

# Effects of high intensity interval training on skeletal muscle metabolism and oxygenation in patients with chronic heart failure

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

## Summary

### ID

NL-OMON38340

### Source

ToetsingOnline

### Brief title

Effects of HIT on skeletal muscle metabolism and oxygenation in CHF

### Condition

- Heart failures

### Synonym

chronic heart failure, left ventricular dysfunction

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Maxima Medisch Centrum

**Source(s) of monetary or material Support:** Stichting 'Vrienden van het Hart Zuid-Oost Brabant'

## Intervention

**Keyword:** Exercise testing, Exercise training, Heart failure, Skeletal muscle metabolism

## Outcome measures

### Primary outcome

Changes in skeletal muscle metabolic recovery after submaximal exercise (leg extension in the supine position) are assessed by <sup>31</sup>P MR spectroscopy measurements in M. vastus lateralis (rate of post-exercise phosphocreatine increase, expressed as \* -PCr). Changes in skeletal muscle re-oxygenation are assessed simultaneously at the same location by Near Infrared Spectroscopy (rate of post-exercise decrease in deoxygenated hemoglobin, expressed as MRT-HHb). Changes in physiological aspects of skeletal muscle oxygenation and metabolism are assessed by oxidative enzyme activity (succinate dehydrogenase and cytochrome-C-oxidase activity), muscle fibre type distribution and capillary density.

### Secondary outcome

Changes in maximal exercise capacity (peak Vo<sub>2</sub>) and submaximal exercise capacity (rate of recovery of oxygen uptake and re-oxygenation after submaximal exercise), left ventricular function (left ventricular ejection fraction and end systolic volume) and Quality of life (Minnesota living with heart failure questionnaire).

# Study description

## Background summary

Patients with chronic heart failure (CHF) suffer from exercise intolerance, mainly due to a decreased cardiac output and impaired skeletal muscle function. Exercise training can improve their functional capacity and reduce their symptoms. To date, it remains unclear what the optimal intensity of exercise should be. A recent randomized controlled trial in elderly CHF patients showed a dramatic gain in exercise capacity using high intensity interval training (HIT) as compared to training at a moderate intensity. This study showed improvements in skeletal muscle metabolism, blood flow and cardiac function. However, as all these measurements were performed at rest it is not clear to what extent these changes account for the increase in exercise performance. Yet, such knowledge is necessary for individualized exercise prescription, specifically aimed at the individual patients' limitations. The present study is designed to investigate the effects of HIT on skeletal muscle metabolism (O<sub>2</sub> utilization) and oxygenation (O<sub>2</sub> delivery) at submaximal exercise.

## Study objective

The main objective of the study is to investigate the physiological effects of high intensity interval training (HIT) at the skeletal muscle level by assessing skeletal muscle re-oxygenation, skeletal muscle metabolic recovery and re-oxygenation after submaximal exercise, oxidative capacity, capillary density and muscle fibre type distribution. Secondary objectives are to investigate the effects of HIT on maximal and submaximal exercise capacity, quality of life and left ventricular function.

## Study design

Prospective semi-crossover 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 Vo<sub>2</sub>) separated by 3 minute active pauses at 50-60% of peak Vo<sub>2</sub>. The entire program is performed in the hospital under direct supervision of trained physiotherapists. Patients in the control group will participate in the training program after completion of the control period of 12 weeks.

## Study burden and risks

No adverse effects of exercise training performed by CHF patients have been reported in literature, nor in our clinical experience. Yet, exercise training was shown to have beneficial effects on maximal exercise capacity, muscle strength and quality of life. The HIT program that will be used in this study has been evaluated extensively in CHF patients and other populations, like elderly patients, and 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.

The assessments that will be done before and after training are completely non-invasive except for sampling of muscle tissue. <sup>31</sup>P magnetic resonance spectroscopy measurements are exclusively performed in patients without pacemaker / implantable cardioverter defibrillator (ICD) or other contra indication for magnetic resonance imaging. The muscle biopsy procedure is performed in a subgroup of 28 patients and has a complication risk that is considered to be very low. By performing these measurements, we will be able to evaluate the physiological effects of HIT. This knowledge may eventually be useful for a more individualized exercise prescription, specifically aimed at the patients\* individual limitations.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Written informed consent

Stable systolic heart failure secondary to ischemic or dilated cardiomyopathy

New York Heart Association (NYHA) class II or III (without change in class or medication < 3 months prior to inclusion)

Left ventricular ejection fraction of  $\geq 40\%$  (assessed within 3 months before inclusion by echocardiography, MRI or radionuclear measurement)

### 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 ( $\geq 2$ /week) in the last year

Intracardiac shunts or congenital heart disease limiting exercise capacity

Orthopaedic, vascular, pulmonary, neuromuscular and other disease limiting exercise capacity

MRI will not be a part of the study protocol in eligible patients with pacemaker / implantable cardioverter defibrillator (ICD) or other contra indication for magnetic resonance imaging

## Study design

### Design

Study type: Interventional

Intervention model: Other

Allocation: Randomized controlled trial

Masking: Open (masking not used)

**Primary purpose:** Treatment

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 07-01-2011  
Enrollment: 40  
Type: Actual

## Ethics review

Approved WMO  
Date: 18-11-2010  
Application type: First submission  
Review commission: METC Maxima Medisch Centrum (Veldhoven)

Approved WMO  
Date: 08-04-2011  
Application type: Amendment  
Review commission: METC Maxima Medisch Centrum (Veldhoven)

Approved WMO  
Date: 23-12-2011  
Application type: Amendment  
Review commission: METC Maxima Medisch Centrum (Veldhoven)

Approved WMO  
Date: 01-02-2012  
Application type: Amendment  
Review commission: METC Maxima Medisch Centrum (Veldhoven)

Approved WMO  
Date: 01-02-2013  
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: 22308

Source: NTR

Title:

## In other registers

Register	ID
CCMO	NL33837.015.10
OMON	NL-OMON22308