Randomized Clinical Trial for optimal Cardiac Rehabilitation: A traditional Dutch Cardiac Rehabilitation Program versus a Canadian High Efficiency Cardiac Rehabilitation Program

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To assess the suitability of the (HR)2 programme in the Dutch setting and compare the efficiency of the (HR)2 programme with traditional cardiac rehabilitation in the Netherlands.

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

Summary

ID

NL-OMON36989

Source
ToetsingOnline

Brief title
Cardiac Rehabilitation

Condition

- Myocardial disorders

Synonym
coronary syndrome, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,direct funding by the Ministry of Health and university medical center

Intervention

Keyword: cardiac, cardiac rehabilitation, lifestyle, physical activity

Outcome measures

Primary outcome

Physical capacity (peak oxygen uptake)

Secondary outcome

- Six minutes walking test [maximum walking distance]

- Vascular structure and function (conduit artery endothelial function, conduit artery diameter, blood flow, IMT, conduit and resistance artery structure, peak hypereamic blood flow, exercise-induced vasodilation, pulse wave velocity)

- Cardiac structure and function (cardiac mass and dimensions, systolic and diastolic function parameters, left and right ventricle strain rate)

- Plaque testing (carotid, femoral and brachial arteries).

- PLAC test (Lp-PLA2)

- Activities of daily living (ADL)

- Cardiovascular Lifetime Score (http://www.lifetimerisk.org)

- Major Cardiovascular Adverse Events (cardiovascular (CV) mortality, all cause mortality, near sudden cardiac death, acute coronary syndrome, CV intervention/surgery, CV hospital admission, CV Emergency visits)

- Quality of life (SF-12, DS-14, GMS, EDS-extended questionnaire)

- Traditional risk factors (i.e. cholesterol, lipid profile, APOB, HbA1C,

Vitamin D3, insulin sensitivity, blood pressure, and body characteristics)

- Care consumption (medication, relapse, (days) admission, outpatient clinic

visits, GP visits, interventions, radiology, nuclear and lab testing).

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. In 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. The Canadian 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 long-lasting 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. This study will be carried out at request of the the Ministry of Health, Welfare and Sport (VWS).

Study objective

To assess the suitability of the (HR)2 programme in the Dutch setting and compare the efficiency of the (HR)2 programme with traditional cardiac rehabilitation in the Netherlands.

Study design

Randomized controlled interventional pilot study

Intervention

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 3 months of traditional cardiac rehabilitation, according to the Dutch guidelines.

Study burden and risks

Noninvasive vascular and cardiac testing procedures in this study are not related to any potential risk for the participant. Headache and dizziness of short duration may occur following nitroglycerin spray. Although inflation of the blood pressure cuff during the vascular measurements may induce a slight uncomfortable sensation, this is brief (5 minutes) and stops when the cuff is deflated. Maximal cycling tests will be performed at the hospital under supervision of highly qualified personnel.
A possible complication of venipuncture is a hematoma, which is induced in ~5% of all cases. To prevent complications, the blood withdrawal will be performed by an experienced professional and sufficient pressure will be provided after withdrawal of the needle.
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 (5 hourly sessions/week). This type of exercise training is safe, and exercise sessions will be supervised on a regular basis. Education will be a key component of the program to stimulate a healthy lifestyle, focusing on risks, medications, exercise, stress and healthy eating habits. To date, more than 50,000 cardiac patients have successfully participated in the Cardiac Rehabilitation Program from Toronto, where the current (HR)2 program is based on. Patients in the other group will undergo 3 months of traditional cardiac rehabilitation, according to the Dutch guidelines.
Taken together, this study involves minimally and non-invasive measures, whilst the (HR)2 program is believed to have a strong and potent health benefit for cardiac patients, and may eventually result in important economic benefits. The results of this study will gain important information about the suitability of the (HR)2 program in the Netherlands.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients suitable for cardiac rehabilitation
- Signed written informed consent
- One of the following criteria:
* Patients with an acute coronary syndrome, including myocardial infarction (MI) within 3 months prior to inclusion
* Patients that underwent a percutaneous coronary intervention (PCI) within 3 months prior to inclusion
* Patients that received coronary artery bypass grafting (CABG) within 3 months prior to inclusion

Exclusion criteria

- Mental impairment leading to inability to cooperate
- Severe impaired ability to exercise of other than cardiovascular causes
- Signs of cardiac ischemia and/or a positive exercise testing on cardiac ischemia
- Insufficient knowledge of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2013
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO

Date:	31-07-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 19956
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL40738.091.12
OMON	NL-OMON19956