
(1) individual patient or couples separately
(2) group of patients or group of couples
(3) both 1 and 2

GUIDELINES FOR CLASSIFICATION OF CONTROL-TREATMENT

Behaviour Modification is defined as: instructional activities focused on health education and/or health behavior change. This involves personal contacts between a health professional and coronary heart patients (and partners) in order to facilitate positive changes in risk factors for coronary heart disease and / or unhealthy behaviours and must include at least one face-to face session.
Physical Training means not information about physical activities or physiotherapy, but actual exercise training (this training can also be directed by a manual).
NB. Information via leaflets belonging to standard care of coronary heart patients should not be labelled as behaviour modification but as minimal information supply (4).

CONTYPE __ The program included: (more than one box may be ticked)
☐ (1) Behaviour modification directed at modification of at least on risk factor
☐ (2) Stress Management
☐ (3) Physical Training
☐ (4) Information supply (by leaflets or education)
☐ (5) Standard care

ST_CARE __ What did standard care consist of?

CODING FOR METHODOLOGICAL QUALITY

RAN __ Assignment to conditions (1) random (2) non-random (9) unknown

MATCH __ Matching (1) by pairs (2) by stratifying (3) no matching (9) unknown

ALLOC __ How was the randomization procedure carried out?...................

ASSESS __ Where the assessors blind? (1) yes (2) no (3) unclear

LOSS_FU __ Loss to follow up? (1) not reported (2) reported but withdrawals not included in analysis (3) withdrawals included in analysis (i.e. intention to treat analysis)

N __ No of participants per condition

DATA ENTRY

BOX B: RESULTS FOR CONTINOUS DATA

DEPENDENT VARIABLE:

Which **CONTINOUS** dependent variables (DVS) have been measured?

Main outcome? Y/N	What was measured? Unit of measurement?	How has it been measured? (i.e. name of questionnaire, type of instrument used)	Type of observation (e.g. self-report, biometrical etc.)

BASE_BASELINE (pretest measurement)..

POSTI_POSTINTERVENTION (measurement directly post intervention)..

FU1_ FOLLOW UP 1 (measurement less than 1 year)..

FU2_ FOLLOW UP 2 (measurement between 1 year and 2 years)...

FU3_ FOLLOW UP 2 (measurement after 2 years)...

Please fill out for each measurement period:

Dependent Variable	N treatment	MEAN treatment (or mean change)	SD treatment (or SD change)	N control	MEAN control (or mean change)	SD control (or control change)	p-value t-test F-test	Change score + F for difference	Effect size + confidence interval	Direction of Effect	One-tailed/ Two-tailed

BOX B: RESULTS FOR CATEGORICAL DATA

DEPENDENT VARIABLE:

Which **CATEGORICAL** dependent variables (DVS) have been measured?

Main outcome? Y/N	Code of dependent variable	How were they measured (e.g. type of instrument/questionnaire, unit of measurement) Name subscales!!	Name of questionnaire	Type of observation (e.g. self-report, biometrical etc.)

BASE_ BASELINE (pretest measurement)..
POSTI_POSTINTERVENTION (measurement directly post intervention)..
FU1_ FOLLOW UP 1 (measurement less than 1 year)...
FU2_ FOLLOW UP 2 (measurement between 1 year and 2 years)..
FU3_ FOLLOW UP 2(measurement after 2 years)...

Please fill out for each measurement period:

Dependent Variable	N total	treatment yes / +	treatment no / -	control yes / +l	control no / -	p-value x2-value	Direction of Effect	Odds ratio	Estimated Effect Size R (ESR)

Appendix 2.
Methodological quality of included studies

Author, year (ref.)	Described as Randomised	Method of Randomization Described and Appropriate	Description of Withdrawals or Losses to Follow-up	Jadad Score
Aldana et al., 2007 (66)	Yes	Unclear	Yes	2
Allison et al., 2000 (67)	Yes	Yes	Yes	3
Brugemann et al., 2007 (68)	Yes	Yes	Yes	3
Campbell et al., 1998 (69) Campbell et al., 1998 (70) Murchie et al., 2003 (34) Murchie et al., 2004 (71) Delaney et al., 2008 (33)	Yes	Yes	Yes	3
Cupples et al., 1994 (47) Cupples et al., 1999 (35)	Yes	Yes	Yes	3
Giannuzzi et al., 2008 (44)	Yes	Yes	Yes	3
Higgins et al., 2001 (72)	Yes	Unclear	Yes	2
Jeong et al., 2002 (42)	Yes	Yes	Yes	3
Jiang et al., 2007 (73)	Yes	Yes	Yes	3
Lear et al., 2002 (36) Lear et al., 2003 (74) Lear et al., 2005 (75) Lear et al., 2006 (76)	Yes	Yes	Yes	3
Lisspers et al., 1999 (77) Hofman-Bang et al., 1999 (85) Lisspers et al., 2005 (48)	Yes	Unclear	Yes	2
McHugh et al., 2001 (78)	Yes	Unclear	Yes	2
Mildestvedt et al., 2007 (38) Mildestvedt et al., 2008 (79)	Yes	Unclear	Yes	2

Author, year (ref.)	Described as Randomised	Method of Randomization Described and Appropriate	Description of Withdrawals or Losses to Follow-up	Jadad Score
Murphy et al., 2009 (50)	Yes	Yes	Yes	3
Nordmann et al., 2001 (32)	Yes	Yes	Yes	3
Ornish et al., 1990 (80) Ornish et al., 1998 (49) Pischke et al., 2008 (39)	Yes	Unclear	Yes	2
Salminen et al., 2006 (81)	Yes	Unclear	Yes	2
Smeulders et al., 2009 (82)	Yes	Yes	Yes	3
The Vestfold Heartcare Study Group (2003) (46)	Yes	Yes	Yes	3
Toobert et al., 1998 (83) Toobert et al., 2000 (40)	Yes	Unclear	Yes	2
Wallner et al., 1999 (43)	Yes	Unclear	Yes	2
Wood et al., 2008 (84)	Yes	Yes	Yes	3
Zwisler et al., 2005 (41) Zwisler et al., 2008 (45)	Yes	Yes	Yes	3

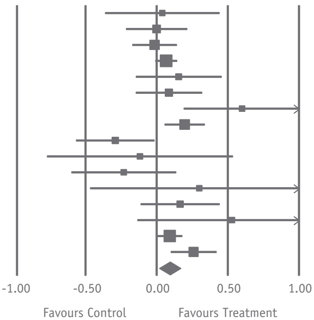
Appendix 3.

Forest plots for all outcomes at posttreatment and follow-up.

Posttreatment effect sizes for systolic blood pressure

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	Systolic blood pressure	Posttreatment	0.040	-0.363	0.443	0.847
Allison (2000)	Systolic blood pressure	Posttreatment	0.000	-0.217	0.217	1.000
Cupples (1994)	Systolic blood pressure	Posttreatment	-0.014	-0.172	0.143	0.859
Gianuzzi (2008)	Systolic blood pressure	Posttreatment	0.067	-0.011	0.145	0.091
Jiang (2006)	Systolic blood pressure	Posttreatment	0.155	-0.147	0.458	0.315
Lear (2003)	Systolic blood pressure	Posttreatment	0.087	-0.148	0.321	0.470
McHugh (2001)	Systolic blood pressure	Posttreatment	0.601	0.188	1.013	0.004
Murphy (2009)	Systolic blood pressure	Posttreatment	0.197	0.055	0.339	0.007
Nordmann (2001)	Systolic blood pressure	Posttreatment	-0.291	-0.568	-0.014	0.040
Ornish (1998) Pischke (2008)	Systolic blood pressure	Posttreatment	-0.117	-0.772	0.537	0.725
Salminen (2005)	Systolic blood pressure	Posttreatment	-0.231	-0.600	0.138	0.220
Toobert (2000)	Systolic blood pressure	Posttreatment	0.300	-0.469	1.068	0.445
Vestfold Heartcare Study Group (2003)	Systolic blood pressure	Posttreatment	0.165	-0.114	0.444	0.246
Wallner (1999)	Systolic blood pressure	Posttreatment	0.530	-0.137	1.197	0.120
Wood (2008)	Systolic blood pressure	Posttreatment	0.092	0.003	0.181	0.043
Zwisler (2008)	Systolic blood pressure	Posttreatment	0.260	0.098	0.422	0.002
			0.092	0.017	0.166	0.015

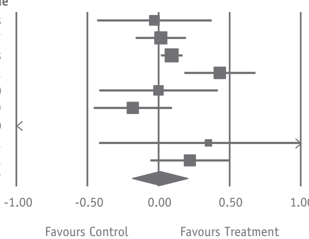
Hedges's g and 95% CI



Follow-up effect sizes for systolic blood pressure

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	Systolic blood pressure	FU medium-term	-0.029	-0.432	0.374	0.888
Cupples (1994) (1999)	Systolic blood pressure	FU long-term	0.016	-0.161	0.194	0.857
Gianuzzi (2008)	Systolic blood pressure	FU long-term	0.093	0.016	0.170	0.018
Lear (2003) (2006)	Systolic blood pressure	FU long-term	0.431	0.181	0.682	0.001
Lisspers (1999) Hofman-Bang (1999)	Systolic blood pressure	FU medium-term	0.000	-0.417	0.417	1.000
Nordmann (2001)	Systolic blood pressure	FU medium-term	-0.181	-0.457	0.095	0.199
Ornish (1998) Pischke (2008)	Systolic blood pressure	FU long-term	-1.974	-2.775	-1.173	0.000
Toobert (2000)	Systolic blood pressure	FU long-term	0.351	-0.419	1.121	0.371
Vestfold Heartcare Study Group (2003)	Systolic blood pressure	FU medium-term	0.221	-0.058	0.500	0.121
			0.008	-0.187	0.203	0.937

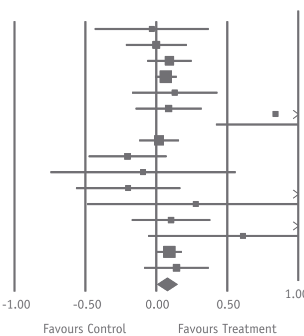
Hedges's g and 95% CI



Posttreatment effect sizes for diastolic blood pressure

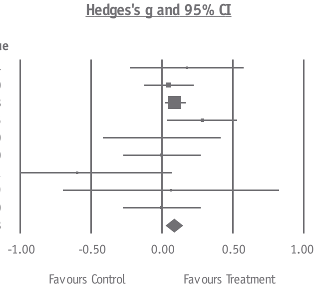
Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	Diastolic blood pressure	Posttreatment	-0.033	-0.436	0.371	0.874
Allison (2000)	Diastolic blood pressure	Posttreatment	0.000	-0.217	0.217	1.000
Cupples (1994)	Diastolic blood pressure	Posttreatment	0.092	-0.065	0.250	0.251
Gianuzzi (2008)	Diastolic blood pressure	Posttreatment	0.067	-0.011	0.145	0.091
Jiang (2006)	Diastolic blood pressure	Posttreatment	0.129	-0.173	0.431	0.403
Lear (2003)	Diastolic blood pressure	Posttreatment	0.087	-0.148	0.321	0.470
McHugh (2001)	Diastolic blood pressure	Posttreatment	0.840	0.419	1.261	0.000
Murphy (2009)	Diastolic blood pressure	Posttreatment	0.019	-0.122	0.161	0.788
Nordmann (2001)	Diastolic blood pressure	Posttreatment	-0.203	-0.479	0.073	0.150
Ornish (1998) Pischke (2008)	Diastolic blood pressure	Posttreatment	-0.094	-0.748	0.561	0.779
Salminen (2005)	Diastolic blood pressure	Posttreatment	-0.199	-0.568	0.170	0.291
Toobert (2000)	Diastolic blood pressure	Posttreatment	0.278	-0.490	1.045	0.478
Vestfold Heartcare Study Group (2003)	Diastolic blood pressure	Posttreatment	0.103	-0.175	0.382	0.466
Wallner (1999)	Diastolic blood pressure	Posttreatment	0.612	-0.059	1.282	0.074
Wood (2008)	Diastolic blood pressure	Posttreatment	0.092	0.003	0.181	0.043
Zwisler (2008)	Diastolic blood pressure	Posttreatment	0.142	-0.087	0.371	0.224
			0.074	0.005	0.144	0.035

Hedges's g and 95% CI



Follow-up effect sizes for diastolic blood pressure

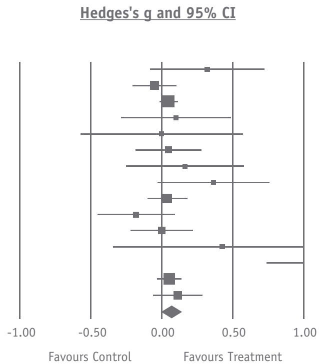
Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	Diastolic blood pressure	FU medium-term	0.176	-0.228	0.580	0.394
Cupples (1994) (1999)	Diastolic blood pressure	FU long-term	0.050	-0.127	0.228	0.580
Gianuzzi (2008)	Diastolic blood pressure	FU long-term	0.093	0.016	0.170	0.018
Lear (2003) (2006)	Diastolic blood pressure	FU long-term	0.285	0.036	0.534	0.025
Lisspers (1999) Lisspers (2005)	Diastolic blood pressure	FU medium-term	0.000	-0.417	0.417	1.000
Nordmann (2001)	Diastolic blood pressure	FU medium-term	0.000	-0.275	0.275	1.000
Ornish (1998) Pischke (2008)	Diastolic blood pressure	FU long-term	-0.595	-1.264	0.073	0.081
Toobert (2000)	Diastolic blood pressure	FU long-term	0.064	-0.699	0.828	0.869
Vestfold Heartcare Study Group (2003)	Diastolic blood pressure	FU medium-term	0.000	-0.278	0.278	1.000
			0.084	0.022	0.146	0.008



Note: Systolic and diastolic blood pressure were reported in mm/Hg. Three studies reported systolic and/or diastolic blood pressure management, as indicated by the % of patients achieving target levels of 140/90 mm/Hg (Wood, 2008; Zwisler, 2008) and 140/85 mm/Hg (Giannuzzi, 2008). Data from one trial (Campbell, 1998; Murchie, 2003) were excluded, as they defined blood pressure as managed when patients had reached target levels or were currently 'receiving attention' (without further definition).

