Physical Exercise Training Programme COPD in Primary care

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON35671

Source
ToetsingOnline

Brief title
Physical Exercise Training Programme in COPD

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
"smokers lung", chronic bronchitis and emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Boehringer Ingelheim,Boehringer-Ingelheim

Intervention

Keyword: COPD, mild to moderate, Physical exercise, Pulmonary rehabilitation

Outcome measures

Primary outcome

Primary outcome measure will be the functional exercise capacity measured by the increase in 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/accelerometer), specific health related quality of life (assessed by questionnaires) and 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

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. There will be positive impacts for the patients and presumably less health care utilization.

Study objective

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, general practitioners, practice nurses and physiotherapists will be the main caregivers. The general practice will be the entrance to the trial and the measurements and the physical exercise training programme will be performed in the physiotherapy practice.

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 usual care group will receive advice to improve the physical condition according to the national guidelines of the Dutch College of General Practitioners (NHG) and will participate in a low-intensity cardiovascular training programme. There will be 1 supervised training session per week. In both groups there will be measurements at baseline, at the end of the training programme and at 6 + 12 months.

Study burden and risks

The main burden for participants is time-investment. Both groups will undergo 4 consults for the measurements (physical tests and questionnaires). Patients in both groups will have to participate in a training programme for 4 months at the physiotherapy practice.
The risks are small. Participants will have to execute a maximal bicycle ergometry, according to the opinion of the caregivers, in order to investigate the safety of exercise.
Participation may lead to an improvement in exercise capacity and/or quality of life in patients with mild to moderate COPD.

Contacts

Public
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
Nederland
Scientific
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

COPD patients visiting their general practitioner because of dyspnoea, impaired exercise capacity and/or a reduced quality of life. COPD patients who have a clinical diagnosis of mild to moderate COPD (supported by FEV1/FVC ratio < 0,7 and FEV1 > 50% of predicted post-bronchodilator) and MRC-score >= 2. And not meeting the level of exercise performance as defined by the Dutch Standard of Healthy Physical Exercise.

Exclusion criteria

Patients who already receive or have received a physical exercise training programme or rehabilitation therapy in the past year. Patients who have had respiratory tract infections within the last 8 weeks. Presence of serious co morbid conditions which would interfere with regular exercise training
- severe orthopaedic, muscular, or neurological disorders
- 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2010
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO Date:	26-11-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-09-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-07-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	4160
CCMO	NL24510.068.08

Study results

Date completed:	27-06-2013
Actual enrolment:	104