ISRCTN06198717 https://doi.org/10.1186/ISRCTN06198717

A lifestyle program for cardiac patients

Submission date
29/08/2011

Recruitment status
No longer recruiting

Registration date
10/10/2011

Overall study status
Completed

Last Edited
10/09/2014

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cardiovascular (heart) disease is the leading fatal illness worldwide, causing more deaths and disability than any other disease. The modification of risk factors and related lifestyle behaviors lies at the very core of cardiac rehabilitation programs. However, research on the maintenance of lifestyle changes shows that many cardiac patients slip back into old habits. It seems that mere will alone is not sufficient to sustain behavior change. On the basis of self-regulation theory, we developed a lifestyle program for cardiac patients targeting the skills and cognitions elementary to long-term lifestyle change. One of the central components of self-regulation theory is personal goal-setting. In a motivational interview carried out by a trained health psychologist, patients will explore what constitute meaningful recovery goals to themselves. In subsequent group sessions and home work assignments, patients will learn the skills necessary to achieve these goals.

Who can participate?
To take part you need to be aged under 75, diagnosed with coronary heart disease and currently entered in a cardiac rehabilitation program.

What does the study involve?
If you take part, you will be invited for an individual intake interview at the end of your cardiac rehabilitation program. During the interview, we will determine your body weight, waist circumference, blood pressure and we will ask you several (standardized) questions about your lifestyle. Also, we will ask you to fill out a questionnaire on wellbeing. Finally, you will be asked to go to your nearest SCAL Lab centre to have your cholesterol levels measured. If you wish, we can send the cholesterol results to your home address. We will then randomly allocate you to either the experimental group or the control group. If you are allocated to the control group, you will receive standard care. This usually involves yearly routine check-up appointments with your own cardiologist. If you are allocated to the experimental group, you will also receive a motivational interview with a health psychologist, during which we will explore your important life and health goals. You are then invited to participate in the group program, which consists of five bi-weekly meetings and two monthly follow-up meetings. The total duration of the program is 5 months. During the group sessions, we will work on your personal goal. You will be taught how to make an action plan, cope with problems, mobilize the help of your partner and/or significant others, monitor your progress, and overcome any emotional and motivational problems you might experience. You will also be given a manual with homework exercises that

follow-up on the meetings. In the two booster sessions, you will be taught to deal with relapse and there will be plenty of opportunity to learn from each others experiences. In addition, you will receive standard care. This usually involves yearly routine check-up appointments with your own cardiologist. Six months and 15 months after the first interview, we will invite all patients in the trial (both the experimental and the control group) for a follow-up interview. Again, we will determine your body weight, waist circumference and blood pressure and we will ask you several (standardized) questions about your lifestyle. Also, we will ask you to fill out a questionnaire on wellbeing and ask you some questions about your personal goal and the processes involved in achieving your goal. Finally, you will be asked to go to your nearest SCAL Lab centre to have your cholesterol levels measured. If you wish, we can send the results to your home address.

What are the possible benefits and risks of participating?
If you are allocated to the experimental group, you will be offered the lifestyle program upon completion of your cardiac rehabilitation program. If you participate in the control condition, you will receive cardiac rehabilitation and standard care. In addition, once the trial has finished, we can send you a self-help booklet that contains the same information that has been given to the experimental group in the group sessions, if you wish to receive this information. There are no known risks to participants.

Where is the study run from?
The study takes place at the cardiology department of the Rijnlands Revalidatie Centre in Leiden, the Netherlands.

When is the study starting and how long is it expected to run?
Patients will be enrolled in the study between January 2008 and September 2009. Follow-up examinations will run until January 2011.

Who is funding the study?
The study is funded internally by Leiden University (Netherlands).

Who is the main contact?
Veronica Janssen
VJanssen@FSW.leidenuniv.nl

Contact information

Type(s)
Scientific

Contact name
Prof Stan Maes

Contact details
PO Box 9555
Leiden
Netherlands
2300 RB
+31 71 527 3737
Maes@FSW.leidenuniv.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A self-regulation intervention for maintenance of lifestyle change following cardiac rehabilitation: a randomized controlled trial

Study objectives
To evaluate the effectiveness of a self-regulation lifestyle intervention focusing on long-term risk behaviour change in cardiac patients by means of a randomized controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, Leiden University Medical Centre [Commissie Medische Ethiek LUMC], 29/05/2007, ref: P07.007

Study design
Single-centre non-blinded randomized-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (Dutch)

Health condition(s) or problem(s) studied
Coronary heart disease

Interventions
1. The experimental condition received the lifestyle intervention
2. The control condition received usual care

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cardiac risk factors at time 1 (post cardiac rehabilitiation), time 2 (6 months later), time 3 (15 months later):
1. Blood pressure (automated blood pressure monitors: Microlife BPA100)
2. Cholesterol levels (blood samples collected by the SCAL Medical Diagnostics Centre)
3. Weight (digital weighing scales: Microlife WS100)
4. Waist circumference (measured to the nearest 0.1 cm at the level of the umbilicus while standing using inflexible tape)
5. Smoking (self-report)
6. Cardiac admissions to hospital (self-report)

Secondary outcome measures
At time 1 (post cardiac rehabilitiation), time 2 (6 months later), time 3 (15 months later):
1. Lifestyle behaviours
1.1. Physical activity (Yamax SW-200 pedometer)
1.2. Dietary behaviour (Maastricht Food Questionnaire)
2. Psychosocial wellbeing:
2.1. Quality of life (MacNew Health-Related Quality of Life questionnaire)
2.2. Anxiety and depression (SCL-90 questionnaire; measured only at T1 and T3)
2.3. Illness perceptions (Brief-Illness Perception Questionnaire)
2.4. Self-regulation skills (Self-Regulation Skills Battery questionnaire)
2.5. Treatment self-regulation (Deci & Ryan Treatment Self-Regulation Questionnaire)
2.6. Benefit-finding (Benefit-Finding Questionnaire)

Overall study start date
01/01/2008

Completion date
01/01/2011

Eligibility

Key inclusion criteria
1. Dutch-speaking
2. Under 75 years of age
3. Diagnosed with ischemic coronary heart disease
4. Attending cardiac rehabilitation at the Rijnlands Revalidatie Centrum

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
Currently receiving psychiatric treatment

Date of first enrolment
01/01/2008

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
PO Box 9555
Leiden
Netherlands
2300 RB

Sponsor information

Organisation
Leiden University (Netherlands)

Sponsor details
c/o Miss Veronica Janssen
PO Box 9555
Leiden
Netherlands
2300 RB

Sponsor type
University/education

Website

http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
University/education

Funder Name
Leiden University (Netherlands)

Alternative Name(s)
Leiden University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2013		Yes	No