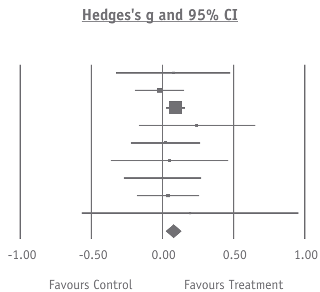
Posttreatment effect sizes for BMI

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	BMI	Posttreatment	0.322	-0.084	0.728	0.120
Cupples (1994) (1999)	BMI	Posttreatment	-0.052	-0.209	0.106	0.520
Gianuzzi (2008)	BMI	Posttreatment	0.048	-0.021	0.117	0.170
Higgins (2001)	BMI	Posttreatment	0.100	-0.291	0.491	0.617
Jeong (2002)	BMI	Posttreatment	0.000	-0.574	0.574	1.000
Lear (2003)	BMI	Posttreatment	0.048	-0.187	0.282	0.690
Lisspers (1999) Hofman-Bang (1999)	BMI	Posttreatment	0.164	-0.254	0.582	0.443
McHugh (2001)	BMI	Posttreatment	0.366	-0.030	0.762	0.070
Murphy (2009)	BMI	Posttreatment	0.041	-0.102	0.184	0.577
Nordmann (2001)	BMI	Posttreatment	-0.181	-0.457	0.095	0.199
Smeulders (2009)	BMI	Posttreatment	0.000	-0.223	0.223	1.000
Toobert (2000)	BMI	Posttreatment	0.425	-0.348	1.197	0.281
Wallner (1999)	BMI	Posttreatment	1.469	0.734	2.203	0.000
Wood (2008)	BMI	Posttreatment	0.052	-0.037	0.141	0.253
Zwisler (2008)	BMI	Posttreatment	0.115	-0.063	0.292	0.206
			0.066	-0.008	0.140	0.079



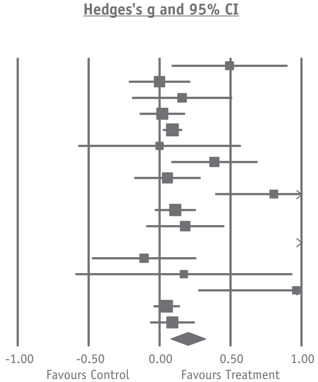
Follow-up effect sizes for BMI

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	BMI	FU medium-term	0.246	-0.159	0.651	0.234
Cupples (1999)	BMI	FU long-term	-0.022	-0.200	0.155	0.807
Gianuzzi (2008)	BMI	FU long-term	0.091	0.022	0.159	0.010
Higgins (2001)	BMI	FU medium-term	0.241	-0.173	0.654	0.254
Lear (2003) (2006)	BMI	FU long-term	0.022	-0.226	0.270	0.860
Lisspers (1999) Hofman-Bang (1999)	BMI	FU medium-term	0.050	-0.367	0.468	0.813
Nordmann (2001)	BMI	FU medium-term	0.000	-0.275	0.275	1.000
Smeulders (2009)	BMI	FU medium-term	0.039	-0.184	0.262	0.733
Toobert (2000)	BMI	FU long-term	0.195	-0.571	0.960	0.618
			0.074	0.017	0.131	0.010



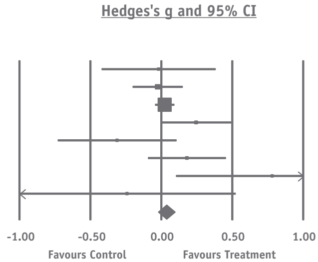
Posttreatment effect sizes for total cholesterol

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	Total cholesterol	Posttreatment	0.493	0.084	0.903	0.018
Allison (2000)	Total cholesterol	Posttreatment	0.000	-0.217	0.217	1.000
Brugemann (2007)	Total cholesterol	Posttreatment	0.159	-0.194	0.512	0.378
Cupples (1994)	Total cholesterol	Posttreatment	0.020	-0.141	0.180	0.811
Gianuzzi (2008)	Total cholesterol	Posttreatment	0.091	0.022	0.159	0.010
Jeong (2002)	Total cholesterol	Posttreatment	0.000	-0.574	0.574	1.000
Jiang (2006)	Total cholesterol	Posttreatment	0.387	0.082	0.691	0.013
Lear (2003)	Total cholesterol	Posttreatment	0.056	-0.179	0.290	0.642
McHugh (2001)	Total cholesterol	Posttreatment	0.806	0.391	1.221	0.000
Murphy (2009)	Total cholesterol	Posttreatment	0.111	-0.034	0.256	0.134
Nordmann (2001)	Total cholesterol	Posttreatment	0.181	-0.095	0.457	0.199
Ornish (1998) Pischke (2008)	Total cholesterol	Posttreatment	4.975	3.638	6.311	0.000
Salminen (2005)	Total cholesterol	Posttreatment	-0.109	-0.478	0.259	0.561
Toobert (2000)	Total cholesterol	Posttreatment	0.171	-0.594	0.937	0.661
Wallner (1999)	Total cholesterol	Posttreatment	0.963	0.272	1.654	0.006
Wood (2008)	Cholesterol management	Posttreatment	0.050	-0.044	0.144	0.297
Zwisler (2008)	Total cholesterol	Posttreatment	0.090	-0.067	0.248	0.261
			0.199	0.077	0.320	0.001



Follow-up effect sizes for total cholesterol

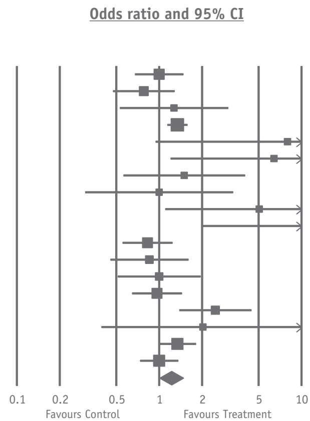
Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	Total cholesterol	FU medium-term	-0.019	-0.422	0.384	0.926
Cupples (1994) (1999)	Total cholesterol	FU long-term	-0.026	-0.203	0.151	0.775
Gianuzzi (2008)	Total cholesterol	FU long-term	0.024	-0.045	0.093	0.500
Lear (2003) (2006)	Total cholesterol	FU long-term	0.245	-0.004	0.494	0.053
Lisspers (1999) Hofman-Bang (1999)	Total cholesterol	FU medium-term	-0.312	-0.731	0.108	0.146
Nordmann (2001)	Total cholesterol	FU medium-term	0.181	-0.095	0.457	0.199
Ornish (1998) Pischke (2008)	Total cholesterol	FU long-term	0.782	0.102	1.461	0.024
Toobert (2000)	Total cholesterol	FU long-term	-0.242	-1.008	0.525	0.537
			0.034	-0.025	0.093	0.252



Note: Three studies reported total cholesterol management, as indicated by the % of patients reaching target levels of 5.2 mmol/l (Wood, 2008; Jeong, 2002) and 4.5 mmol/l (Zwisler, 2008). Data from one trial (Campbell, 1998; Murchie, 2003) were excluded, as they defined cholesterol as managed when patients had reached target levels or were currently 'receiving attention' (without further definition).

Posttreatment effect sizes for smoking

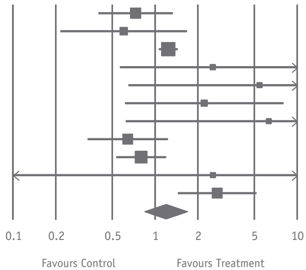
Study name	Outcome	Time point	Odds ratio	Lower limit	Upper limit	p-Value
Allison (2000)	Smoking	Posttreatment	1.000	0.674	1.483	1.000
Campbelll (1998) Murchie (2003)	Smoking	Posttreatment	0.780	0.473	1.287	0.331
Cupples (1994)	Smoking	Posttreatment	1.273	0.528	3.068	0.591
Gianuzzi (2008)	Smoking	Posttreatment	1.343	1.137	1.586	0.001
Higgins (2001)	Smoking	Posttreatment	7.977	0.940	67.662	0.057
Jeong (2002)	Smoking	Posttreatment	6.413	1.199	34.308	0.030
Jiang (2006)	Smoking	Posttreatment	1.500	0.559	4.025	0.421
Lear (2003)	Smoking	Posttreatment	1.000	0.301	3.320	1.000
Lisspers (1999) Hofman-Bang (1999)	Smoking	Posttreatment	5.051	1.100	23.187	0.037
McHugh (2001)	Smoking	Posttreatment	16.333	1.996	133.634	0.009
Murphy (2009)	Smoking	Posttreatment	0.828	0.551	1.244	0.364
Nordmann (2001)	Smoking	Posttreatment	0.854	0.452	1.611	0.626
Salminen (2005)	Smoking	Posttreatment	1.000	0.511	1.959	1.000
Smeulders (2009)	Smoking	Posttreatment	0.966	0.644	1.449	0.866
Vestfold Heartcare Study Group (2003)	Smoking	Posttreatment	2.481	1.380	4.462	0.002
Wallner (1999)	Smoking	Posttreatment	2.029	0.392	10.518	0.399
Wood (2008)	Smoking	Posttreatment	1.343	0.990	1.821	0.058
Zwisler (2008)	Smoking	Posttreatment	1.000	0.732	1.365	1.000
			1.214	1.001	1.471	0.049



Follow-up effect sizes for smoking

Study name	Outcome	Time point	Odds ratio	Lower limit	Upper limit	p-Value
Campbelll (1998) Murchie (2003)	Smoking	FU long-term	0.730	0.399	1.336	0.308
Cupples (1999)	Smoking	FU long-term	0.602	0.215	1.684	0.333
Gianuzzi (2008)	Smoking	FU long-term	1.239	1.060	1.448	0.007
Higgins (2001)	Smoking	FU medium-term	2.550	0.564	11.535	0.224
Lear (2003) (2006)	Smoking	FU long-term	5.436	0.648	45.627	0.119
Lisspers (1999) Hofman-Bang (1999)	Smoking	FU medium-term	2.220	0.613	8.033	0.224
Mildestvedt (2007)	Smoking	FU medium-term	6.319	0.621	64.346	0.119
Nordmann (2001)	Smoking	FU medium-term	0.643	0.334	1.236	0.186
Smeulders (2009)	Smoking	FU medium-term	0.799	0.532	1.198	0.277
Toobert (2000)	Smoking	FU long-term	2.556	0.095	68.999	0.577
Vestfold Heartcare Study Group (2003)	Smoking	FU medium-term	2.739	1.445	5.192	0.002
			1.186	0.840	1.676	0.332

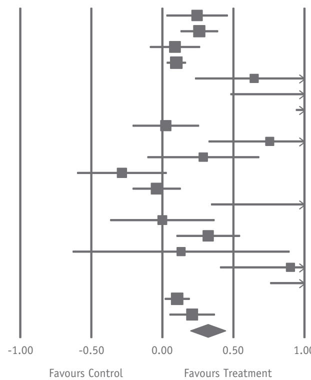
Odds ratio and 95% CI



Posttreatment effect sizes for exercise

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Allison (2000)	Exercise	Posttreatment	0.245	0.027	0.462	0.027
Campbelll (1998) Murchie (2003)	Exercise	Posttreatment	0.260	0.127	0.393	0.000
Cupples (1994)	Exercise	Posttreatment	0.089	-0.089	0.266	0.327
Gianuzzi (2008)	Exercise	Posttreatment	0.099	0.030	0.168	0.005
Higgins (2001)	Exercise	Posttreatment	0.647	0.229	1.064	0.002
Jeong (2002)	Exercise	Posttreatment	1.215	0.477	1.952	0.001
Jiang (2006)	Exercise	Posttreatment	1.270	0.939	1.601	0.000
Lear (2003)	Exercise	Posttreatment	0.024	-0.210	0.259	0.838
Lisspers (1999) Hofman-Bang (1999)	Exercise	Posttreatment	0.756	0.324	1.188	0.001
McHugh (2001)	Exercise	Posttreatment	0.288	-0.107	0.683	0.153
Mildestvedt (2008)	Exercise	Posttreatment	-0.284	-0.601	0.032	0.078
Murphy (2009)	Exercise	Posttreatment	-0.040	-0.210	0.131	0.649
Ornish (1998) Pischke (2008)	Exercise	Posttreatment	1.040	0.342	1.738	0.004
Salminen (2005)	Exercise	Posttreatment	0.000	-0.368	0.368	1.000
Smeulders (2009)	Exercise	Posttreatment	0.323	0.098	0.547	0.005
Toobert (2000)	Exercise	Posttreatment	0.132	-0.632	0.897	0.735
Vestfold Heartcare Study Group (2003)	Exercise	Posttreatment	0.902	0.405	1.399	0.000
Wallner (1999)	Exercise	Posttreatment	1.495	0.758	2.232	0.000
Wood (2008)	Exercise	Posttreatment	0.105	0.015	0.194	0.021
Zwisler (2008)	Exercise	Posttreatment	0.210	0.049	0.371	0.010
			0.319	0.195	0.442	0.000

