Reducing exacerbations in patients with chronic obstructive pulmonary disease with physiotherapy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON39765

Source
ToetsingOnline

Brief title
Reducing exacerbations in patients with COPD with physiotherapy

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive pulmonary disease, persistent lung disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Koninklijk Nederlands Genootschap voor Fysiotherapie (KNGF): Wetenschappelijk College Fysiotherapie (WCF)

Intervention

Keyword: chronic obstructive pulmonary disease, exacerbations, physiotherapy

Outcome measures

Primary outcome

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

Secondary outcome measures will be exacerbation frequency, duration and severity. Furthermore, health related quality of live, 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.

Study description

Background summary

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.

Study 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?*.

Study design

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.

Intervention

Physiotherapy according to the latest KNGF guideline physiotherapy in COPD patients (2008) will be compared to sham-treatment reflecting usual care. 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). Besides, the patients from the control group receive very low-intensity training that can be seen as sham-treatment. 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.

Study burden and risks

Independently of the randomised group, patients will visit a COPD certified physiotherapist five times in a two-year period for counseling and physical examination/questionnaires. These visits for measurements are part of standard procedure. Patients from the experimental group will visit their physiotherapist for COPD related high intensity physiotherapy treatment two times every week, for one year. Besides, they are asked to do physical activity on their own for one-three times a week for one year. Patients from the control group are only asked to do physical activity on their own for three-five times a week for one year, with the opportunity to train in the physiotherapy practice for 30 minutes once a week. All visits for treatment and all advises for home training are part of standard procedure, following the latest KNGF guideline physiotherapy in COPD patients (2008) and the Dutch norm of healthy activity (NNGB).
The study can only be done using patients suffering from a recent exacerbation. By the information, COPD certified physiotherapists derive from frequent physical examination and in most cases spirometry and a maximal bicycle test, risks to participate in the study are very small and equivalent to standard COPD related physiotherapeutic care and even smaller than risks associated with patients who exercise on their own without physiotherapeutic control moments (usual care). By participating in the study, patients may experience a self-regulative and active way of reducing COPD related complaints, besides standard medication treatment. No adverse events of pulmonary rehabilitation (including physiotherapy) were reported in former studies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

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: Known by their general practitioner with the diagnosis COPD in GOLD stage 2, 3 or 4 (supported by a post-bronchodilator FEV1/FVC ratio < 0.7 and a post-bronchodilator FEV1 < 60% of predictive value).
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.

Exclusion criteria

1: COPD patients in GOLD stage 1 and stage 2 (supported by a post-bronchodilator FEV1 > 60% 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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	17-09-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-01-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-01-2011

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-06-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-03-2014
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
CCMO	NL28718.068.09
Other	TC=1972 toegekend door het NTR