Optimal cardiac rehabilitation for obese patients

Published: 12-01-2017
Last updated: 15-05-2024

Aim is to determine (cost-) effectiveness and underlying working mechanisms of a novel CR program specific for obese cardiac patients, OPTICARE-XL, in comparison with usual CR.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON45525

Source
ToetsingOnline

Brief title
OPTICARE-XL

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
obese heart patients, obese patients with coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW,stichting Capri Hartrevalidatie (4e geldstroom)

Intervention

Keyword: Cardiac Rehabilitation, Cost-effectiveness, Obesity, Quality of Life

Outcome measures

Primary outcome

Health-related quality of life

Secondary outcome

Body composition, cardiometabolic risk, daily exercise, sedentary behavior,

fitness; echocardiography

Study description

Background summary

Obese cardiac patients currently participate in usual cardiac rehabilitation (CR) programs. However, effects achieved are substantially smaller than in non-obese patients, and non-lasting.

Study objective

Aim is to determine (cost-) effectiveness and underlying working mechanisms of a novel CR program specific for obese cardiac patients, OPTICARE-XL, in comparison with usual CR.

Study design

Multicenter randomized controlled trial

Intervention

*OPTICARE XL: A one-year tailor-made behavioral group intervention including after-care, specific for obese patients, with strong focus on self-management. Upon usual education sessions and facultative modules (stress management/smoking cessation), OPTICARE-XL includes peer group modules on healthy weight and active lifestyle management. Besides, the usual fitness training is more tailored (aerobic and muscle strength training).
Or

*USUAL CARE: Usual 3-month CR group program without after-care in which both obese and non-obese patients participate. Usual CR combines aerobic fitness training with education sessions and facultative modules (stress management/smoking cessation).

Study burden and risks

Both groups will receive minimally CR as recommended by the guidelines. Subjects randomized to the OPTCARE XL will receive on top of that behavioural therapy for healthy diet (1x/week 60 min during 12 weeks) and to stimulate an active lifestyle (1x/3 weeks 45 minutes during 12 weeks) and a behavioural after-care program is organized with 6 meeting (1 hour each) between weeks 13-52. Besides, the exercise program during the first 12 weeks will be more tailored.
Independent of randomization, all participant are invited to visit the rehabilitation center 4 times for a physical examination and to perform 2 short fitness tests (30 min in total). Besides, patients receive 4 times a number of questionnaires (30 min) and blood samples will be collected 4 times in a laboratory. Furthermore, subjects will wear a small accelerometer around their waist 4 times for 7 days during waking hours. During this period they also keep a dairy in which they note the wear time of the accelerometer. The questionnaires may be possible personal and / or confrontational for patients. In addition, blood samples can result in small bruises or pain. Despite the accelerometer is only small, wearing it can be experienced as a burden. Patients will have no direct benefit from participating in this study.

In a subpopulation (n=50, included in the intervention or control group at 'Capri Hartrevalidation' in Rotterdam) participating in a supplementary echocardiography study (voluntarily), two echocardiographic examinations (30-45 minutes per echo) are performed at the hospital

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

s-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

s-Gravendijkwal 230
Rotterdam 3015 CE

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Obese patients (BMI>30) who are referred to cardiac rehabilitation with documented coronary artery disease (myocardial infarction [ST-segment elevation myocardial infarction; non- ST-segment elevation myocardial infarction], stable angina pectoris) or nonvalvular atrial fibrillation and who fulfill the guidelines for cardiac rehabilitation participation are included, after screening for psychopathology by a psychiatrist.

Exclusion criteria

Exclusion criteria are heart failure, left ventricle ejection fraction<40%, implantable cardioverter defibrillator, psychological or cognitive impairments which may limit cardiac rehabilitation, renal failure or other severe co-morbidity (e.g. severe chronic obstructive pulmonary disease, active malignancy, poorly controlled diabetes, intermittent claudication, musculoskeletal impairments) which could impair participation in cardiac rehabilitation

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):	08-02-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	12-01-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-06-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 27667
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59297.078.16
OMON	NL-OMON27667