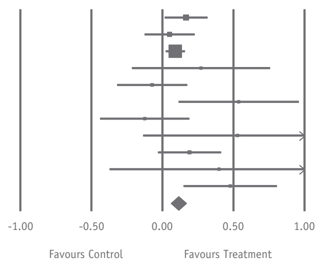
Hedges's g and 95% CI



Follow-up effect sizes for exercise

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Campbelll (1998) Murchie (2003)	Exercise	FU long-term	0.167	0.015	0.319	0.031
Cupples (1994) (1999)	Exercise	FU long-term	0.051	-0.127	0.228	0.576
Gianuzzi (2008)	Exercise	FU long-term	0.091	0.022	0.159	0.010
Higgins (2001)	Exercise	FU medium-term	0.272	-0.215	0.759	0.274
Lear (2003) (2006)	Exercise	FU long-term	-0.072	-0.320	0.176	0.569
Lisspers (1999) Hofman-Bang (1999)	Exercise	FU medium-term	0.537	0.112	0.961	0.013
Mildestvedt (2008)	Exercise	FU medium-term	-0.124	-0.440	0.191	0.439
Ornish (1998) Pischke (2008)	Exercise	FU long-term	0.529	-0.137	1.195	0.120
Smeulders (2009)	Exercise	FU medium-term	0.191	-0.033	0.414	0.094
Toobert (2000)	Exercise	FU medium-term	0.399	-0.373	1.170	0.311
Vestfold Heartcare Study Group (2003)	Exercise	FU medium-term	0.477	0.147	0.807	0.005
			0.112	0.059	0.165	0.000

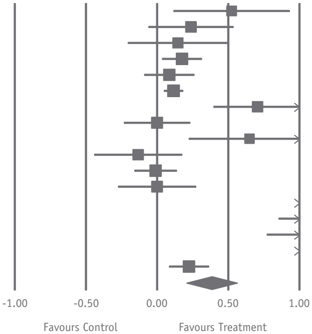
Hedges's g and 95% CI



Posttreatment effect sizes for dietary behaviour (fat intake)

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	Dietary behaviour (fat intake)	Posttreatment	0.524	0.114	0.934	0.012
Allison (2000)	Dietary behaviour (fat intake)	Posttreatment	0.238	-0.062	0.538	0.120
Brugemann (2007)	Dietary behaviour (fat intake)	Posttreatment	0.146	-0.207	0.499	0.417
Campbelll (1998) Murchie (2003)	Dietary behaviour (fat intake)	Posttreatment	0.175	0.034	0.316	0.015
Cupples (1994)	Dietary behaviour	Posttreatment	0.086	-0.092	0.263	0.342
Gianuzzi (2008)	Dietary behaviour	Posttreatment	0.116	0.047	0.185	0.001
Jiang (2006)	Dietary behaviour	Posttreatment	0.706	0.395	1.018	0.000
Lear (2003)	Dietary behaviour (fat intake)	Posttreatment	0.000	-0.235	0.235	1.000
Lisspers (1999) Hofman-Bang (1999)	Dietary behaviour	Posttreatment	0.650	0.221	1.078	0.003
Mildestvedt (2007)	Dietary behaviour (fat intake)	Posttreatment	-0.133	-0.443	0.177	0.401
Murphy (2009)	Dietary behaviour (fat intake)	Posttreatment	-0.010	-0.161	0.141	0.893
Nordmann (2001)	Dietary behaviour	Posttreatment	0.000	-0.275	0.275	1.000
Ornish (1998) Pischke (2008)	Dietary behaviour (fat intake)	Posttreatment	12.636	9.604	15.667	0.000
Toobert (2000)	Dietary behaviour (fat intake)	Posttreatment	1.758	0.852	2.664	0.000
Vestfold Heartcare Study Group (2003)	Dietary behaviour (fat intake)	Posttreatment	1.072	0.770	1.374	0.000
Wallner (1999)	Dietary behaviour (fat intake)	Posttreatment	1.797	1.026	2.567	0.000
Wood (2008)	Dietary behaviour (fat intake)	Posttreatment	0.225	0.083	0.366	0.002
			0.382	0.205	0.560	0.000

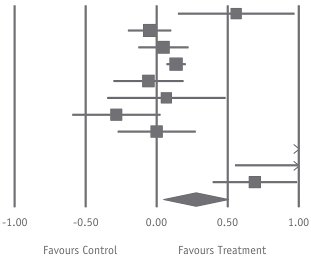
Hedges's g and 95% CI



Follow-up effect sizes for dietary behaviour (fat intake)

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Aldana (2007)	Dietary behaviour (fat intake)	FU medium-term	0.560	0.149	0.971	0.008
Campbelll (1998) Murchie (2003)	Dietary behaviour (fat intake)	FU long-term	-0.050	-0.204	0.103	0.522
Cupples (1994) (1999)	Dietary behaviour	FU long-term	0.047	-0.130	0.225	0.601
Gianuzzi (2008)	Dietary behaviour	FU long-term	0.137	0.068	0.206	0.000
Lear (2003) (2006)	Dietary behaviour (fat intake)	FU long-term	-0.058	-0.306	0.190	0.649
Lisspers (1999) Hofman-Bang (1999)	Dietary behaviour	FU medium-term	0.068	-0.349	0.486	0.748
Mildestvedt (2007)	Dietary behaviour (fat intake)	FU medium-term	-0.284	-0.595	0.028	0.074
Nordmann (2001)	Dietary behaviour	FU medium-term	0.000	-0.275	0.275	1.000
Ornish (1998) Pischke (2008)	Dietary behaviour (fat intake)	FU long-term	6.896	5.153	8.639	0.000
Toobert (2000)	Dietary behaviour (fat intake)	FU long-term	1.409	0.551	2.266	0.001
Vestfold Heartcare Study Group (2003)	Dietary behaviour (fat intake)	FU medium-term	0.691	0.393	0.989	0.000
			0.274	0.046	0.503	0.019

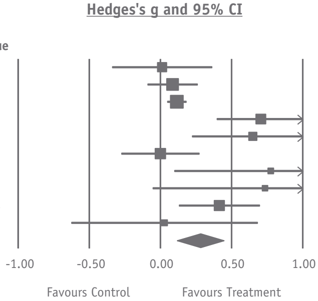
Hedges's g and 95% CI



Note : Dietary behaviour was recorded as fat intake, reported in grams per day (Vestfold Heart Care Study Group, 2003; Ornish, 1998/ Pischke 2008; Brugemann, 2007), % of calories (Aldana, 2007; Lear, 2003; Toobert, 2000; Wallner, 1999; Wood, 2008), 'fat score' (Murphy 2009), or as % of patients reaching a low fat diet (Mildestvedt, 2007; Campbell, 1998; Allison, 2000). Five studies reported adherence to a healthy diet, defined as 'an improved frequency of eating poultry, green vegetables, and high fibre food and decreased frequency of eating red meat, fried foods, biscuits, sweets, and saturated fat' (Cupples, 1999), 'Mediterranean-like diet score' (Giannuzzi, 2008), 'meeting the step II diet criteria of saturated fat <8% of total calories and cholesterol <250 mg (Jiang 2007), atherogenic diet index (Nordmann, 2001), 'heart-healthy diet of fat <30%, saturated fat < 10%, protein 15%, carbohydrates 60% (Lisspers, 1999/Hofman-Bang, 1999).

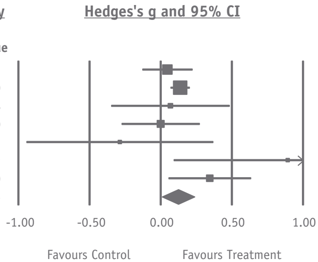
Posttreatment effect sizes for dietary behaviour (energy intake)

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Brugemann (2007)	Dietary behaviour (energy intake)	Posttreatment	0.012	-0.341	0.365	0.946
Cupples (1994)	Dietary behaviour	Posttreatment	0.086	-0.092	0.263	0.342
Gianuzzi (2008)	Dietary behaviour	Posttreatment	0.116	0.047	0.185	0.001
Jiang (2006)	Dietary behaviour	Posttreatment	0.706	0.395	1.018	0.000
Lisspers (1999) Hofman-Bang (1999)	Dietary behaviour	Posttreatment	0.650	0.221	1.078	0.003
Nordmann (2001)	Dietary behaviour	Posttreatment	0.000	-0.275	0.275	1.000
Ornish (1998) Pischke (2008)	Dietary behaviour (energy intake)	Posttreatment	0.776	0.097	1.455	0.025
Toobert (2000)	Dietary behaviour (energy intake)	Posttreatment	0.735	-0.055	1.526	0.068
Vestfold Heartcare Study Group (2003)	Dietary behaviour (energy intake)	Posttreatment	0.415	0.129	0.700	0.004
Wallner (1999)	Dietary behaviour (energy intake)	Posttreatment	0.029	-0.627	0.685	0.931
			0.279	0.116	0.443	0.001



Follow-up effect sizes for dietary behaviour (energy intake)

Study name	Outcome	Time point	Hedges's g	Lower limit	Upper limit	p-Value
Cupples (1994) (1999)	Dietary behaviour	FU long-term	0.047	-0.130	0.225	0.601
Gianuzzi (2008)	Dietary behaviour	FU long-term	0.137	0.068	0.206	0.000
Lisspers (1999) Hofman-Bang (1999)	Dietary behaviour	FU medium-term	0.068	-0.349	0.486	0.748
Nordmann (2001)	Dietary behaviour	FU medium-term	0.000	-0.275	0.275	1.000
Ornish (1998) Pischke (2008)	Dietary behaviour (energy intake)	FU long-term	-0.287	-0.945	0.370	0.392
Toobert (2000)	Dietary behaviour (energy intake)	FU long-term	0.893	0.090	1.696	0.029
Vestfold Heartcare Study Group (2003)	Dietary behaviour (energy intake)	FU medium-term	0.345	0.054	0.637	0.020
			0.122	0.008	0.236	0.036



Note: Dietary behaviour was recorded as energy intake, reported in kJ or kC per day, Five studies reported adherence to a healthy diet, defined as 'an improved frequency of eating poultry, green vegetables, and high fibre food and decreased frequency of eating red meat, fried foods, biscuits, sweets, and saturated fat' (Cupples, 1999), 'Mediterranean-like diet score' (Giannuzzi, 2008), 'meeting the step II diet criteria of saturated fat <8% of total calories and cholesterol <250 mg (Jiang 2007), atherogenic diet index (Nordmann, 2001), 'heart-healthy diet of fat <30%, saturated fat < 10%, protein 15%, carbohydrates 60% (Lisspers, 1999/Hofman-Bang, 1999).

4.

Beyond Resolutions? A Randomized Controlled Trial of a Self-Regulation Lifestyle Program for Post-Cardiac Rehabilitation Patients

Janssen, V. / De Gucht, V. / Van Exel, H. / Maes, S (2012)
Beyond resolutions? A randomized controlled trial of a self-regulation lifestyle program for post-cardiac rehabilitation patients.
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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 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). 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 months thereafter.
Results ANCOVAs showed a significant effect of the lifestyle program after 6 months on blood pressure, waist circumference and exercise behavior.
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.
Trial Registration ISRCTN06198717 Controlled-trials.com

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

Introduction

The modification of risk factors and related health behaviors lies at the very core of adequate cardiac disease management. Meta-analytic reviews have shown cardiac rehabilitation (CR) programs to have positive effects on blood pressure, cholesterol, body weight, smoking behavior, physical exercise and dietary

habits, and to successfully reduce mortality and the incidence of 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 six months (9-11). Qualitative research on patients' perspectives suggest that motivation for lifestyle change tends to wane around three 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 programs 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.
That being said, merely extending program duration or increasing contact frequency is not sufficient to prevent deterioration of risk factors and lifestyle behavior (14,15). Rather, programs should be tailored to the psychological mechanisms specific to the maintenance of behavior, as these differ from those involved in the adoption of new behavior (16,17). For example, whereas planning and implementation strategies play a role in moving from resolution to action, maintenance of the changed behavior 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 behavior change techniques (18,20).

Self-regulation theories of behavior are centered on the idea that all behavior 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 programs based on self-regulation theory are successful in sustaining weight loss (19,20) physical activity (8,23,24), and healthy eating (20). Within the field of cardiac rehabilitation, there are no comprehensive lifestyle maintenance programs based on self-regulation theory that we are aware of. Existing lifestyle maintenance programs show inconsistent results (25-32). Furthermore, these programs 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 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. The aim of the present study is to investigate whether this self-regulation lifestyle program is capable of instigating and maintaining changes in risk factors and related health behaviors at six-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 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, 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 three-month outpatient CR program. In accordance with the Dutch Guidelines for Cardiac Rehabilitation (33) the comprehensive CR program 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) 4 two-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 two-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 program 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 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). These sessions were held at the cardiac rehabilitation centre and included up to 12 members per 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 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 (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 behavior 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 program and developing the intervention was not included. Based on 12 participants per group, it was estimated that health psychologists spent an average of 45 hours per 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 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 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

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 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 (38). 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 (39,40). 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. 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 five-point scale, ranging from 0 (no complaints) to 4 (maximal complaints).

