Physical Exercise Training Programme COPD in primary care

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24492

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Chronic Obstructive Pulmonary Disease (COPD), exercise, Chronisch Obstructieve Longaandoening, trainingsprogramma

Sponsors and support

Primary sponsor: University Maastricht (UM), CAPHRI Research Institute
Source(s) of monetary or material Support: Boehringer-Ingelheim

Intervention

Outcome measures

Primary outcome

Primary outcome measure will be the functional exercise capacity measured by the increase in six Minute Walking Distance (6MWD) at 4 months compared to baseline.

Secondary outcome

Secondary outcome measures will be:

- peripheral muscle strength (measured with a handheld dynamometer)

- physical activity (assessed by a pedometer)
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- specific health related quality of life (assessed by questionnaires)

- global perceived effect of the treatment according to the patients (measured on a GPE scale).

There will also be some exploratory outcome measures, for example lung function, general health status, motivation and some safety and feasibility parameters.

Study description

Background summary

Background:
Physical activity is important for patients with COPD, for the short term as well as for the long term. For patients with severe and very severe COPD it is known that pulmonary rehabilitation has a positive effect on dyspnoea, exercise capacity and quality of life. The effects of a physical exercise training programme in a primary care setting for patients with mild to moderate COPD are unknown. It is suggested that there will be considerable gains if these patients can counteract the systemic consequences of the disease in an early stage.

Objectives:
1) To assess the effectiveness of a physical exercise training programme in patients with mild to moderate COPD in the primary care setting, in comparison with usual care.
2) To analyse the main physiological (and behavioural) characteristics of patients with mild to moderate COPD that determine success of the treatment.

Study design:
In this RCT 102 patients will be analysed. The intervention group will participate in a 4-month physical exercise training programme. The control group will receive verbal and written advice to improve physical condition.
Measurements will take place at baseline, after 4 monhs and after 7 months.

Primary outcome:
Functional exercise capacity measured by the increase in 6 MWD. Secondary outcome:

peripheral muscle strength, physical activity, specific health related quality of life and global perceived effect of the treatment.

Study objective

A physical exercise training programme in patients with mild to moderate COPD is more effective in comparison with usual care (i.e. advice given by the general practitioner) in a primary care setting.

Study design

T=0 (baseline)

T=1 (4 months post-baseline)

T=2 (7 months post-baseline)

Intervention

The intervention group will participate in a 4-month physical exercise training programme in a physiotherapy setting.
This programme consists of a combination of endurance/interval training, resistance training, training of specific skills and breathing exercises. There will be 2 supervised and 1 unsupervised training sessions per week. The control group will receive "care as usual", i.e. they will receive advice to improve the physical condition according to the national guidelines of the Dutch College of General Practitioners (NHG). In both groups there will be measurements at baseline, at 4 months and at 7 months.

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Eligibility criteria

Inclusion criteria

1. COPD patients visiting their general practitioner because of dyspnoea, impaired exercise capacity and/or a reduced quality of life;

2. Bronchus obstruction detected by spirometry: FEV1/FVC-ratio < 70% and postbronchodilatory FEV1 > 50% predicted (= mild or moderate COPD / GOLD I or II);
3. MRC-score 2 or more;

4. Not meeting the level of exercise performance as defined by the Dutch Standard of Healthy Physical Exercise;
5. Competent enough in speaking the Dutch language.

Exclusion criteria

1. Patients who already receive or have received a physical exercise training programme or rehabilitation therapy in the past year;
2. Patients who have had respiratory tract infections within the last 8 weeks;
3. Presence of serious co-morbid conditions which would interfere with regular exercise training (severe orthopaedic, muscular, or neurological disorders and cardiovascular conditions liable to be aggravated by exercise).

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):	01-11-2008
Enrollment:	102
Type:	Anticipated

Ethics review

Positive opinion Date:	01-10-2008
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
NTR-new	NL1411
NTR-old	NTR1471
Other	MEC : 08-3-065
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A