Neuropsychological functioning of COPD patients and the influence on health status, daily functioning and treatment.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON38032

Source
ToetsingOnline

Brief title
Neuropsychological functioning of COPD patients.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COPD, daily functioning, neuropsychological functioning, pulmonary rehabilitation

Outcome measures

Primary outcome

Raw scores on the different subtest of the neuropsychological test battery and

5 compound scores for the cognitive domains: motor speed, memory, cognitive

flexibility, planning and general cognitive functioning (cognitive index).

Secondary outcome

*demographics: age, level of education and social status;

*clinical characteristics:

-general psychological functioning: Symptom Checklist-90, Hospital Anxiety and

Depression scale, Beck Depression Inventory, Utrecht coping list, Dutch

personality questionnaire en St George's Respiratory Questionnaire.

-other clinical characteristics: blood gasses, comorbidities (Charlson

comorbidity index), pulmonary function, diffusion capacity, saturation measure,

Obstructief Slaap Apneu Syndroom, medication, oxygen therapy, smoking

behaviour, Body Mass Index, knowlegde about the lung disease and exercise

capacity (6-minute walking distance test).

*problematic activities of daily life (*Canadian Occupational Performance

Measure*).

* patient information needs (Lung Information Needs Questionnaire).

* enablement to participate as an active partner in health care (Patient

Enablement Instrument en Partner in Health scale);

* expectations and views of the caregiver with respect to participation of the

patient as an active partner in health care (Clinician Support for Patient

Activation Measure]).

Study description

Background summary

Patients with Chronic Obstructive Pulmonary Disease (COPD) may experience dyspnoea, fatigue and problems in daily functioning, despite optimal pharmacological treatment. It is important that patients follow a number of precepts in order to minimize the consequences of the illness. Before a patient is willing to follow the precepts, a patient needs to experience that the new behaviour yields more advantages, compared to the old behaviour. Patients need specific cognitive abilities in order to make a considered choice. Previous research suggests that the cognitive functions of COPD patients may be impaired. However, results of previous research are disputable. To date, remains unclear which clinical characteristics are related to cognitive functioning in COPD patients and whether and to what extent cognitive functioning is related to daily functioning, health status and the outcome of pulmonary rehabilitation.

Study objective

The first aim of this study is to determine the prevalence of cognitive impairment in COPD patients compared with persons without COPD and to compare cognitive functioning between patients referred by their general practitioner, patients referred by their chest physician and patients referred for pulmonary rehabilitation. The second aim is to study the clinical characteristics of COPD patients with cognitive impairment. The third aim is to assess whether and to what extent cognitive functioning is related to daily functioning in COPD patients entering pulmonary rehabilitation. The fourth aim is to assess whether and to what extent cognitive functioning may influence important outcome parameters of pulmonary rehabilitation: general psychological functioning, knowledge about COPD, daily functioning and exercise capacity. The fifth aim is to study the needs for information and possibility to participate as an active partner in health care.

Study design

This study consists of two parts: an observational comparative study and an observational study with repeated measurements.

Study burden and risks

This study will provide more insight in cognitive functioning of patients with COPD. This insight will help us to improve management programmes for COPD patients. Risks for participations are minimal. Patients have no individual benefit from participation.

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

Patients:
*Diagnosis: COPD according to the Global Initiative For Chronic Obstructive Lung Disease (GOLD) definition. ;Matched control group:

*partner, brother or sister of an included patient
*smoking status comparable with smoking status form included patient (current smoker; non smoker; former smoker).

Exclusion criteria

Patients:
*Patient is not clinically stable during 4 weeks preceding enrolment
*Previous diagnosis of dementia
*Patient does not speak Dutch well enough to participate
*At the moment of testing, patients who were referred by their general practitioner but are also treated by a chest physician or are currently referred for pulmonary rehabilitation.
*At the moment of testing, patients who were referred by the chest physician but are also referred for pulmonary rehabilitation. ;Matched control group:
*Diagnoses of COPD or Asthma
*Previous diagnosis of dementia
*Participant does not speak Dutch well enough to participate
*Age of the matched control differ more than 10 years from the age of the patient for who he/she was matched
*level of education of the matched control differ more than 3 levels from the level of education for who he/she was matched

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2013
Enrollment:	345

Type:	Anticipated

Ethics review

Approved WMO Date:	14-12-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-03-2012
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	NL36715.068.11