Statistical Analyses

Based on previous meta-analyses of lifestyle modification programs for CHD patients (1,2) effect sizes of 0.1 to 0.3 can be expected. A priori analyses carried out in G*Power (42) 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. 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 value ± 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 ($M = 3.79\%$, $SD = 2.91$) 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 algorithm was used to generate 5 imputation data sets, which were analyzed 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 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 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) 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). 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 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 (45), 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 and waist circumference. The mean change from T1 to T2 in systolic blood pressure in the intervention group was -6.86 mm/Hg (95% CI -9.45 to -4.27), whereas in the control group this was -1.45 mm/Hg (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 to1.57]). Furthermore, there was a near-significant (p =0.067) time by group effect for diastolic blood pressure (mean change in intervention group -3.80 mm/Hg [95% CI -5.64 to -1.95]; mean change in control group -1.16 mm/Hg [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 (F(1,204)= 3.54, p =0.061).

Health behavior change

Repeated-measures ANCOVAs showed a significant time by group interaction for physical activity (Table 4). The mean change in the intervention group was +1142 steps per day (95% CI 338 to 1947), whereas in the control group this was -522 steps per day (95% CI -1039 to -5.45). There were no significant group differences for dietary behavior (fat intake and fruit & vegetable intake; Table 4). Repeating the repeated-measures ANCOVAs using intention-to-treat (LOCF procedure) confirmed the significant result for physical activity ($F(1,190)= 8.63$, $p =0.004$). 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 behaviors at six-month follow-up. Benefits were evident for blood pressure, waist circumference and exercise behavior (average steps per 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 programs 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 mm/Hg in systolic blood pressure for the intervention group as compared to 1.5 mm/Hg 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 as little as a

2 mm/Hg lower than usual systolic blood pressure 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 per 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 per day of moderate-intensity physical activity on ≥5 days per week (52). This equates to 8000-9000 steps per 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 behavior.

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 behavior may be explained by ceiling effects, as evidenced by the relatively high fruit & 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 grams per day. In our cohort, patients' fruit and vegetable consumption was already sufficient before the start of the intervention (467 grams/day for the intervention group and 441 grams/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 grams per 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 27.2 (39) and 27.5 (58) 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 program that all participants attended prior to entering our study included a fairly intensive focus on healthy nutrition, which may have lead to near-optimal nutrition habits at the start of the intervention.

Previous studies evaluating comprehensive maintenance programs for cardiac patients show inconsistent results. Some found effects on both risk factor reduction and health behaviors (32) 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 behaviors (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 programs and the behavior change techniques used is unclear (59,60). A recent systematic review on physical activity programs after CR showed that more extensive intervention programs using a combination of cognitive techniques and behavioral strategies were most successful in sustaining exercise behavior in post-CR patients (8). Earlier meta-analyses on secondary prevention programs, however, showed that lengthy, more complex programs 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 programs. Future research should investigate what constitutes the optimal mix of duration, contact frequency, and (theory-based) behavior 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 reincidence 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 behavior. 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 programs (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 program 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 program 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 15-months post-CR is in progress.

Declaration of Conflicting Interests: The authors declare that there is no conflict of interest.

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Figure 1. Participant flow.

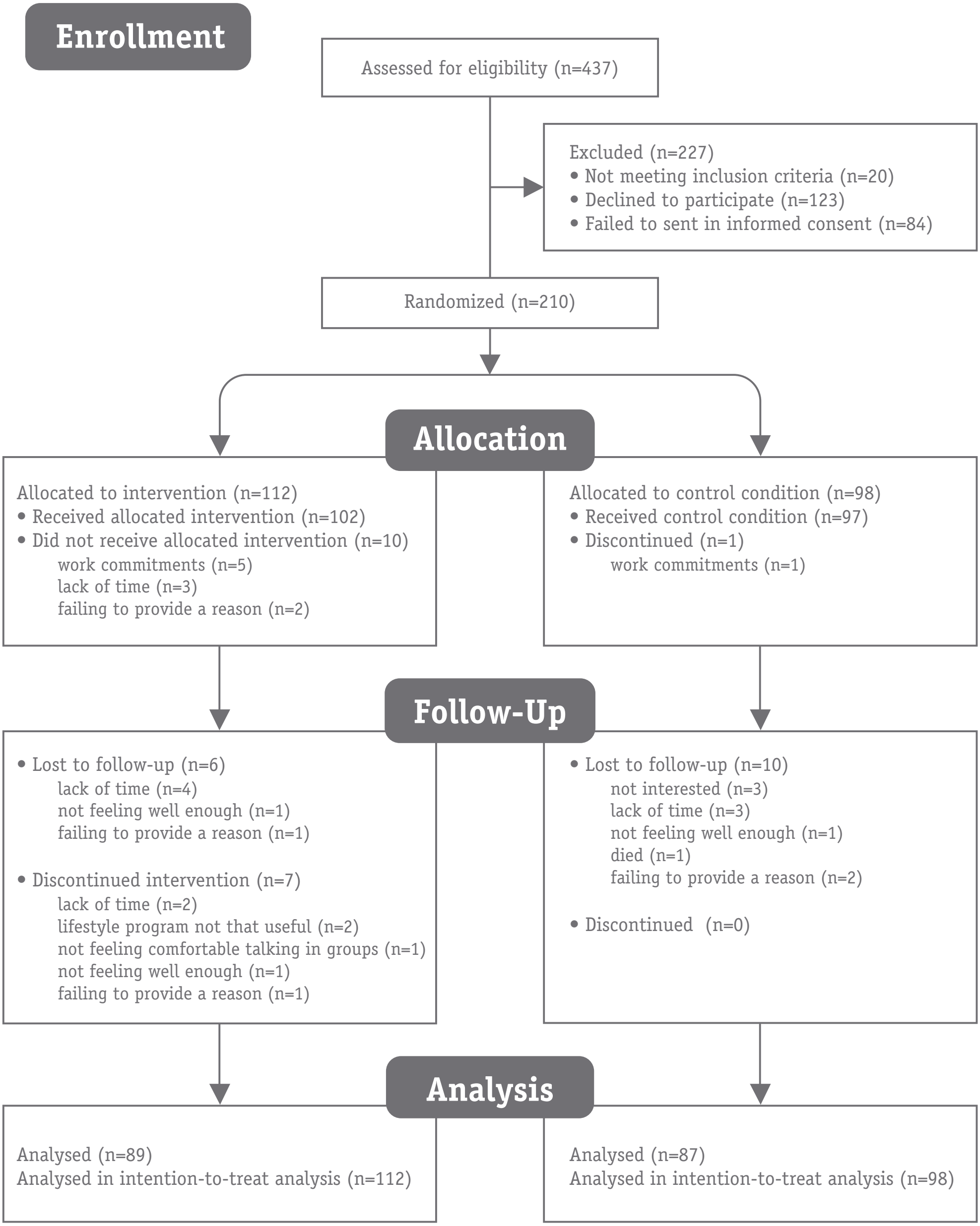

Table 1.
Content of the intervention by session based on the CALO-RE Taxonomy (34)

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	Intervention n = 89		Control n = 87		Group effect†			
	T1	T2	T1	T2	Adjusted F§ (df=1,171)	P	Unadjusted F (df=1,174)	P
Systolic blood pressure (mm/Hg)	138 ± 15	131 ± 14	139 ± 18	138 ± 17	6.28	.01	6.49	.01
Diastolic blood pressure (mm/Hg)	83.8 ± 9.7	80.0 ± 8.7	83.4 ± 9.3	82.3 ± 10.0	3.41	.07	3.41	.07
Waist circumference (cm)	102 ± 10	100 ± 10	103 ± 11	103 ± 11	8.63	.00	8.45	.00
BMI (kg/m²)	27.8 ± 3.4	27.8 ± 3.5	28.0 ± 4.0	28.1 ± 4.3	0.63	.43	0.51	.48
Total cholesterol (mmol/l)	3.90 ± 0.88	3.83 ± 0.85	3.97 ± 0.90	3.95 ± 0.94	0.08	.78	0.08	.95
Triglycerides (mmol/l)	1.59 ± 0.99	1.50 ± 0.81	1.64 ± 0.83	1.65 ± 1.00	0.63	.43	0.20	.66
HDL (mmol/l)	1.19 ± 0.30	1.20 ± 0.75	1.18 ± 0.33	1.19 ± 0.33	0.00	.96	0.00	.94
LDL (mmol/l)	2.04 ± 0.75	2.03 ± 0.72	2.10 ± 0.83	2.04 ± 0.82	0.28	.60	0.73	.39

Data are presented as mean ± SD. Abbreviations: BMI, Body Mass Index; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol
†Time x treatment interaction by repeated measures ANOVA
§ Adjusted for age, disease severity and cardiac history

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

Variable	Intervention n = 89		Control n = 87		Group effect†			
	T1	T2	T1	T2	Adjusted F§ (df=1,171)	P	Unadjusted F (df=1,174)	P
Physical activity: steps per day	8093 ± 3508	9235 ± 3852	8156 ± 4280	7634 ± 3844	11.75	.00	11.86	.00
Dietary behavior: fat intake	16.8 ± 5.9	16.3 ± 5.8	16.5 ± 5.9	16.8 ± 5.9	1.44	.23	1.02	.31
Dietary behavior: fruit & vegetable intake	467 ± 228	494 ± 234	441 ± 211	457 ± 199	0.46	.50	0.11	.74

Data are presented as mean ± SD.
†Time x treatment interaction by repeated measures ANOVA

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5.

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

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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.

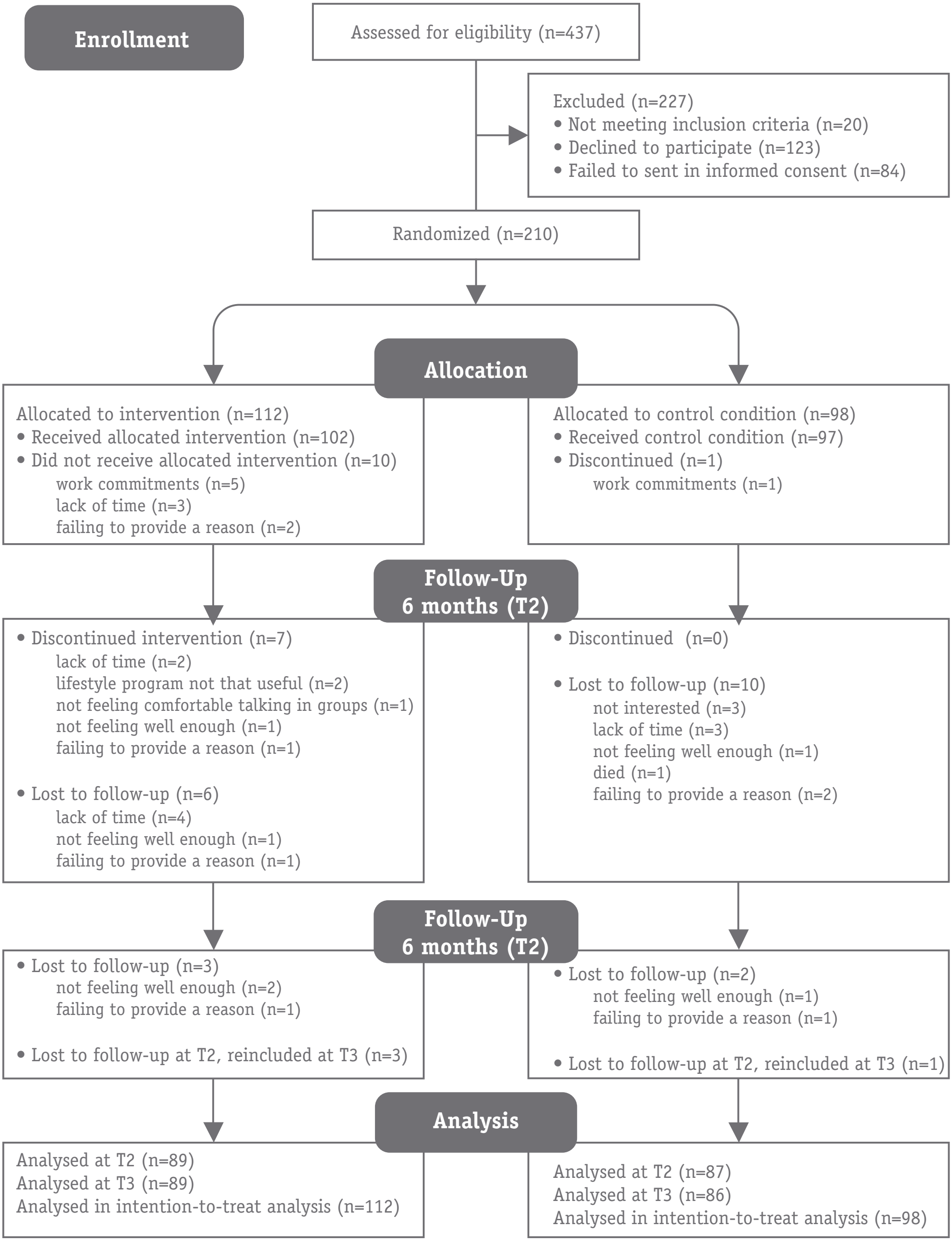
	Baseline (completion of CR)				Posttreatment (6 months post CR)			
	Lifestyle intervention (n=89)	Control group (n=86)			Lifestyle intervention (n=89)	Control group (n=86)		
Obesity†	19 (21.3)	24 (27.9)	1.02	.31	20 (22.5)	27 (31.4)	1.77	.18
Increased waist circumference §	51 (57.3)	44 (51.2)	0.67	.42	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	39 (44.3)	35 (41.2)	0.17	.68	47 (54.7)	34 (40.0)	3.68	.06
2-6 risk factors	49 (55.7)	50 (58.8)			39 (45.3)	51 (60.0)		

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	46 (52.3)	31 (36.9)	4.11	.04
2-6 risk factors	42 (47.7)	53 (63.1)		

Figure 1. Participant flow.



