

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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27667

Bron

Nationaal Trial Register

Verkorte titel

OPTICARE XL

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus Medical Centre, Rotterdam

Overige ondersteuning: ZonMw

Capri Hartrevalidatie, Rotterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Health-related quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	23-01-2017
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	16-01-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45525
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten