Effects of a community-based physical exercise programme in patients with a combination of COPD and chronic heart failure: the CHEST-study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON33468

Source
ToetsingOnline

Brief title
CHEST-study

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: Astmafonds

Intervention

Keyword: COPD, Exercise, Heart failure, Physiotherapy

Outcome measures

Primary outcome

The primary outcome measure is exercise capacity measured with the 6 Minutes

Walking Test, and daily activity rate, measured by pedometer.

Secondary outcome

Secondary outcomes are: health-related quality of life (disease specific:

Clinical COPD Questionnaire, Minnesota Living with Heart Failure Questionnaire,

and generic: Euroqol 5D, SF-36), health-related behaviour (European Heart

Failure Self-care Behaviour Scale) and self-efficacy (COPD Self-efficacy

scale), and exercise capacity measured with the Incremental Shuttle Walk Test.

Study description

Background summary

Chronic heart failure (CHF) and chronic obstructive pulmonary disease (COPD) are important causes of morbidity and mortality. The prevalence and incidence of COPD as well as CHF are still rising. CHF is an important co-morbidity in COPD and vice versa . It is estimated that approximately one quarter of primary care patients with COPD also has CHF.
Beneficial effects of exercise based rehabilitation programmes on exercise capacity have already been demonstrated in patients with solely COPD or solely CHF. However, no studies are known investigating these effects in patients with both

Study objective

The aim of this study is to assess the effects of a small-group community based physical exercise programme on functional exercise capacity, activity rate and health-related quality of life in patients with chronic heart failure (CHF) and chronic obstructive pulmonary disease (COPD).

Study design

The CHEST-study is a multicenter randomised controlled trial in patients with both COPD and CHF, with a 12-month follow-up. Patients will be randomly assigned to an intervention and a control group. Patients in the intervention group will participate in a 6-month community based physical exercise programme, preceded by participation in four self-management sessions. Patients in the control group will also participate in four self-management sessions, additional to usual care. Measurements will be performed at baseline, and directly, a half year and one year after completion of the physical exercise programme.

Intervention

Patients in the intervention group will participate in a community-based physical exercies programme. In this programme, patients will exercise in small groups under supervision of a community based physiotherapist. The intervention lasts 6 months and is divided into two periods. In the first period, lasting 4 months, the patients will exercise twice a week in the physiotherapy practice, and once a week at home. The goal of this phase of the program is to achieve an optimal improvement of exercise capacity and muscle strength. During the second period, lasting 2 months, patients will exercise once a week in the physiotherapy practice and once a week at home. The goal of this phase is to maintain training effects and to make the shift from training under supervision of a physiotherapist to training at home.

All patients will participate in 4 small group self-management sessions which will be given by a respiratory nurse and a heart failure nurse. Also, a physiotherapist and a dietician will contribute to the programme. Patients will be encouraged to come to the sessions with his or her partner or another person that is close to him or her. The sessions will be planned prior to the reactivation programme.

Study burden and risks

The risk for adverse events in this study is negligible. Earlier studies showed that physical exercise in patients with COPD or CHF is safe and effective. Also, the pilot-study COPEIII (P08-43) and the COPE-II study were conducted without occurrence of any adverse events. Medical treatment of the patients in this study is no other than in regular care, thus no adverse advents are

expected.

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

- Age between 40 and 75 years
- A clinical diagnosis of COPD defined by the GOLD-criteria stage 2 and 3
- A diagnosis of chronic heart failure defined by NYHA class II-III
- A left ventricular ejection fraction (LVEF) < 40% measured by echocardiogram
- A history of smoking of at least 10 pack-years

Exclusion criteria

- Serious other diseases with a survival rate of less than 1 year
- Other diseases which generate symptoms of dyspnoea and/or decreased exercise capacity, or which seriously influence the ability to walk
- Participation in a pulmonary or cardiac rehabilitation programme less than 1 year ago

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	13-08-2009
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL28404.044.09