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

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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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