Pulmonary Rehabilitation in patients with COPD: Effects on Cognitive Performance, Mood, Anxiety, and Quality of Life.

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

Summary

ID

NL-OMON34268

Source
ToetsingOnline

Brief title
effects on cognition in patients with COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease; COPD; chronic bronchitis&emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W,nog onbekend;aanvraag wordt ingediend bij het Astmafonds

Intervention

Keyword: Chronic Obstructive Pulmonary Disease (COPD), cognition, physical exercise, Quality of Life

Outcome measures

Primary outcome

The difference between the experimental group and the waiting list control group on the change of cognitive performance, QoL, mood, and anxiety between baseline measurement (both groups) and second moment of measurement, either before treatment (waiting list control group) or after treatment (experimental group). Cognitive functioning is measured with objective neuropsychological tests and a self report questionnaire for subjective cognitive functioning.

Mood, anxiety, and QoL are measured with self report questionnaires.

Secondary outcome

not applicable

Study description

Background summary

In Chronic Obstructive Pulmonary Disease (COPD) pulmonary function progressively declines because of airway obstructions as a result of inflammation and/or lung emphysema. In addition, people with COPD can suffer from a wide variety of extrapulmonary consequences, impairment in psychosocial function (e.g., depression, anxiety), and decline in cognitive function. As a result, people with COPD often report diminished Quality of Life (QoL).

The exact underlying mechanism for cognitive impairment in patients with COPD is unclear. It is expected that physical as well as psychological factors play a role. For example a decrease in blood-oxygen saturation, as well as depression, and anxiety are all associated with COPD and can all impair cognitive functioning. It has been suggested that cognitive impairment has a negative influence on treatment adherence, the course of COPD and QoL.

Therefore, a possible treatment of cognitive impairment is necessary. There is however hardly attention yet for cognitive impairment in the usual care for patients with COPD and research on treatment of cognitive impairment in COPD is in its infancy.

Pulmonary rehabilitation has become an evidence-based treatment for people with COPD. Improving physical endurance and QoL are the main goals of pulmonary rehabilitation for people with COPD. Improved physical endurance appears to improve cognitive performance in healthy people and cognitively impaired people. In addition to physical optimization, pulmonary rehabilitation can result in decreased depression and/or anxiety which can lead to improved cognitive function as well. Therefore, it is expected that cognitive performance in people with COPD will improve after pulmonary rehabilitation.

Study objective

The aim of the study is to improve the clinical care and QoL for patients with COPD. We want to do this by means of the evaluation of the efficacy of pulmonary rehabilitation on cognitive function, mood, anxiety, and QoL in people with COPD. In addition we investigate the relation between physical functioning, mood, anxiety, Quality of Life and cognitive functioning in people with COPD, by looking at the predictive value of physical measures, mood, and/or anxiety on cognitive improvement and by looking at the predictive value of physical measures, cognitive functioning, mood, and anxiety on the improvement of Quality of Life.

Study design

Randomized Controlled Trial (RCT) with an experimental and a waiting list control group. The experimental group is tested at baseline and after treatment in the last week of the rehabilitation program; the waiting list control group is tested at baseline and after waiting time, in the first week of the rehabilitation program. For the experimental group, time between the first and second measurement can vary from 12 to 29 weeks, with an avarage of 17 weeks. For the waiting list control group, time between the first and second measurement can vary from 1 to 17 weeks, with an avarage of 5 weeks. We can correct for these differences in time interval with statistical analysis techniques.

Intervention

A multidisciplinary, fulltime Extensive Pulmonary rehabilitation Program with a duration of 12 weeks, developed at Schoondonck - Centre for pulmonary Rehabilitation according to the current guidelines on pulmonary rehabilitation.

Study burden and risks

This study is embedded in a 12 week, fulltime pulmonary rehabilitation program for people with COPD at Schoondonck - Centre for pulmonary Rehabilitation. For the purpose of this study a NeuroPsychological Assessment (NPA) of approximately 1 and 30 minutes is added to clinical care as usual. The study burden is considered low: the extra time for participation is approximately 3 hours in total. There are no known risks associated with a NPA. There are no direct benefits for participants. Individual results are not reported to participants.

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

diagnosis COPD

reference to Extensive Pulmonary Rehabilitation at Schoondonck

Exclusion criteria

Education level lower than II (=unfinished to the coding system of Verhage (1983)
Reference to the Compact Pulmonary rehabilitation Program at Schoondonck.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-01-2011
Enrollment:	312
Type:	Actual

Ethics review

Approved WMO Date:	10-11-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	29-08-2012
Application type:	Amendment

Review commission: METC Brabant (Tilburg)

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	NL33713.008.10