Physical Exercise Training Programme COPD in primary care

Gepubliceerd: 01-10-2008 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24492

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: University Maastricht (UM), CAPHRI Research Institute
Overige ondersteuning: Boehringer-Ingelheim

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

T=0 (baseline)

T=1 (4 months post-baseline)

T=2 (7 months post-baseline)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2008
Aantal proefpersonen:	102
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-10-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1411
NTR-old	NTR1471
Ander register	MEC : 08-3-065
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A