

# Effects of High intensity Interval Training on CENTRAL hemodynamics at rest and during exercise

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Heart failures
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON37552

### Source

ToetsingOnline

### Brief title

HIT-CENTRAL

### Condition

- Heart failures

### Synonym

Chronic heart failure, left ventricular systolic dysfunction

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Maxima Medisch Centrum

**Source(s) of monetary or material Support:** unrestricted grant  
Medtronic;wetenschapsfonds maxima medisch centrum

## Intervention

**Keyword:** Cardiac output, Central hemodynamics, Chronic Heart Failure, Exercise training

## Outcome measures

### Primary outcome

Primary endpoints:

1. Training induced changes in resting cardiac output as determined by cMRI.
2. Correlation between training induced changes in resting cardiac output and cardiac output during maximal exercise (LiDCO).

### Secondary outcome

Secondary endpoints:

Correlation between training induced changes in resting c.q. exercising cardiac output and changes in the following variables:

- \* Cardiac size at rest (cMRI)
- \* Cardiac output onset and recovery kinetics at submaximal exercise (LiDCO)
- \* Recovery kinetics of muscle tissue oxygenation after submaximal exercise (Near Infrared Spectroscopy)
- \* Quality of life (Minnesota Living With Heart Failure Questionnaire)

## Study description

### Background summary

Physical training has beneficial effects on exercise capacity, cardiac function, quality of life and mortality in patients with chronic heart failure (CHF). However, the optimal training mode and intensity are not yet established.

In a recent small trial in elderly CHF patients, high intensity interval training (HIT) was shown to be superior to moderate intensity exercise

training. Whereas both training modalities resulted in improved skeletal muscle metabolism and perfusion, HIT also induced improvements in cardiac function and size. However, as cardiac function was assessed at rest only, and measurements were performed by 2D echocardiography, which has limited accuracy for this purpose in patients with remodeled hearts, definitive conclusions cannot be drawn from this study.

## **Study objective**

The main objectives of this study are to evaluate the effects of HIT in CHF patients on cardiac output at rest assessed with cardiac magnetic resonance imaging (cMRI), and to investigate the relation between changes in resting cardiac output and changes in cardiac output during maximal exercise (assessed by LiDCO). Secondary objectives are to investigate the relation between training-induced changes in central haemodynamics and changes in the following variables: cardiac size at rest, cardiac output kinetics during and after submaximal exercise, local oxygen delivery in skeletal muscles and quality of life

## **Study design**

prospective randomised controlled intervention trial

## **Intervention**

HIT is performed 3 times a week during 12 weeks and consists of 4 intervals of 4 minutes cycling on a ergometer at 85-95% of the peak aerobic capacity (peak  $\text{Vo}_2$ ) separated by 3 minute active pauses. The entire program is performed in the hospital under direct supervision of trained physiotherapists.

## **Study burden and risks**

Exercise training performed by patients with chronic heart failure patients is considered to be safe and has a class Ia recommendation for treatment of CHF patients.

The HIT program that will be used in this study has been evaluated in a similar population of elderly CHF patients and also in patients with coronary artery disease without any documented harmful effects. In order to reduce potential risks of exercise training all patients perform a maximal cardiopulmonary exercise test at baseline, excluding patients with myocardial ischaemia and ventricular arrhythmias during exercise. Training sessions will be under supervision of trained physiotherapist in a clinical setting.

Regarding the study procedures:

Cardiac output during exercise is evaluated by using a method (LiDCO) requiring radial artery cannulation. Radial artery cannulation is considered to be relatively safe with complication rate of 0.09% for permanent ischemia of the

hand. To ensure collateral circulation a normal Allen test must be present. Puncture will be under local anaesthesia to minimize patients burden. In patients who take oral anticoagulation , dosage will be temporarily adjusted (INR <1,5) for the safety of the procedure. Patients will be screened for contra indications before cardiac MRI.

## Contacts

### Public

Maxima Medisch Centrum

de run 4600  
5504 DB Veldhoven  
NL

### Scientific

Maxima Medisch Centrum

de run 4600  
5504 DB Veldhoven  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

\* Written informed consent.

\* Systolic heart failure due to ischemic cardiomyopathy (due to one or more myocardial infarction, as confirmed with echocardiography) or dilating cardiomyopathy (no history of myocardial infarction, no proven ischemia, no congenital heart disease en no severe valve

disorder)

- \* Left ventricular ejection fraction (LVEF) \* 40% (assessed within 3 months before inclusion by echocardiography, MRI or radionuclear measurement)
- \* New York Heart Association (NYHA) class II or III
- \* Optimal medical treatment

## Exclusion criteria

- \* Myocardial infarction or unstable angina less than 3 months prior to inclusion
- \* Clinical signs of decompensated heart failure
- \* Ventricular tachycardia or ischemia during exercise
- \* Participation in a training program (\*2/week) in the last year
- \* Intracardiac shunts or congenital heart disease limiting exercise capacity
- \* Orthopaedic, vascular, pulmonary, neuromuscular and other disease limiting exercise capacity in a way that the training program is not feasible.
- \* Pathological Allen test , In casu no sufficient collateral circulation to the hand, in case of radial artery cannulation.
- \*MRI will not be part of the study protocol in eligible patients with pacemaker/ICD or other contra indications for MRI

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	29-11-2011
Enrollment:	30
Type:	Actual

## Ethics review

Approved WMO

Date: 01-11-2011

Application type: First submission

Review commission: METC Maxima Medisch Centrum (Veldhoven)

Approved WMO

Date: 01-02-2012

Application type: Amendment

Review commission: METC Maxima Medisch Centrum (Veldhoven)

## 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: 28867

Source: Nationaal Trial Register

Title:

### In other registers

Register	ID
Other	3041
CCMO	NL37770.015.11
OMON	NL-OMON28867