

A novel tailor-made cardiac rehabilitation program for obese patient with coronary artery disease.

No registrations found.

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

Summary

ID

NL-OMON27667

Source

Nationaal Trial Register

Brief title

OPTICARE XL

Health condition

Cardiac rehabilitation, obesity, physical activity, fitness, sedentary behavior, coronary artery disease

Sponsors and support

Primary sponsor: Erasmus Medical Centre, Rotterdam

Source(s) of monetary or material Support: ZonMw
Capri Hartrevalidatie, Rotterdam

Intervention

Outcome measures

Primary outcome

Health-related quality of life.

Secondary outcome

body composition (weight, height, BMI, waist circumference), blood pressure, lipid profile and glucose in Fasting blood sample, smoking status, physical activity level, aerobic fitness, muscle strength

Study description

Background summary

Obese patients with coronary artery disease currently participate in usual cardiac rehabilitation programs. However, effects achieved are substantially smaller than in non-obese patients, and non-lasting. The OPTICARE XL study investigates a novel tailor-made cardiac rehabilitation program, especially designed for this (still increasing) patient group. Upon usual education sessions and facultative modules (stress management/smoking cessation), OPTICARE-XL has a strong focus on self-management and includes peer group modules on healthy weight and active lifestyle management, and tailored fitness training (aerobic and muscle strength training).

Study objective

OPTICARE XL will lead to behavioral change towards a healthier lifestyle, resulting in improved health and quality of life. While the novel program requires some extra costs, OPTICARE XL is expected to be cost-effective, even with a time horizon of 1 year.

Study design

Intervention: Tpre (for cardiac rehabilitation program), Tmid (after cardiac rehabilitation program), Tpost (after after-care of 9 months), TFU6 (6 months after Tpost).

Control: Tpre, Tpost (after cardiac rehabilitation program), TFU6 (6 months after Tpost), TFU15 (15 months after Tpost).

Intervention

OPTICARE XL: a one-year tailor-made behavioral group intervention including after-care, specific for obese CAD patients, with strong focus on self-management. Upon usual education sessions and facultative modules OPTICARE XL includes peer group modules on healthy weight and active lifestyle management, and tailored fitness training (aerobic and muscle strength). Control group receives usual cardiac rehabilitation care.

Contacts

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Eligibility criteria

Inclusion criteria

BMI >30, age >18, coronary artery disease (myocardial infarction, angina pectoris), nonvalvular atrial fibrillation, referred to cardiac rehabilitation

Exclusion criteria

Heart failure, left ventricle ejection fraction <40%, implantable cardioverter defibrillator, psychological or cognitive impairments which may limit cardiac rehabilitation, renal failure or other severe comorbidities which could impair cardiac rehabilitation

Study design

Design

Study type:

Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	23-01-2017
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion	
Date:	16-01-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45525
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5589
NTR-old	NTR6181
CCMO	NL59297.078.16
OMON	NL-OMON45525

Study results