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6.

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 ± 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 x 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.

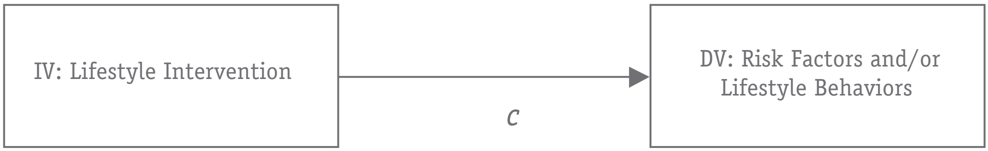
Table 1.
Demographic and clinical characteristics of patients who received the allocated condition.

	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

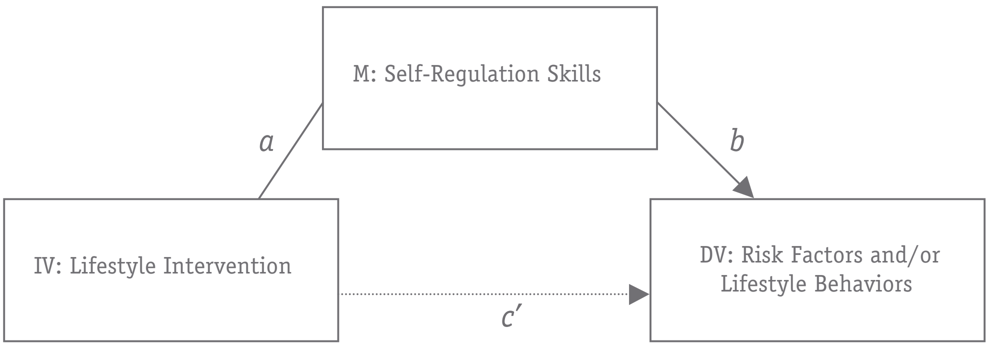
Note: Values are shown as n(%) or mean ± SD where appropriate.
 # CABG, Coronary Artery Bypass Surgery
† PCI, Percutaneous Coronary Intervention
§ Prosthetic valve or valve repair surgery (Intervention n=3, Control n=2), angina pectoris (Intervention n=2, Control n=3)
‡ Includes antecedent cardiac events 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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7.

Summary & General Discussion

Introduction

Despite the demonstrated effectiveness of cardiac rehabilitation programs on disease outcome, many cardiac rehabilitation patients fail to achieve secondary prevention targets, such as healthy blood pressure, cholesterol levels, body mass index, and smoking cessation, in the long-term (1). Seemingly, the majority of cardiac patients adopt healthier lifestyles during cardiac rehabilitation, but relapse into old habits when returning to everyday life. Existing programs that focus on maintenance of lifestyle change and risk factor modification in cardiac patients often lack a theoretical background and show inconsistent results (2–4). In various domains, research has shown that lifestyle modification programs based on self-regulation theory have more lasting effects, for example in terms of maintenance of weight loss (5,6), physical activity (7–9), or healthy eating (10).

In order to prevent relapse after cardiac rehabilitation, we developed a relatively brief lifestyle maintenance program for post-cardiac rehabilitation patients, based on self-regulation theory.

Summary of Main Findings

Changes in illness perceptions and quality of life during cardiac rehabilitation (Chapter 2)

This chapter focused on the role of self-regulation cognitions in cardiac disease outcome. More specifically, we investigated whether illness cognitions change during cardiac rehabilitation and, if so, whether these changes are paralleled by improvements in health-related quality of life. Our findings show that illness beliefs of cardiac patients improve over the course of CR. Patients perceived fewer consequences of their disease, attributed fewer symptoms to their illness, experienced an increased sense of illness coherence, a greater sense of control, and reported a lessened emotional impact of the disease. Furthermore, we found that these changes in illness cognitions were related to improvements in health-related quality of life.

Clinical trials have shown illness beliefs in cardiac patients to be modifiable during hospital admission (11,12). Our results suggest that CR also provides a window of opportunity during which negative illness beliefs that are not in accordance with disease severity can be altered and positive beliefs can be strengthened.

Lifestyle modification programs for patients with coronary heart disease: a systematic review and meta-analysis of randomized controlled trials (Chapter 3)

Existing lifestyle modification programs have incorporated a myriad of techniques aimed at promoting behavior change but it is unclear which combination of theory-derived strategies is effective. Therefore, we carried out a systematic review and meta-analysis comparing the efficacy of programs incorporating all four self-regulation techniques of behavior change (i.e., goal-setting, planning, self-monitoring and feedback) to programs that utilized none of these techniques. Overall results of this systematic review and meta-analysis show that recently tested lifestyle modification programs (1999-2009) are associated with reduced mortality and re-incidence, and improved risk factors and lifestyle behaviors - over and above benefits achieved by routine clinical care alone. Furthermore, programs that included all four self-regulation techniques were more successful in changing exercise behavior and dietary habits (fat intake) compared to interventions that included none of these techniques. However, at long-term follow-up we found these differences to dissipate, implying that the beneficial effects of such techniques seem to wear off once the program has terminated. Future lifestyle modification programs should therefore incorporate (self-regulation) strategies that not only focus on behavior change, but also specifically target relapse prevention and maintenance of behavior change.

Beyond resolutions? A randomized controlled trial of a self-regulation lifestyle program for post-cardiac rehabilitation patients (Chapter 4)
Long-term follow-up of a lifestyle program for post-cardiac rehabilitation patients: are effects maintained? (Chapter 5)

Following completion of cardiac rehabilitation, 210 patients were randomized to receive either the self-regulation lifestyle program (n=112) or standard care (n=98). The program consisted of a motivational interview, 7 group sessions and homework assignments. In chapters 4 and 5 we investigated the effectiveness of this self-regulation lifestyle program.

At 6-month assessment, we found a significant effect of the lifestyle program on blood pressure, waist circumference and exercise behavior. At 15-month follow-up, this effect remained significant for exercise behavior. Furthermore, 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. The program was well received by patients as indicated by high patient satisfaction rates and good session adherence.

Our results indicate that a relatively brief self-regulation program is capable of instigating and maintaining beneficial changes in lifestyle and risk factors after cardiac rehabilitation. Thus, a self-regulation-based intervention may be an efficient means of maintaining cardiac rehabilitation benefits.

Changing for good: the role of self-regulation in exercise adherence following cardiac rehabilitation (Chapter 6)

This chapter investigated whether self-regulation skills explain the long-term treatment effect of the brief self-regulation lifestyle program for post-cardiac rehabilitation patients. Secondary prevention programs for cardiac patients have been proven effective, but less is known about the psychological mechanisms by which they bring about change. The lifestyle group reported improved self-regulation 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 self-regulation skills are at least partly responsible for the lasting change in exercise adherence.

General Discussion

Prior to developing the self-regulation intervention, we aimed to gain greater insight in the role of self-regulation cognitions and skills in relation to cardiac disease management in cardiac patients. Hereto we conducted an empirical study (chapter 2) and a meta-analysis (chapter 3). Our findings showed that cardiac rehabilitation represents a period of time during which cognitions regarding the impact of, and control over the disease are still susceptible to change (chapter 2). Whether changes in illness cognitions are brought about by participation in cardiac rehabilitation, or whether they are a nonspecific effect of adaptation to illness cannot be inferred from our study. Either way, in line with previous research we found illness cognitions to be predictive of wellbeing (13,14). Nonetheless, self-regulation cognitions do not necessarily lead to better cardiac disease management. Research shows that illness cognitions are poorly associated with secondary preventive behaviors such as exercise, diet, smoking and medication adherence (15,16). From a theoretical point of view, this makes good sense: it has repeatedly been shown that health behavior is not changed by a mere act of will. Rather, actual behavior change is viewed as a function of both cognitions and skills, or the interaction between the belief that engaging in a new pattern of behavior will serve to reach a desired state, and the ability to enact the new pattern of behavior. It is exactly this tension between motivation and mastery that makes adoption of a new behavior difficult (17,18).

From an intervention perspective, this implies that attention should be paid to both beliefs and skills. In the context of cardiac disease management, this means that cardiac rehabilitation on the whole may serve to facilitate adaptation to the illness and help dispute any irrational, self-defeating beliefs regarding the illness or behavior change. Subsequently, lifestyle modification programs should teach patients how to set salient and realistic goals health goals, and help them develop the skills to regulate their emotions and behavior in order to attain these goals (i.e., adaptive self-regulation). Support for this notion comes from our meta-analysis and systematic review (chapter 3), which showed that lifestyle modification programs that incorporated a combination of self-regulation behavior change strategies (i.e., goal-setting, self-monitoring, planning and feedback) were more effective than programs that did not promote these skills.

A central tenet in self-regulation theories is the belief that behavior is goal-driven and feedback-controlled. It follows that goal-setting is a key element – and this applies in particular to the field of rehabilitation. Cardiac rehabilitation aims to restore a patient to full physical and psychosocial functioning (19), therefore, identifying appropriate rehabilitation goals and working towards these goals constitute core elements of the recovery process (20,21). A large body of research has linked goal-setting with better disease management in cardiac patients (22–25). Moreover, studies have shown that setting specific goals, rather than general 'do your best' type of goals, and personally relevant goals, rather than assigned goals, have been associated with increased performance (26–28). Self-regulation theories propose that goals are hierarchically organized, both in terms of level of abstraction (abstract versus concrete) and duration (long-term versus short-term) (29). Abstract, long-term goals are the so-called 'be' goals (i.e. be happy, be loved, be healthy etc.); these are salient life goals that generate concrete, short-term 'do' goals, which fuel specific action (i.e., quit smoking, take my medication on time, exercise three times a week etc.). An important implication of this hierarchical model is that behavior that is not innately interesting or satisfying - unfortunately a tenet of most health behaviors - will only be engaged in if it is fulfilling or rewarding in another way, i.e., if it is consistent with the individual's super-ordinate goals. Therefore, theorists emphasize that adaptive self-regulation requires setting low-level, concrete goals that are linked to higher-order life goals (18,20,30). Thus, goal attainment will increase wellbeing and bolster people's confidence, which, in turn, will facilitate further action.

In the context of cardiac disease management, this means that health professionals should help patients to set salient health or recovery goals that feed in to higher-order life goals. Subsequently, patients should be taught the necessary (self-regulation) skills to improve their health behaviors and related risk factors in order to attain these goals. Thus experiencing better disease management may give patients an increased sense of control over (and better understanding of) their illness and facilitate maintenance of the new lifestyle.

Translating theory into practice

Self-regulation models have been criticized for providing little operative guidance in terms of intervention building (31). Maes & Karoly (18) formulated a set of guiding principles derived from self-regulation theory to aid the development of intervention programs. Cornerstones include setting specific, personally relevant health goals, monitoring action and obtaining goal-related feedback.

On the basis of these orienting principles, we developed an intervention for post-cardiac rehabilitation patients targeting maintenance of lifestyle change. Starting point of the intervention was the perspective of the patient. In the individual intake interview, we explored the patient's higher-order life goals and investigated what constituted meaningful recovery goals to the patient him/herself. Thus, patients set themselves a salient health goal that was directly linked with one of their life goals. The subsequent group sessions (five sessions in the first three months and two booster sessions in the fourth and fifth month) aimed to enhance the self-regulation skills relevant to goal attainment and maintenance. For instance, patients were encouraged to self-monitor their goal-related behavior, develop specific action plans when necessary, obtain progress-related feedback, exchange problem-solving strategies and generate alternative pathways to goal attainment. Patients were also encouraged to bring their partner (or a significant other) to one of the sessions and discuss strategies to increase social support. During the sessions, particular attention was paid to increasing self-efficacy through specific assignments and group discussion. Furthermore, satisfaction with outcomes was considered and patients were encouraged to adjust the goal if the outcome failed to meet expectations (i.e., if outcome satisfaction was low) or if the goal proved unattainable. In order to facilitate progress-related feedback we distributed pedometers, which allowed the continued monitoring of exercise behavior - even after termination of the program. Without monitoring progress and obtaining feedback, it is virtually impossible to stay 'on-track', i.e. adjust goal-achievement strategies, renew goal-related effort, or rescale unattainable goals.

