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

No registrations found.

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

Summary

ID

NL-OMON28024

Source
NTR

Brief title
DO-IT COPD

Health condition

chronic obstructive pulmonary disease
COPD
exacerbations
physiotherapy
physical therapy
counseling
RCT
cohort
prognostic profiles

chronisch obstructieve longziekten
exacerbaties
fysiotherapie
prognostische profielen

Sponsors and support

Primary sponsor: Prof. dr. RA de Bie
Universiteit Maastricht
Source(s) of monetary or material Support: Universiteit Maastricht
Koninklijk Nederlands Genootschap voor Fysiotherapie (KNGF): Wetenschappelijk College Fysiotherapie (WCF)

Intervention

Outcome measures

Primary outcome

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.

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

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 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 objective

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 design

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 ad 24 months. The measurements are health care contacts, number, degree and type of symtoms (based on Anthonissen), CCQ, CRQ, 6MWT, Euro-Qol (EQ-5D), DS-14, level of dyspneu, 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.

Intervention

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.

Contacts

Public
Department of Epidemiology
Faculty of Health, Medicine and Life Sciences
School for Public Health and Primary Care (CAPHRI)
Peter Debyeplein 1, room A2.19
P.O. Box 616
E. Beekman
Department of Epidemiology
Faculty of Health, Medicine and Life Sciences
School for Public Health and Primary Care (CAPHRI)
Peter Debyeplein 1, room A2.19
P.O. Box 616
Maastricht 6200 MD
The Netherlands
+31 (0)43-3882367
Scientific
Department of Epidemiology
Faculty of Health, Medicine and Life Sciences
School for Public Health and Primary Care (CAPHRI)
Peter Debyeplein 1, room A2.19
P.O. Box 616
E. Beekman
Department of Epidemiology
Faculty of Health, Medicine and Life Sciences
School for Public Health and Primary Care (CAPHRI)
Peter Debyeplein 1, room A2.19
P.O. Box 616
Maastricht 6200 MD
The Netherlands
+31 (0)43-3882367

Eligibility criteria

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 - a: A general practitioner/pulmonologist diagnosed COPD in GOLD stage 2, 3 or 4 (confirmed by a post-bronchodilator FEV1/FVC < 0.7 and FEV1 < 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.

Exclusion criteria

1. COPD patients in GOLD stage 1 (supported by a post-bronchodilator FEV1 > 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).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-01-2008
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-08-2009
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	NL1860
NTR-old	NTR1972
Other	METC Unimaas : MEC 09-3-040
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A