Randomized Clinical Trial for Optimal Cardiac Rehabilitation.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19956

Source
NTR

Brief title
(HR)2-study Nijmegen

Health condition

Myocardial infarction, Cardiac rehabilitation, percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG)

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre
Source(s) of monetary or material Support: HoogRendement Hartrevalidatie

Intervention

Outcome measures

Primary outcome

Physical capacity (peak oxygen uptake).

Secondary outcome

1. Vascular structure and function;

2. Cardiac structure and function;

3. Activities of daily living (ADL);

4. General mental health;

5. Traditional risk factors;

6. Cardiovascular Lifetime Score;

7. Number of Major Cardiovascular Adverse Events (MACE).

Study description

Background summary

Cardiovascular diseases (CVDs) are the leading cause of death and a major cause of disability and loss of productivity in adults worldwide. the Netherlands, the substantial burden of CVD is further exemplified by an estimated 45% increase of the number of patients with CVD from 2000-2020.Compliance after cardiac rehabilitation, which is generally limited to 12 weeks, is found to be relatively low and less than half of the patients continue their physical training after initial rehabilitation. The ´HoogRendement HartRevalidatie´ (HR)2 is a method of cardiac rehabilitation based on the highly successful cardiac rehabilitation program from Toronto. This program helps people with heart diseases to improve their fitness and strength, and, importantly, helps them to reduce their chance of future heart problems by making longlasting lifestyle changes. It has been shown that only 6.2% of patients that underwent the Toronto cardiac rehabilitation program required rehospitalization within 10 years, which is in major contrast with the 44% of rehospitalization within 5 years in the Netherlands. In a recent study it was demonstrated that 52-weeks of combined supervised and unsupervised exercise sessions was effective in improving both physical and mental health, with the peak observed at 38 weeks (~nine months). It was suggested that further economies of cost might be realized by introducing progressive tapering of supervision.

The (HR)2 program comprises 18 months of cardiac rehabilitation, in which participants perform 5 hourly sessions/week of an individual tailored exercise program (i.e. walking/jogging at moderate intensity). During the first 9 months, one weekly session will be supervised (1 hour exercise, 1 hour education lifestyle), whereas in the last 9 months, one monthly session will be supervised (1 hour exercise, 1 hour education lifestyle).

The main aim of the present study is to assess the suitability of the (HR) 2 programme in a Dutch setting and to compare the efficiency of the (HR) 2 program with traditional cardiac rehabilitation in the Netherlands, according to current guidelines. For this purpose, 105 cardiac patients will be included in each group and physical fitness, cardiovascular structure and function measures, activities in daily living, cardiovascular lifetime risk score, traditional risk factors, MACE and general mental health will be compared between both groups at baseline, and after 2, 9 and 18 months. The study is carried out at the request of the the Ministry of Health, Welfare and Sport (VWS).

Study objective

The purpose of this study is to assess the suitability of a high efficient cardiac rehabilitation program from Canada in a Dutch setting in patients with a MI, PCI or CAGB within 3 months prior to inclusion and compare the efficiency of this program with a traditional cardiac rehabilitation program in the Netherlands.

Study design

All patients (control and intervention group) wil have testing moments at baseline, 2, 9 and 18 months.

Intervention

Patients who meet the inclusion criteria and non of the exclusion criteria will be randomized in:

1. A new cardiac rehabilitation program of 18 months;

2. A traditional Dutch cardiac rehabilitation program of 2 months.

The new cardiac rehabilitation program is called ´HoogRendement HartRevalidatie´ (HR)2 and is a method of rehabilitation based on the highly successful cardiac rehabilitation program from Toronto (Canada). Patients in the (HR)2 program will undergo 18 months of an individually tailored exercise training, i.e. walking and jogging at a moderate intensity. The outcomes of the maximal exercise tests will enable to personalize the exercise program that best meets the condition and abilities of the patient. Participants will undergo 5 hourly exercise sessions/week of walking/jogging at moderate intensity. During the first 9 months of the program one weekly session will be supervised (1 hour exercise, 1 hour education lifestyle). In the last 9 months, one monthly session will be supervised (1 hour exercise, 1 hour education lifestyle). The other exercise sessions will be performed in the home environment of the patient. The education sessions aim to stimulate a healthy lifestyle, focusing on risks, medications, exercise, stress and healthy eating habits.

Cardiac patients that are randomized to the other intervention group will undergo 2 months of traditional cardiac rehabilitation, according to the Dutch guidelines.

Contacts

Public
UMC St Radboud
Department of Physiology
Postbus 9101
L.F. Prins
Nijmegen 6500 HB
The Netherlands
+31 (024) 3614906
Scientific
UMC St Radboud
Department of Physiology
Postbus 9101
L.F. Prins
Nijmegen 6500 HB
The Netherlands
+31 (024) 3614906

Eligibility criteria

Inclusion criteria

1. Acute coronary syndrome, including myocardial infarction (MI) within 3 months prior to inclusion;

2. Patients that underwent a percutaneous coronary intervention (PCI) within 3 months prior to inclusion;

3. Patients that received coronary artery bypass grafting (CABG) within 3 months prior to inclusion.

Exclusion criteria

1. Mental impairment leading to inability to cooperate;

2. Severe impaired ability to exercise of other than cardiovascular causes;

3. Signs of cardiac ischemia and/or a positive exercise testing on cardiac ischemia;

4. Insufficient knowledge of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012
Enrollment:	210
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-10-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36989
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2627
NTR-old	NTR3667
CCMO	NL40738.091.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36989

Study results

Summary results
N/A