Effectiveness of the intervention

Our findings showed that the self-regulation lifestyle program was relatively successful in instigating and maintaining beneficial changes in lifestyles and risk factors post cardiac rehabilitation (chapters 4 and 5). Treatment resulted in better exercise adherence, blood pressure and waist circumference at posttreatment. At long-term follow-up, the lifestyle intervention group still showed lower blood pressure and waist circumference, but these differences were no longer significant. For exercise behavior, however, the treatment effect remained. In addition, a significantly greater proportion of patients in the lifestyle intervention group achieved the secondary prevention target goals for physical activity and obesity.

The magnitude of changes we observed is comparable to that reported by meta-analyses of lifestyle modification programs for cardiac patients (32–34,chapter 3). Typically, trials of effective lifestyle modification programs report small effect sizes for risk factors and small-to-moderate effect sizes for lifestyle changes (3,35). 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 (36).

The most substantial effect we found was for exercise adherence. Research has shown that exercise behavior has both direct and indirect effects (i.e., through reduction of other risk factors) on cardiac mortality (37). Nonetheless, long-term adherence to recommended levels of physical activity have been shown to be problematic (38–40). It is promising that by training self-regulation skills maintenance of this behavior seems to be facilitated (chapter 6).

Trials evaluating previous comprehensive lifestyle modification programs for cardiac patients show inconsistent results. In the short-term (i.e., follow-up between 6 and 12 months) some found effects on both risk factor reduction and health behaviors (3,24), some showed benefits in terms of maintained lifestyle change but not risk factors (41,42). Yet others showed no effects on either risk factors or health behaviors (2,39,43). In the long-term, effects were maintained in two trials (3,35) but largely waned over time in other trials (41,42,44). Such differences in effectiveness may be partly attributed to the timing and setting of the intervention, and the intervention strategies used (46,47,chapter 3). The two trials that maintained treatment effects both offered an ongoing intervention program, with risk factor counseling sessions continuing for two to three years (3,35). In addition, patients were coached by a multidisciplinary team and followed-up regularly. Also, both intervention programs actively involved families in the process and placed a large emphasis on integrating the changed lifestyles in the home-environment.

Interestingly, this facet of interventions has not been paid much attention to in the literature. Generally, research has focused on the setting of the intervention (i.e., home-based versus hospital-based) as a moderator of effectiveness (34,48,49). However, it may not be the setting of the actual intervention that is the differentiating factor but rather the extent to which the intervention is capable of smoothing the transition from one setting to another that determines success. Adherence behavior is known to remain relatively unstable in the first year post-discharge (50–52). This period is characterized by the re-uptake of relational, social and professional roles, and requires a return to work for most people. The literature shows that during this time patients may experience social and emotional problems (e.g., anxiety and depression) or physical difficulties (e.g., fatigue) – none of which are conducive to maintaining a new lifestyle (53,54). Thus, several authors have argued that early adaptation of the new behavior to the home environment is important in long-term maintenance (9,49,55).

In the self-regulation lifestyle program, special attention was paid to addressing patients' needs after discharge from cardiac rehabilitation and smoothing the transition from the rehabilitation setting to home. Qualitative data from the satisfaction survey (data not shown) indicated that patients in the self-regulation lifestyle intervention felt that the program had helped them integrate the new lifestyle in their daily lives. Furthermore, some patients reported that some of the

motivational group materials and the pedometers had acted as powerful reminders to keep them on the right track.
Thus, the integration of settings may be of particular importance in lifestyle maintenance. The self-regulation lifestyle program and the aforementioned trials by Giannuzzi and colleagues (3) and Giallauria and colleagues (35) seem to point towards the importance of taking this into consideration. Future interventions may also consider shifting rehabilitation care from hospitals and formal rehabilitation centers to more diverse setting, such as specifically equipped community health care centers. Such centers tend to be close to home and less resemblant of the hospital-environment. Such community-based cardiac rehabilitation has been shown to be a safe, effective and viable alternative (56).

Strengths and limitations

As far as we are aware, this self-regulation intervention is the first comprehensive lifestyle maintenance program that has been developed from a theoretical perspective. A further strength of the study is the randomized controlled design and the reliance on mostly objective (or near-objective) outcome measures, such as weight, blood pressure, waist circumference, cholesterol levels and pedometer assessments. A final strength is the timing of the intervention. Research suggests that motivation for lifestyle change is likely to wane 3 months after a cardiac incident (57,58) - a time that is likely to coincide with termination of most cardiac rehabilitation programs. Thus, patients are left to their own devices at an especially vulnerable moment in time. In order to prevent relapse, the lifestyle intervention program was offered upon termination of the cardiac rehabilitation program, which smoothed the transition between cardiac rehabilitation and home. In conclusion, we offer a theory-based, relatively simple, cost-effective intervention program that is empirically supported. However, a number of limitations need to be addressed.

First, we tested the intervention in a sample of cardiac patients all of whom participants who had recently completed a comprehensive outpatient cardiac rehabilitation program. A caveat to using a cardiac rehabilitation sample is that populations known to be at a disadvantage for participation in CR, such as women, ethnic minorities, or the elderly, may be under-represented. Second, our sample was relatively young and 'healthy' as evidenced by good New York Heart Association (NYHA) functional capacity scores, which may have introduced bias into the sample. Third, we tested our intervention program in a single-center trial. A recent meta-analysis showed that single-center trials tend to show larger treatment effect sizes than multi-center trials (59), among other reasons as a result of their reliance on more homogenous samples (60). Thus, the external validity of single-center trials may be limited. Nonetheless, promising results from single-center studies allow larger, multi-center trials to be planned effectively and powered appropriately. Thus, future research may conduct a larger, multi-center randomized controlled trial with a longer follow-up to test the self-regulation intervention. Such a trial would not only increase the generalizability of our findings to clinical populations with heart disease, it would also be powered to detect changes in cardiovascular end points, such as clinical events and mortality.

A final limitation of the study may lie in the participation rate. Approximately half of eligible patients in our trial refused participation, which may have introduced selection bias in the sample. Even though we found no differences between participants and non-participants in terms of demographic characteristics or self-reported cardiac risk factors (chapter 4), patients may have differed in motivational preparedness to change their lifestyle. Frequently mentioned reasons for refusal included dislike of the format, lack of time, lack of interest, the idea that their lifestyle did not need further improving, and work commitments or transportation problems (chapter 4).

Research on attendance to cardiac rehabilitation has outlined similar reasons for non-attendance and drop-out (61). Possible solutions to the problem may lie in offering different modes of delivery (i.e., internet-based versus face-to-face and individual versus group) and shifting care from hospitals and rehabilitation centers to health care centers in the community. A further avenue worth exploring is offering participants the possibility to self-monitor their risk factors and titrate their medication depending on the outcome of the measurements. This is currently tried out in innovative treatments for hypertensive patients to increase motivation for participation, and first results seem promising (62).

Future directions

Taken together, this thesis suggests that long-term health behavior change may be facilitated by strategies that aid goal-setting and the monitoring and feedback of (goal-related) performance. Furthermore, it is demonstrated that the necessary skills can be successfully trained in an intervention setting (chapters 4, 5, 6). However, the waning of some treatment effects with time also implies that merely training these self-regulation skills is not enough; upon termination of the program some form of continuation needs to be offered to leverage the skills developed. This is supported by findings from the meta-analysis, which showed that programs promoting self-regulation skills were more effective in terms of lifestyle change, but that the beneficial impact of such strategies seemed to wear off once the program had terminated (chapter 3). Thus, patients may need ongoing attention and guidance in order to maintain the new behaviors for life.

There is some evidence for the effectiveness of telephone and face-to-face booster sessions following cardiac rehabilitation (50,63), but continuity of care could also be offered using multimedia channels. An early web-based intervention targeting secondary prevention in CHD patients encouraged goal-setting and the online entry of self-monitored weight, dietary and exercise data. In turn, patients received progress graphs, small rewards and tailored feedback from health professionals. Positive effects were found in terms of weight reduction and recurrent cardiovascular events (64). Recently, advances in technology have opened up further possibilities; innovative health behavior change interventions are now using combinations of pre-programmed smartphones, e-coaching and social media (65,66).

Thus, future interventions focused on lifestyle maintenance might sustain treatment benefits by encouraging patients to continue self-monitoring their dietary habits, exercise and smoking behavior, blood pressure, body weight and cholesterol after termination of the program. This could be done using telemedicine technology and/or smartphones. Social media and online support forums may increase peer support, serve as a buddy system and prevent relapse. This could be coupled with online feedback from health professionals, i.e., 'e-coaches'. Thus, relapse can be detected at an early stage, and patients are more likely to stay motivated and to continuously renew their goal efforts.

Furthermore, future interventions should consider carefully both what constitutes the 'optimal intervention mix', i.e., the timing, setting and duration of the intervention, the mode of delivery and the type of behavior change technique used. In particular, this rings true for self-regulation cognitions and skills as self-regulation theories propose that the skills and cognitions that predict initiation of a new behavior differ from those involved in the maintenance of that behavior (17,18). Emerging evidence shows that in cardiac patients, self-efficacy and outcome expectancies (67), coping planning (68) and stage of change (69) impact effectiveness of lifestyle modification programs. Satisfaction with outcomes has emerged as an important moderator of successful maintenance of behavior change in other areas of research (70,71) but this has not been investigated within the field of cardiac rehabilitation. Thus, future research might examine predictors of successful maintenance in cardiac patients and investigate (a) whether these differ from predictors of initiation of a new behavior and (b) to what extent they moderate or mediate treatment effectiveness of maintenance interventions.

Finally, future intervention studies should pay attention to psychological distress in cardiac patients. Research has shown that the majority of cardiac patients suffer from anxious or depressive symptoms, which have been associated with poor adherence to lifestyle recommendations and medication regimens (72). Depression and anxiety have not only been reported in the acute phase, but also during the more chronic phases of the illness (54,73). For example, in approximately one third of initially depressed patients symptoms persist throughout the year following hospital discharge. Similarly, approximately one third of initially non-depressed patients develop symptoms of depression at some stage during the first year (74). Not only do depression and anxiety complicate self-adherence, psychological distress has also been shown to lower the treatment effect of lifestyle modification interventions (75). Thus, it would be advisable to screen regularly for anxiety and depression, and offer patients adequate treatment prior to enrolling them in a lifestyle modification (maintenance) program. This is in accordance with the current Dutch Guidelines for Cardiac Rehabilitation (76), which advise regular screening for anxiety and depression, both during and after cardiac rehabilitation. Whereas such screening instruments have now been developed and are carefully being implemented, interventions treating psychological problems in aftercare do not exist as of yet. Therefore, we are currently developing a self-regulation intervention targeting distress in patients with elevated levels of depression and anxiety in an attempt to meet this need. This intervention is largely based on the self-regulation lifestyle program evaluated in this thesis and will be tested for feasibility and efficacy in a pilot-study in a Dutch hospital (77).

Implementation into clinical practice

This thesis describes the development and evaluation of a lifestyle intervention program for post-cardiac rehabilitation patients based on self-regulation theory. The current Dutch Guidelines for Cardiac Rehabilitation (76) place large emphasis on continuity of care after discharge from hospital/cardiac rehabilitation and underscore the importance of (evidence-based) aftercare initiatives. However, in the Netherlands there are no evidence-based intervention programs meeting this need that we are aware of. By developing a self-regulation program for maintenance of lifestyle change we offer an alternative. However, we must heed the warning that implementation in practice is often not as straightforward as it may seem. Research on the implementation of evidence-based health care innovations in practice documents poor uptake of new interventions and guidelines (78). Obstacles to change may be a result of the knowledge and attitudes of the health care providers, the organizational context, available resources, the political environment, or the implementation strategies used (79). Therefore, when deliberating implementation of the self-regulation lifestyle intervention several factors need to be considered.

First, a recent investigation commissioned by the Dutch Ministry of Health, Welfare and Sports evaluated the care for coronary heart disease patients in the Netherlands and concluded that there is a need for lifestyle and self-management interventions for cardiac patients. Simultaneously, they point out that existing interventions are scarce and mostly uncovered by the insurance (80). Unfortunately, the current political climate in the Netherlands is not particularly conducive to change. Current government policy plans substantial cuts to healthcare services, in particular disease prevention and health

promotion initiatives (81). Thus, implementation of the self-regulation lifestyle intervention will largely depend on available funding. The projected cost of running one lifestyle group with 12 members is an estimated 1500 euros (chapter 4).
Secondly, once financial barriers have been overcome, successful implementation will depend on the effectiveness of implementation strategies employed (82). Research shows that psychologists can be trained to adequately deliver evidence-based cognitive-behavioral interventions. Effective training methods include provision of a treatment manual in combination with a didactic seminar and supervised sessions, or web-based guidance (83). With regards to training health care psychologists to implement the self-regulation lifestyle intervention it is estimated that a half-day didactic seminar in combination with the treatment manual and one or two follow-up sessions (possibly web-based) would prove to be sufficient.

To end

This thesis describes the development and evaluation of a theory-based lifestyle program for post-cardiac rehabilitation patients. We tested the intervention in a randomized sample of cardiac patients and found that participation in the self-regulation lifestyle intervention was associated with better exercise adherence and fewer uncontrolled risk factors at long-term follow-up as compared to standard care. Taken together, results suggest that a relatively brief intervention based on self-regulation theory is capable of instigating and maintaining beneficial changes in lifestyle and risk factors after cardiac rehabilitation, and that the skills necessary for lifestyle change can be successfully trained in an intervention setting. Nonetheless, changing one’s lifestyle for life is arduous and patients may need ongoing attention and guidance, for example in the form of (internet-based) booster sessions.

