

# The effects of a reactivation programme for patients with both COPD and heart failure on exercise capacity and quality of life, a pilot study

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This pilot study will investigate whether patients with both COPD and CHF who participated in a community based reactivation programme have a higher exercise capacity and a better health related quality of life after the programme in comparison with...

<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-OMON32830

### Source

ToetsingOnline

### Brief title

Pilot study reactivation programme COPE III

### Condition

- Heart failures
- Respiratory disorders NEC

### Synonym

COPD, heart failure

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente

**Source(s) of monetary or material Support:** Het Astmafonds

## Intervention

**Keyword:** COPD, heart failure, intervention, reactivation

## Outcome measures

### Primary outcome

The primary outcome measure is exercise capacity, measured with the six minute walking test. .

### Secondary outcome

Secondary outcome measure is health related quality of life measured with disease specific and generic questionnaires

## Study description

### Background summary

Congestive heart failure (CHF) is an important co-morbidity in patients with chronic obstructive pulmonary disease (COPD). The beneficial effects of community based reactivation programmes on exercise tolerance have already been demonstrated in patients with solely COPD or solely CHF. However, the evidence for treatment of patients with a combination of COPD and CHF is surprisingly slim since patients with co-morbidity are more or less routinely excluded from the majority of studies.

### Study objective

This pilot study will investigate whether patients with both COPD and CHF who participated in a community based reactivation programme have a higher exercise capacity and a better health related quality of life after the programme in comparison with before.

### Study design

The design of the study is a pilot intervention study with a measurement before and after the study.

## **Intervention**

The patients will participate in a 10 weeks community based reactivation programme under supervision of a physiotherapist. The programme contains cycling, walking, lifting and muscle strength training of the m. Quadriceps. Two self-management session under supervision of a nurse practitioner will also be part of the intervention.

## **Study burden and risks**

The risk of the study is negligible. Patients will train under supervision of educated physiotherapists. The physiotherapists will stop or modify the training intervention when one of the following symptoms occur: 1) marked shortness of breath or fatigue (Borg scale >13); 2) respiratory rate > 40/minute during exercise; 3) weight gain of more than two kilograms within 2-3 days. The patients have to come three times to the hospital to undergo physical tests and to fill in questionnaires.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patient between 40 and 75 years with COPD (GOLD II-III) and heart failure (NHYA II-III)

### Exclusion criteria

Other serious diseases, diseases which seriously influence the ability to walk

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL  
Recruitment status: Recruitment stopped

Start date (anticipated): 01-03-2009

Enrollment: 9

Type: Actual

## Ethics review

Approved WMO

Date: 28-11-2008

Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

Register	ID
CCMO	NL25518.044.08