

# Reducing sudden worsening of the patient's condition in patients with progressive lung disease, with physiotherapy.

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Physiotherapy treatment is effective and cost-effective in patients who recently experienced a COPD exacerbation by reducing the frequency, duration and severity of following exacerbations. In addition, it will improve the functional health status...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON28024

### Bron

NTR

### Verkorte titel

DO-IT COPD

### Aandoening

chronic obstructive pulmonary disease

COPD

exacerbations

physiotherapy

physical therapy

counseling

RCT

cohort

prognostic profiles

chronisch obstructieve longziekten

exacerbaties

fysiotherapie

prognostische profielen

## Ondersteuning

**Primaire sponsor:** Prof. dr. RA de Bie  
Universiteit Maastricht

**Overige ondersteuning:** Universiteit Maastricht  
Koninklijk Nederlands Genootschap voor Fysiotherapie (KNGF): Wetenschappelijk College  
Fysiotherapie (WCF)

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Change 20-3-2016: The primary outcome is exacerbation frequency, the number of COPD exacerbations experienced by the patient. The initial primary outcome in the study protocol was listed as "time to exacerbation". However, the outcome exacerbation frequency is more informative seen the insight that a history of previously treated events is the best predictor of having frequent exacerbations. Moreover, the time to the next expected exacerbation can be derived directly from the outcome exacerbation frequency, which is the average number of exacerbations over a period of twelve months.

## Toelichting onderzoek

### Achtergrond van het onderzoek

Background:

Chronic obstructive pulmonary disease (COPD) is a major public health problem, and is difficult to manage. The disease is highly prevalent and one of the main causes of morbidity and mortality worldwide. Especially exacerbations of COPD represent a large burden from both a patient- and healthcare perspective, since these events often result in decreased physical health, impaired quality of life and hospitalisation of patients.

Comprehensive rehabilitation programs, like guideline driven physiotherapy, have shown to be effective in enhancing exercise capacity, reversing skeletal muscle dysfunction and improving quality of life in COPD patients. However, more information is needed to evaluate the efficacy of physiotherapy treatment on COPD exacerbations. The focus on prevention of exacerbations by means of physiotherapy treatment fits one of the prime management goals for COPD, which is 'reducing the frequency of hospitalisations due to exacerbations'. The hypothesis in this study is: physiotherapy treatment is effective and cost-effective in patients who recently experienced a COPD exacerbation by reducing the frequency, duration and severity of following exacerbations. In addition, it will improve the functional health status

and quality of life of COPD patients.

#### Objective:

This study aims to investigate the potential of guideline driven physiotherapy treatment as a supportive measure to postpone or prevent acute exacerbations in COPD patients. So, the primary research question is: "What is the efficacy of adding physiotherapy treatment to usual care on exacerbation frequency, duration and severity in COPD patients who have recently experienced a COPD exacerbation?". Secondary research questions are: "What is the effect of physiotherapy treatment on health status and quality of life in COPD patients who have recently experienced an exacerbation?" and "What is the cost-effectiveness of adding physiotherapy treatment to usual care on exacerbations and hospitalisation of COPD patients who have recently experienced a COPD exacerbation?".

#### Methods:

A cohort-nested, prospective, randomised, controlled trial with a 2-year follow-up will be started to assess the efficacy and cost-effectiveness of physiotherapy treatment in patients who recently experienced a COPD exacerbation.

COPD patients in GOLD stage 2, 3 or 4 (supported by a post-bronchodilator FEV1/FVC ratio  $< 0,7$  and FEV1  $< 60\%$  of predictive value), above 18 years of age, suffering from a recent exacerbation will be invited to participate in the study.

Physiotherapy according to the latest KNGF guideline physiotherapy in COPD patients (2008) will be compared to usual care (counseling). Participants from the experimental group will receive care as usual as provided by their general practitioner and / or pulmonologist, controlled by their physiotherapist, combined with evidence based physiotherapy (KNGF guideline COPD, 2008). The usual care will be delivered according to standard of the Dutch college of general practitioners (NHG standard, 2007). Participants from the control group receive care as usual as provided by their general practitioner and / or pulmonologist, but also controlled by their physiotherapist (according to NHG standard, 2007). Both groups will be monitored by a specific COPD electronic documentation system and physiotherapists will also use this system as guidance for treatment of the experimental group.