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Nederlandse Samenvatting

Inleiding

In Nederland overlijden gemiddeld 58 vrouwen en 52 mannen per dag aan de gevolgen van hart- en vaatziekten (1). Dankzij ontwikkelingen in preventie en behandeling zijn de overlevingskansen van patiënten over de jaren echter fors toegenomen. Waar hart- en vaatziekten jarenlang de belangrijkste doodsoorzaak vormden, is tegenwoordig kanker de meest voorkomende oorzaak van sterfte (1). Wel worden er jaarlijks steeds meer mensen opgenomen in het ziekenhuis na een hartinfarct of voor een hartoperatie of dotterbehandeling. Zo steeg in de periode van 1980 tot 2010 het (voor bevolkingstoename gecorrigeerde) opnamecijfer voor acuut hartinfarct bij mannen met 43% en bij vrouwen met 28% (1). Dit betekent dat een toenemend aantal mensen leeft met een hartaandoening als chronische ziekte. De vooruitzichten voor deze groep zijn helaas niet zonder meer goed; een belangrijk deel van deze mensen wordt opnieuw opgenomen in het ziekenhuis met hartproblemen of overlijdt uiteindelijk aan de gevolgen van een volgend hartinfarct (2).
Verschillende factoren beïnvloeden de prognose van hartaandoeningen. Naast erfelijkheid, leeftijd, geslacht en co-morbiditeit spelen hypertensie, een te hoog cholesterolgehalte, (abdominale) obesitas en ongezond gedrag, zoals roken, een gebrek aan lichaamsbeweging en verkeerde voeding, een belangrijke rol (3). Het aanpakken van beïnvloedbare risicofactoren door medicatie en leefstijlverandering (secundaire preventie) is dan ook essentieel in het verlagen van het risico.
In hartrevalidatie werken onder anderen cardiologen, fysiotherapeuten, diëtisten en psychologen samen met de patiënt aan (lichamelijk en geestelijk) herstel en secundaire preventie. Nationaal en internationaal onderzoek wijst uit dat hartrevalidatie gunstige effecten heeft op leefgewoonten, risicofactoren en kwaliteit van leven. Deelname aan multidisciplinaire hartrevalidatie vermindert de kans op een

nieuw hartinfarct of nieuwe ziekenhuisopnamen en leidt tot circa 30% minder sterfgevallen door hartproblemen (4-8).

Leefstijl na hartrevalidatie: met goede bedoelingen dempt men de gracht?

Ondanks de effectiviteit van hartrevalidatie, worden hierdoor niet alle problemen definitief opgelost. Een groot internationaal onderzoek uitgevoerd in 15 Europese landen, bekeek de prevalentie van risicofactoren onder 5540 hartpatiënten circa anderhalf jaar na ontslag uit het ziekenhuis (9). Ruim een derde van deze groep (n = 1949) had hartrevalidatie gevolgd. Hoewel de groep hartrevalidanten er iets beter voorstond dan de groep die geen hartrevalidatie had gevolgd, was het percentage risicofactoren in beide groepen schrikbarend hoog: in de hartrevalidatie groep had 49% een te hoge bloeddruk (versus 51% in de niet-revalidatiegroep), 55% een te hoog cholesterol gehalte (versus 60% in de niet-revalidatiegroep), was 28% obees (versus 33% in de niet-revalidatiegroep) en rookte 19% nog steeds of weer opnieuw (versus 22% in de niet-revalidatie groep) (9). Kennelijk maken veel patiënten een goede start met gezonder leven tijdens de hartrevalidatie, maar valt het merendeel terug in hun oude gewoonten na afloop. Er ontbreken precieze getallen over de omvang van terugval in de Nederlandse setting, maar internationale studies noemen terugvalpercentages van wel 60% in het eerste half jaar (10-12). Dit is verontrustend, niet in de laatste plaats omdat onderzoek laat zien dat bij hartpatiënten de verbetering in levensverwachting door leefstijlverandering vergelijkbaar is met die van veelgebruikte cardiale medicatie (13, 14). Het belang van het volhouden van de nieuwe gezonde leefstijl is duidelijk, maar hier lijkt echter meer voor nodig te zijn dan goede bedoelingen alléén.

Zelfregulatietheorie: van willen naar kunnen

In essentie kan zelfregulatie gezien worden als de capaciteit van een individu om zich aan te passen aan de (veranderende) omgeving. In de context van ziekte wordt vaak de term 'zelfmanagagement' genoemd, wat gedefinieerd kan worden als het zodanig omgaan met een chronische aandoening (symptomen, behandeling, lichamelijke en psychosociale consequenties en bijbehorende leefstijlaanpassingen) dat de aandoening optimaal wordt ingepast in het leven (15). Met andere woorden, zelfmanagement gaat over de capaciteit van het individu om de eisen die de ziekte stelt te verzoenen met zijn of haar eigen wensen, idealen en levensdoelen. Adequaat zelfmanagement vereist dan ook goede zelfregulatie. Zelfregulatietheorie stelt de persoonlijke doelen van de patiënt centraal (16, 17). Motivatie voor gedragsverandering wordt binnen de zelfregulatietheorie gezien als het gevolg van een discrepantie tussen een individu's huidige staat van zijn en zijn/haar gewenste staat van zijn (het doel). Het nastreven en bereiken van deze doelen is een continu proces dat in verschillende fasen onder te verdelen valt. Bij elke fase horen cognities en vaardigheden die het bereiken van het doel vergemakkelijken. Voorbeelden van vaardigheden zijn het stellen van concrete, haalbare doelen, het monitoren van gedrag en voortgang, en het leren herkennen van en anticiperen op lastige situaties (17). Geloof in eigen kunnen (self-efficacy), mate van tevredenheid over de kosten en baten van het nieuwe gedrag en 'ownership' van het nieuwe gedrag zijn belangrijke cognities voor het volhouden van nieuwe (leef) gewoonten (18). Verschillende studies hebben de meerwaarde van zelfregulatie aangetoond – zowel voor het bereiken als voor het behouden van een gezonde leefstijl. Zo blijken leefstijlprogramma's gebaseerd op zelfregulatietheorie goede resultaten te boeken wat betreft langdurig gewichtsverlies (19,20), lichaamsbeweging (21-23) en gezonde voeding (24).

Er bestaan echter weinig zelfregulatieprogramma's gericht op het aanpakken van meerdere risico-en leefstijlfactoren tegelijkertijd en deze hebben nog nauwelijks toepassing gevonden binnen de hartrevalidatie. Daarom ontwikkelden wij een multifactorieel zelfregulatieprogramma gericht op behoud van leefstijlverandering na hartrevalidatie. Wij evalueerden dit programma vervolgens in een gerandomiseerd design.

Een zelfregulatieprogramma voor leefstijl na hartrevalidatie

Dit proefschrift richt zich op de rol van zelfregulatiecognities en -vaardigheden in het veranderen van gezondheidsgedrag bij hartpatiënten. In een eerste studie onderzoeken we hoe zelfregulatiecognities ten aanzien van ziekte en gezondheid veranderen tijdens deelname aan een multidisciplinair hartrevalidatieprogramma (hoofdstuk 2). In een systematisch literatuuronderzoek en meta-analyse (hoofdstuk 3) zetten we vervolgens bestaande leefstijlprogramma's voor hartpatiënten op een rij en onderzoeken we de effectiviteit van programma's die veel zelfregulatietechnieken gebruikten versus programma's die deze technieken niet gebruikten. In een volgende stap ontwikkelden wij zelf een leefstijlprogramma voor hartpatiënten in de postrevalidatiefase, gebaseerd op de zelfregulatietheorie. Dit programma hebben wij geëvalueerd in een gerandomiseerd design op zowel de korte (hoofdstuk 4) als de lange termijn (hoofdstuk 5). In het laatste hoofdstuk bekijken we de link tussen verbeteringen in leefstijl (i.e. lichaamsbeweging) en zelfregulatie-vaardigheden.

Belangrijkste bevindingen

In hoofdstuk twee onderzochten we of ziektecognities veranderen tijdens deelname aan hartrevalidatie en, zo ja, of deze veranderingen geassocieerd zijn met verbeteringen in

kwaliteit van leven. Patiënten bleken hun hartaandoening als minder schadelijk te gaan ervaren tijdens de revalidatie: zo ondervonden patiënten steeds minder negatieve consequenties van hun hartaandoening, ervoeren zij meer controle over de ziekte, hadden zij het gevoel hun hartziekte beter te zijn gaan begrijpen, schreven zij minder fysieke klachten toe aan hun hartaandoening en werd de emotionele impact van de ziekte op hun leven kleiner. Deze verandering in ziektecognities bleek gerelateerd aan een verbetering in kwaliteit van leven; hoe minder consequenties patiënten ervoeren van hun ziekte en hoe minder fysieke klachten zij ervoeren, hoe beter hun gezondheid-gerelateerde kwaliteit van leven.
Hoewel kwaliteit van leven een belangrijke uitkomstmaat is, is het met name een indicator van (psychosociaal) herstel; verbeteringen in kwaliteit van leven verhouden zich dan ook niet één op één tot verbeteringen in leefstijl en risicofactormanagement. Sterker nog, uit de literatuur blijkt dat (veranderde) ziektecognities wel gerelateerd zijn aan veranderingen in kwaliteit van leven, maar niet tot nauwelijks aan veranderingen in leefstijl of medicatiegebruik (25,26). Binnen het zelfregulatiekader is dit goed te verklaren: volgens zelfregulatietheorie is het juist de interactie tussen cognities en vaardigheden die zorgt voor gedragsverandering. Vanuit een interventie oogpunt betekent dit dat een goed leefstijlprogramma niet alleen aandacht moet besteden aan het ontwikkelen van kennis en adaptieve cognities over de ziekte (i.e. Wat vind ik van mijn ziekte? Wat kan ik hier zelf in veranderen? In hoeverre geloof ik in mijn eigen kunnen?), maar ook aan het aanleren van de juiste vaardigheden (i.e. Hoe stel ik concrete, haalbare doelen, hoe monitor ik mijn voortgang en wat doe ik als het mis gaat?). Wij vroegen ons af in hoeverre bestaande leefstijlprogramma's voor hartpatiënten gestoeld zijn op het aanleren van zelfregulatievaardigheden.

Om inzicht te krijgen in inhoud en effectiviteit van bestaande leefstijlprogramma's voor hartpatiënten voerden we een systematisch literatuuronderzoek en meta-analyse uit in hoofdstuk 3. Om verbeteringen in standaard cardiale zorg, zoals die het afgelopen decennium hebben plaatsgevonden, recht te doen, richtten wij ons enkel op recent geëvalueerde leefstijlprogramma's (1999-2009). Onze meta-analyse laat zien dat deelname aan leefstijlprogramma's leidt tot 34% minder sterfte en 35% minder heropnames en nieuwe cardiale incidenten bij hartpatiënten. Bovendien hebben deze programma's gunstige effecten op risicofactormanagement en leefstijl. Vervolgens keken we naar de mate waarin deze programma's gebruik maken van zelfregulatietechnieken. We vonden dat programma's die patiënten de belangrijkste zelfregulatievaardigheden (i.e. het stellen van doelen, het plannen van acties die naar het doel leiden, het monitoren van deze acties en het gebruik van feedback over voortgang naar het doel) aanleerden effectiever waren in het veranderen van leefstijl dan programma's die dit niet deden.

In een volgende stap ontwikkelden wij een leefstijlprogramma voor hartpatiënten in de postrevalidatiefase, gebaseerd op de zelfregulatietheorie (hoofdstuk 4 en 5). In een individueel motivational interview en zeven groepsbijeenkomsten leerden patiënten hoe zij hun nieuwe leefgewoonten kunnen inpassen in hun dagelijks leven en hoe zij zichzelf kunnen motiveren de gezonde leefstijl vol te houden. Patiënten ontvingen ook een cursus map met thuiswerkopdrachten, die gekoppeld waren aan de groepsbijeenkomsten. De persoonlijke doelen van de patiënt vormden het uitgangspunt van de interventie. Het nastreven en bereiken van doelen is een continu proces dat in vier fasen onder te verdelen valt; 'kijken', 'kiezen', 'doen' en 'checken'. In de eerste fase, 'kijken', gaat het om het bewust worden en definiëren van persoonlijke doelen op het gebied van geluk, gezondheid, leefstijl en stressmanagement. In het individuele motivational interview werden samen met de patiënt belangrijke (levens)doelen verkend en concrete leefstijldoelen hieraan gekoppeld. De tweede fase, 'kiezen', gaat over herkennen en signaleren van gedrag dat bijdraagt aan het bereiken van deze persoonlijke doelen. Op basis van het systematisch registreren van dit gedrag (self-monitoring) werd een concreet en haalbaar gedragsdoel gesteld. Belangrijk in deze fase was dat heel duidelijk werd hoe het veranderen van een bepaald gedrag ervoor zorgt dat iemand dichter bij zijn of haar persoonlijke (levens)doel komt. In de derde fase, 'doen', gingen patiënten aan de slag met het door hen gekozen doel. De nadruk in deze fase lag op het nauwkeurig observeren en registreren van wat wel en niet goed ging, welke gedachten en overtuigingen een rol speelden, welke moeilijke situaties men tegenkwam en hoe men hiermee om kon gaan. Ook was het belangrijk gewaar te worden op welke manier de omgeving hierbij kon helpen; dit was ook de fase waarin partners van de patiënten actief bij het programma betrokken werden. De laatste stap was 'checken'; het (blijven) meten van voortgang en het inpassen van de nieuwe leefgewoonten in het dagelijks leven. In deze fase werd aandacht besteed aan het vol blijven houden van het veranderde gedrag zodat het kon bestendigen en aan het continu blijven registreren van voortgang (bijvoorbeeld met behulp van de stappentellers). Daarnaast lag de focus in deze fase op het leren omgaan met terugval en het bekrachtigen van de eigen interne motivatie (bijvoorbeeld door het maken van een ansichtkaart met daarop een motiverende boodschap).

