A Self-Regulation Intervention Program for Lifestyle Change in Cardiac Patients

Published: 16-07-2007
Last updated: 08-05-2024

To develop an effective lifestyle intervention for cardiac patients based on self-regulation theory aimed at health behavior change and maintenance.

Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON30435

Source
ToetsingOnline

Brief title
Self-Regulation and Cardiac Patients

Condition

- Myocardial disorders
- Vascular hypertensive disorders

Synonym
cardiac disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: coronary heart disease, lifestyle change, risk factors, self-regulation

Outcome measures

Primary outcome

Short-term targets (6 months after start of cardiac rehabilitation) of the

study are:

a) (maintenance of) risk behavior change (i.e., smoking, exercising, eating

behavior)

b) improved self-regulation skills

c) improved quality of life

Long-term targets (two years after start of cardiac rehabilitation) include:

d) improvement in cardiovascular risk factors (cholesterol, blood pressure,

weight)

(e) reduced health care utilization

(f) better return to work

Secondary outcome

Please see above

Study description

Background summary

Coronary heart disease (CHD) is the leading fatal illness in the Netherlands, accounting for 33% of all deaths in 2003 (Koek, van Dis, Peters & Bots, 2005). Extensive clinical and epidemiological studies have identified several risk factors for CHD. The most important factors include smoking, diabetes mellitus,

high blood pressure, high cholesterol, heredity, and obesity. Cardiac rehabilitation programs focusing on behavior modification and stress management have been shown to successfully reduce the incidence of new cardiac events and cardiac mortality and to have positive effects on blood pressure, cholesterol, body weight, smoking behavior, physical exercise, and eating habits (Dusseldorp, Van Elderen, Maes, Meulman & Kraaij, 1999). However, these effects on behavior change were primarily measured on a short-term basis. Research on the maintenance of health-behavior change indicates that sustaining recommended health behaviors over time is still problematic. A European survey on lifestyle and risk factor management in coronary patients six months to one and a half years after discharge from hospital, showed that in the Netherlands, 28% of the patients smoked cigarettes, 79% were overweight, 28% were obese, 54% had raised blood pressure, and 44% had elevated serum total cholesterol (Euroaspire II Study Group, 2001). Thus, there seems considerable room for improvement.

Study objective

To develop an effective lifestyle intervention for cardiac patients based on self-regulation theory aimed at health behavior change and maintenance.

Study design

Randomised controlled study.

Upon completion of the cardiac rehabilitation program, patients in the experimental condition will participate in the self-regulation lifestyle intervention. Patients in the control condition will receive standard cardiac care.

Intervention

The intervention will start with a motivational interview in which the patient*s motivation and self-efficacy for health behavior change and/ or maintenance will be discussed, and the patient is encouraged to select a salient health goal that he or she feels motivated to achieve. Following the interview, patients will participate in seven group sessions focusing on acquiring self-regulation skills associated with successful goal pursuit. The group sessions will be based on the guidelines for self-regulation interventions (Maes & Karoly, 2005) and will incorporate the *Look, Choose, Act, and Check* structure. Patients will be encouraged to first *Look* at their behavior and monitor the frequency and context in which the behavior tends to occur. This may include keeping a food diary or wearing a pedometer. This information will form the basis for the *Choose* stage, in which patients formulate small steps towards goal achievement and select ways of rewarding themselves when progress is made. Techniques for effective self-monitoring, anticipatory coping methods, and evaluation of progress will be discussed in

the *Act* stage. Special attention will be paid to conflicting or competing goals and situations that may trigger nonadherence. Patients will also be encouraged to engage in positive self-talk. In the final stage, patients will be taught how to *Check* and evaluate their progress towards their goal. Patients will also focus on how to receive social support from the environment (i.e., partner, family, friends) and how to profit from this. All of the group-sessions will be paralleled by homework assignments, offered in the Self-Regulation Manual.

Study burden and risks

All patients will be asked to fill out a set of questionnaires (35 min) at four different moments over a period of two years. In addition, patients will be interviewed about their lifestyle in a short telephone interview (20 min). Secondly, trained psychologists will visit patients at home to measure weight and bloodpressure. Finally, patients are required to have their cholesterol measured at SCAL Diagnostisch Centrum.

Patients in the experimental group will also participate in a motivational interview (1hr), and will be asked to attend seven group sessions at the rehabilitation centre.

Contacts

Public
Universiteit Leiden

Postbus 9555
2300 RB Leiden
NL
Scientific
Universiteit Leiden

Postbus 9555
2300 RB Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Presence of one or more of the following risk factors: hypertension, dislipidaemia, smoking, being overweight, and physical inactivity. (For definitions of these risk factors see research protocol, page 8). Fluency in the Dutch language, a minimum age of 18 and a maximum age of 75.

Exclusion criteria

Absence of any of the aforementioned risk factors. Being currently under psychiatric treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL15017.058.07