#### Outcomes:

The primary outcome measure will be "time to exacerbation", calculated as the time between randomisation and the onset of the first subsequent exacerbation for the first occurrence, and as the time between two exacerbations for following events.

Exacerbations will be identified by means of an event based approach (seeking medical attention) and symptom based approach (clear increase of respiratory symptoms). Given the definition of the primary outcome measure 'time to exacerbation', results of the trial will be reported as a risk ratio for an exacerbation in the physiotherapy group versus the usual care

group.

Secondary outcome measures will be exacerbation frequency, duration and severity. Furthermore, health related quality of life, level of effective mucus clearance, level of motivation, peripheral muscle strength, functional exercise capacity, physical activity level and patients' perceived benefit will be assessed. Also, co-morbidities, smoking and therapy compliance as well as health care contacts due to COPD will be recorded.

## **Doel van het onderzoek**

Physiotherapy treatment is effective and cost-effective in patients who recently experienced a COPD exacerbation by reducing the frequency, duration and severity of following exacerbations. In addition, it will improve the functional health status and quality of life of COPD patients.

## **Onderzoeksopzet**

The project in total will take 5 years. During the first 2 years of the project, COPD patients will be recruited at participating physiotherapy practices. The included patients will be assigned to one of two treatment arms, and followed for 2 years by means of the COPD electronic documentation system, clinical tests and questionnaires. Duration of the treatment in both the intervention and control group will be one year. Exacerbation frequency is seasonal in many climates and particularly related to influenza and other viral epidemics. Any comparisons need to follow the subjects over exactly the same periods of time and place. Studies covering periods of 12 months help overcome this confounding. Measurements are taken at baseline, at 3 and 6 weeks and at 3, 6, 12 and 24 months. The measurements are health care contacts, number, degree and type of symptoms (based on Anthonissen), CCQ, CRQ, 6MWT, Euro-Qol (EQ-5D), DS-14, level of dyspnea, level of effective mucus clearance, level of physical activity (physical activity questionnaire and activity monitor), level of motivation, GPE, BMI, FFE and peripheral muscle strength. The last year of the project is reserved for the processing and analysis of data, as well as the publication of results.

## **Onderzoeksproduct en/of interventie**

Physiotherapy according to the latest KNGF guideline physiotherapy in COPD patients (2008) will be compared to usual care (counseling). Participants from the experimental group will receive care as usual as provided by their general practitioner and / or pulmonologist, controlled by their physiotherapist, combined with evidence based physiotherapy (KNGF guideline COPD, 2008). The usual care will be delivered according to standard of the Dutch college of general practitioners (NHG standard, 2007). Participants from the control group receive care as usual as provided by their general practitioner and / or pulmonologist, but also controlled by their physiotherapist (according to NHG standard, 2007). Both groups will be monitored by a specific COPD electronic documentation system and physiotherapists will also use this system as guidance for treatment of the experimental group.

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. COPD patients contacting a physiotherapist (within eight weeks after primary

exacerbation), mostly but not exclusively, after visiting their general practitioner or pulmonologist because of an exacerbation, confirmed by general practitioner or pulmonologist;

2 - a: A general practitioner/pulmonologist diagnosed COPD in GOLD stage 2, 3 or 4 (confirmed by a post-bronchodilator  $FEV_1/FVC < 0.7$  and  $FEV_1 < 80\%$  of predicted).

2 - b: Eligible for reimbursement by health insurance companies for physical therapy (post-bronchodilator Tiffeneau-index  $< 0.6$ ).

3. Known by their general practitioner of having an adequate and optimal medication (inhalation) regimen;

4. Motivated to collaborate both in the physiotherapy treatment and in the attainment of goals that will be established and need to sign informed consent;

5. Competent enough to speak and understand the Dutch language.

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

1. COPD patients in GOLD stage 1 (supported by a post-bronchodilator  $FEV_1 > 80\%$  of predictive value).

2. Suffering from significant exercise limitations or co-morbidities that would prohibit a patient from following the physiotherapy program;

3. Patients who are expected to be lost for follow-up (e.g. because of a planned change of residency).

## **Onderzoeksopzet**

### **Opzet**

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

### **Deelname**

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	09-01-2008
Aantal proefpersonen:	200
Type:	Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies	
Datum:	27-08-2009
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	NL1860
NTR-old	NTR1972
Ander register	METC Unimaas : MEC 09-3-040
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Resultaten

## **Samenvatting resultaten**

N/A