Effects of a phyisiotherapeutic exercise programme in patients with a combination of COPD and chronic heart failure: the CHEST-study.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26228

Source
NTR

Brief title
CHEST

Health condition

Chronic heart failure and COPD.

Sponsors and support

Primary sponsor: Department of Pulmonary Medicine, Medisch Spectrum Twente Enschede
Source(s) of monetary or material Support: Netherlands Asthma Foundation

Intervention

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:

1. Health-related quality of life (disease specific: Clinical COPD Questionnaire, Minnesota Living with Heart Failure Questionnaire, and generic: Euroqol 5D, SF-36);

2. Health-related behaviour (European Heart Failure Self-care Behaviour Scale);

3. Self-efficacy (COPD Self-efficacy scale);

4. Exercise capacity measured with the Incremental Shuttle Walk Test.

Study description

Background summary

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 reactivation 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, directly, a half year, and one year after finishing the physical exercise programme.

Study population:

100 patients with a combination of COPD (GOLD 2 or 3) and chronic heart failure (NYHA II or III) will be recruited from the outpatient departments of pulmonology and cardiology of Medisch Spectrum Twente in Enschede, UMCG and one other hospital.

The primary outcome measure is exercise capacity measured with the 6 Minutes Walking Test, and daily activity rate, measured by pedometer. 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 objective

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.

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

Measurements will be done at baseline, directly, half a year, and one year after completion of the community based 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. Patients in the control group will receive usual care in addition to the self-management programme.

Contacts

Public
M. Zwerink
[default]
The Netherlands
Scientific
M. Zwerink
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

1. Age between 40 and 75 years;

2. A clinical diagnosis of COPD defined by the GOLD-criteria stage 2 and 3;

3. A diagnosis of chronic heart failure defined by NYHA class II-III;

4. A left ventricular ejection fraction (LVEF) < 40% measured by echocardiogram;

5. A history of smoking of at least 10 pack-years.

Exclusion criteria

1. Serious other diseases with a survival rate of less than 1 year;

2. Other diseases which generate symptoms of dyspnoea and/or decreased exercise capacity, or which seriously influence the ability to walk;

3. 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1729
NTR-old	NTR1839
Other	CCMO / Netherlands Asthma Foundation : 28404 / AF 3.4.07.038
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A