Dit leefstijlprogramma gebaseerd op zelfregulatietheorie hebben we vervolgens geëvalueerd in een gerandomiseerd gecontroleerd onderzoek. Na afloop van de hartrevalidatie zijn 199 patiënten met een coronaire aandoening (MI, CABG, PCI of arrhythmia) gerandomiseerd toegewezen aan de interventiegroep (leefstijlprogramma) of de controlegroep (standard care). Risico factoren en gezondheidsgedrag zijn gemeten op baseline (einde van de hartrevalidatie) en postinterventie (na 6 maanden) met een follow-up na 15 maanden. ANCOVA's lieten zien dat deelname aan het leefstijlprogramma gunstige effecten had op de bloeddruk, buikomvang en lichaamsbeweging van de patiënten in de interventiegroep na zes maanden (hoofdstuk 4). Ook op de lange termijn was het leefstijlprogramma redelijk effectief: na vijftien maanden vertoonden patiënten in de interventiegroep beter risicofactor management en deden zij nog steeds meer aan lichaamsbeweging (hoofdstuk 5). De effecten op buikomvang en bloeddruk waren echter verdwenen. Eerdere interventie studies laten zien dat niet alleen initiële gedragsverandering, maar vooral ook behoud van gedragsverandering op de lange termijn notoir lastig is. Langdurige gedragsverandering vereist een combinatie van (voortdurende) registratie van gedrag en voortgang-gerelateerde feedback. De patiënten die deelnamen aan het leefstijlprogramma werden getraind in het gebruik van zelf-monitoring en feedback technieken, en werden aangemoedigd hun bewegingsgedrag met behulp van stappentellers te blijven registeren – ook na afloop van de interventie. Het gebruik van dit soort feedbackinstrumenten, die werken als een soort 'stok achter de deur', zou een verklaring kunnen zijn voor de langdurige effecten op lichaamsbeweging (hoofdstuk 5). Concluderend kan gesteld worden dat het leefstijlprogramma bijdraagt aan behoud van een gezonde leefstijl na hartrevalidatie, maar dat een vorm van continuatie, bijvoorbeeld door middel van (online) registratie en feedback in combinatie met telemonitoring instrumenten (zoals bloeddrukmeters en accelerometers), van groot belang is.

In het laatste hoofdstuk onderzochten we de psychologische mechanismen achter blijvende leefstijlverandering.
De interventiegroep rapporteerde verbeterde zelfregulatievaardigheden na afloop van deelname aan het programma. Mediatieanalyses illustreerden dat het effect van de interventie op lichaamsbeweging verklaard kon

worden door verbeterde zelfregulatievaardigheden. Dit suggereert dat zelfregulatievaardigheden (in ieder geval ten dele) verantwoordelijk zijn voor de langdurige effecten lichaamsbeweging.

Implementatie in de praktijk en verder onderzoek

In de nieuwe Multidisciplinaire Richtlijn Hartrevalidatie (3) wordt de nadruk gelegd op screening en begeleiding in de postrevalidatie fase. Echter, nazorgprogramma's op dit gebied ontbreken nog. Dit blijkt ook uit het rapport van CVZ (27) waarin wordt geconstateerd dat er veel vraag is naar leefstijlinterventies tijdens en na de hartrevalidatie, maar dat het huidige aanbod schaars is. Wij bieden een evidence-based zelfregulatieprogramma aan voor (behoud van) een gezonde leefstijl dat door ziekenhuizen en revalidatie centra eenvoudig te implementeren is. Het cursusmateriaal bestaan uit een werkboek voor patiënten en een trainersmanual voor de begeleiders. Het verdient de voorkeur dat begeleiding gebeurt door getrainde psychologen. Onderzoek laat zien dat het goed mogelijk is psychologen te trainen in het geven van evidence-based cognitieve-gedragsmatige behandelingen (28). Uit de literatuur blijkt dat de meest effectieve trainingsmethoden bestaan uit het combineren van een trainers-manual met een cursusgedeelte (face-to-face of webbased). Wij schatten in dat het verschaffen van de trainersmanual in combinatie met een halfdaagse cursus en daarna een follow-up supervisiesessie voldoende zal zijn. De kosten voor het draaien en begeleiden van een groep bestaande uit 12 hartpatiënten zijn geraamd op ongeveer 1500 euro per groep.

De resultaten van ons onderzoek bieden belangrijke aangrijpingspunten voor de ontwikkeling van verdere nazorgprogramma's op het gebied van leefstijl. Een belangrijke toevoeging zou het integreren van multimediacomponenten zijn.

Te denken valt aan het monitoren van gedrag en voortgang met behulp van telemonitoring instrumenten (e.g. bloeddrukmeters, accelerometers en smartphones) gekoppeld aan een vorm van webbased feedback, bijvoorbeeld in de vorm van e-coaching. Nieuw te ontwikkelen nazorgprogramma's zouden ook meer aandacht moeten besteden aan psychosociaal welbevinden. Psychosociale problemen bij hart- en vaatziekten worden niet alleen gerapporteerd tijdens ziekenhuisopnamen en de revalidatieperiode (de acute fase), maar vooral ook in de daaropvolgende chronische fase (29,30). Het einde van de hartrevalidatie luidt een periode in die vaak gepaard gaat met uitdagingen op het gebied van arbeidsreintegratie, sociaal functioneren, het leren omgaan met (blijvende) beperkingen en veranderde toekomstverwachtingen, en het integreren van leefstijlveranderingen in het dagelijks leven. Dit betekent niet alleen dat reeds bestaande psychosociale klachten dit proces nog verder zullen bemoeilijken, maar ook dat zich bij een gedeelte van de patiënten nieuwe psychosociale problematiek, zoals angst, depressie, stress of aanpassingsproblemen, kan ontwikkelen (31). De nieuwe Multidisciplinaire Richtlijn Hartrevalidatie (3) adviseert regelmatige screening opdat deze problemen tijdig gesignaleerd worden en er een passend behandeltraject ingezet kan worden. Echter, wederom geldt dat er op dit moment weinig tot geen (evidence-based) nazorg programma's gericht op het verbeteren van psychosociaal welbevinden in de postrevalidatie fase bestaan. Wij hebben het door ons ontwikkelde zelfregulatieprogramma voor leefstijl na de revalidatie aangepast voor angst en depressie en zijn dit in samenwerking met de Nederlandse Hartstichting op het moment aan het implementeren en testen in het Medisch Centrum Zuiderzee.

Conclusie

Tijdens de hartrevalidatie maken veel patiënten een zeer goede start met het veranderen van ongezonde leefgewoonten die het risico op een nieuw incident of heropname vergroten. Echter, onderzoek wijst uit dat de échte uitdaging na de revalidatie begint; dan blijkt het voor veel patiënten vaak moeilijk om de nieuwe leefstijl vol te houden. Wij ontwikkelden een zelfregulatieprogramma ter voorkoming van terugval na de revalidatie en evalueerden dit in een gerandomiseerd design. Op de korte termijn (na 6 maanden) bleek dat het leefstijlprogramma een gunstig effect had op de bloeddruk, buikomvang en lichaamsbeweging van de deelnemers. Op de lange termijn (15 maanden) bleven patiënten in de interventiegroep meer aan lichaamsbeweging doen en hadden zij minder risicofactoren voor hart- en vaatziekten dan mensen in de controlegroep. Concluderend kan gesteld worden dat dit relatief goedkope, eenvoudig te implementeren nazorgprogramma hartpatiënten wezenlijk kan helpen in het volhouden van een gezonde leefstijl en het verbeteren van risicofactoren na afloop van de hartrevalidatie, maar dat een vorm van continuatie, bijvoorbeeld door middel van (online) registratie en feedback in combinatie met telemonitoring instrumenten (zoals bloeddrukmeters en accelerometers), van groot belang is.

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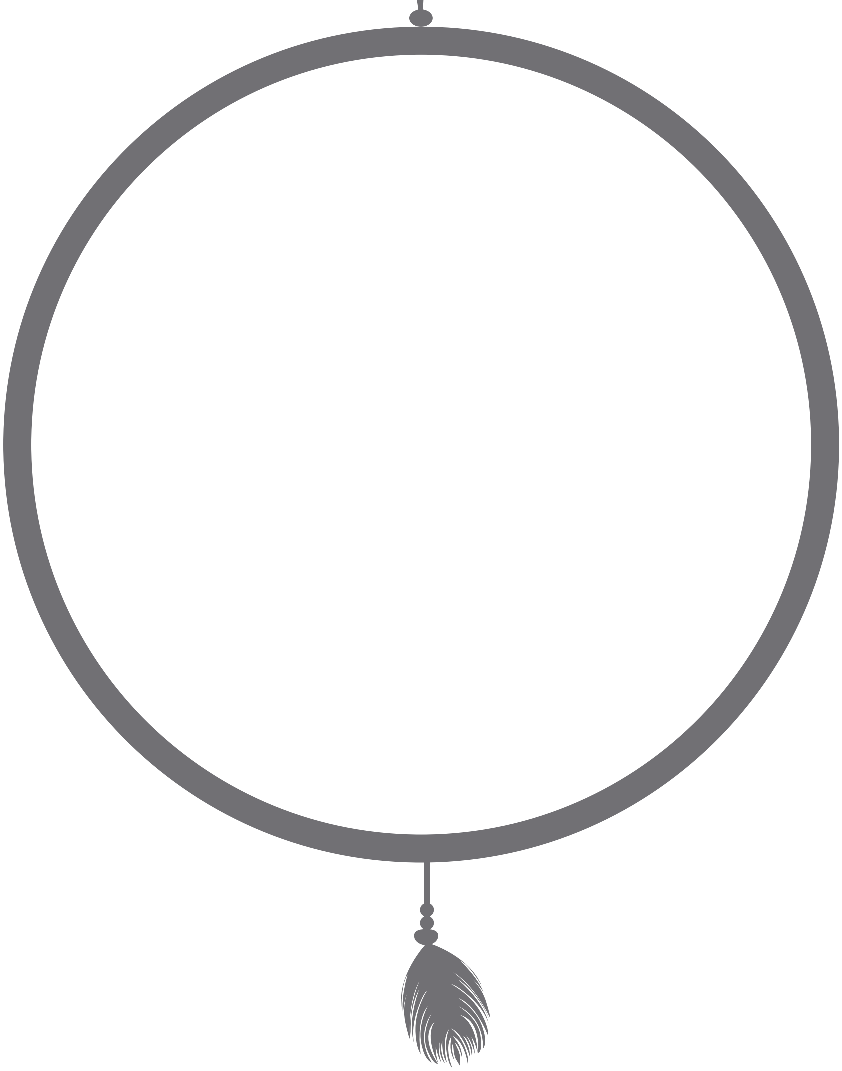
Curriculum Vitae

Curriculum Vitae

Veronica Janssen was born on 18th February 1979 in Amsterdam, the Netherlands. After completing her secondary school education at St. Ignatius Gymnasium, Amsterdam, in 1997, she left for Nepal and England. She graduated from Royal Holloway, University of London, in 2001 with a First Class BSc (Hons) in Psychology for which she received two Academic Achievement awards. She moved back to the Netherlands and pursued a Master's degree in Health Psychology at Leiden University, graduating cum laude from this program in 2004.
After her graduation she ran a stress management program for cardiac patients at the Rijnlands Revalidatie Centrum (RRC) and held a teaching position at the department of Health Psychology at Leiden University. A year later, she commenced her PhD in the same department. She also started training as a cognitive-behavioral therapist, for which she worked with patients at the RRC and at the department of Endocrinology, Leiden University Medical Center. As a spinoff from her intervention research she developed and ran the e-coachings trajectory 'Gelukkig Gezond' for the Volkskrant in 2008.
At present, she runs a self-regulation program for anxiety and depression after cardiac rehabilitation for the Dutch Heart Foundation. She also represents the Netherlands Institute of Psychologists (NIP) in the Multidisciplinary Association for Cardiac Rehabilitation (LMDO-H) and is chair of the National Working Group on Cardio-Psychology (LWCP). Most recently, she qualified as cognitive-behavioral therapist (VGCt-registered) and became assistant professor in the department of Health Psychology, Leiden University.



We'll sit for hours and let the scenery break our hearts
into millions of tiny little pieces.
And then we'll watch, astonished, as, in the space of a breath,
the very same scenery fuses those pieces back together again.

As if we'd been kissed by life.

And then we'll go for a coffee.

Jeff Foster (2010)