Train hard is smart for the heart.

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

Samenvatting

ID

NL-OMON23141

Bron
Nationaal Trial Register

Verkorte titel
Train hard is smart for the heart

Aandoening

Heart Failure
Cardiac Failure
Myocardial Failure
Congestive Heart Failure
Heart Decompensation

Ondersteuning

Primaire sponsor: Radboud University Medical Centre
Overige ondersteuning: Radboud University Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Physcial fitness;
2. Brachial artery NO-dependent endothelium-dependent vasodilation;
3. Forearm resistance artery vascular bed NO-(in)dependent vasodilation;
4. Contribution of ET to the baseline forearm resistance artery vascular tone.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

In Western countries, heart failure (HF) is a major cause of death. Despite current advances in the pharmacological management of HF, the prevalence is rapidly increasing and the prognosis remains poor. Physical fitness is the single best predictor of both cardiac and all-cause deaths among patients with cardiovascular disease and outperforms ejection fraction as a prognostic index (for survival) in HF. Despite the overwhelming evidence to promote physical activity, little is known regarding the type of exercise that yields optimal beneficial effects in HF. Some studies in healthy subjects or those with cardiovascular risk suggest greater fitness and cardiovascular adaptations after high intensity exercise than with 'traditional' moderate exercise. The rationale is that high intensity exercise (i.e. short bouts of exercise at ~90% of the maximal heart rate) allows patients to complete work at higher workload/intensity, but for a short period of time, inducing beneficial peripheral adaptations in vessels and muscles, without overloading the heart. A sound comparison between the effects of 'traditional' moderate versus high intensity exercise training in HF patients has never been examined. Moreover, little is known about the underlying mechanisms that explain the beneficial effects of exercise in HF.

Objective:

This study aims to investigate the effects of 12 weeks of continuous versus interval exercise training versus a HF control group on physical fitness and cardiovascular health in heart failure patients. Furthermore the mechanisms of exercise-induced improvements in cardiovascular health will be investigated through vascular function measurements and assessments of changes on an genetic level.

Hypothesis:

We expect that continuous training will produce a moderate increase in physical fitness and accordingly a modest improvement in prognosis for heart failure patients. We expect that interval training will provide an optimal stimulus for peripheral improvements, leading to

beneficial adaptations in vessels and muscles, but will also lead to an improvement in function and structure of the heart. Therefore, interval training will induce larger improvements in physical fitness and a larger improvement in prognosis for heart failure patients.

Study design:

Intervention study.

Study population;

84 heart failure patients.

Intervention:

Subjects will be randomly allocated to a 12-week intervention: 1. moderate-intensity exercise training, 2. high-intensity exercise training, or 3. control.

Main study parameters/endpoints:

1. Physical fitness (measured with a maximal cycling test);

2. NO-mediated endothelium-(in)dependent vasodilation of the forearm resistance arteries;

3. Contribution of ET to the baseline vascular tone of the forearm vascular bed.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The brachial catheterisation can induce a haematoma (~5%). However, this is completely reversible within 2 weeks and will not lead to permanent damage. Subjects will be informed regarding this potential risk associated with the invasive procedure of the test. During this test, also blood will be taken for later analysis. Therefore, the number of invasive procedures will be minimised to 2.

The pharmaceutical drugs are all accepted for human use and will be infused in the forearm only (not in systemic doses), leading to a localised effect only. In addition, all substances will

be removed by the body within minutes to hours (dependent on the substance). Moreover, >4,000 studies have previously used one or more of these substances to examine the local effects of endothelin and nitric oxide in the arms or legs of healthy humans as well as various patient groups (including heart failure). To the best of our knowledge, none of these previous studies reported the presence of (serious) adverse events.
Exercise training is not associated with a health risk. Moreover, exercise training typically causes a decreased cardiovascular risk, whilst vascular and cardiac function and structure improve after a period of exercise training. Also a number a previous studies have demonstrated that the cardiac workload during high intensity training is not significantly different to the (traditional)moderate-intensity training. Some studies have even demonstrated that the beneficial effects of exercise on remodelling of the heart are superior during high-intensity training compared with traditional moderate-intensity training in subjects with heart failure. Therefore, both types of exercise are not associated with an increased risk for development of health-related problems.

Doel van het onderzoek

We expect that the control group will show no increase or possibly even a decrease in physical fitness in the three-month period of the study. We expect that continuous training will produce a moderate increase in physical fitness however, we expect that interval training will induce the largest improvement in physical fitness in heart failure patients.

Onderzoeksopzet

Zero weeks (baseline) and twelve weeks (post-intervention).

Onderzoeksproduct en/of interventie

1. 12 weeks of high-intensity interval exercise training, twice a week;

2. 12 weeks of moderate-intensity continuous exercise training, twice a week;

3. A control group who recieves usual care.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Heart failure NYHA classification II/III;

2. Ejection fraction < 45%;

3. Stable situation (clinically and pharmacological).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Diabetes mellitus;

2. Hypercholesterolaemia;

3. Exercise-induced ischaemia;

4. Pre-menopausal females;

5. Pathology/disease that restricts patients from participation to exercise.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-07-2011
Aantal proefpersonen:	84
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-10-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3495
NTR-old	NTR3671
Ander register	METC / ABR : 2010/065 / NL31612.091.10;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A