

# Clinical, physiological and psychosocial determinants of the COPD Assessment Test (CAT).

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON21987

### Source

NTR

### Health condition

Health status, COPD, heart failure as comorbidity

## Sponsors and support

**Primary sponsor:** CIRO+, Centre of expertise for chronic organ failure, Horn, the Netherlands

**Source(s) of monetary or material Support:** GlaxoSmithKline, Astmafonds

## Intervention

## Outcome measures

### Primary outcome

CAT scores of COPD patients and healthy controls; change in CAT score before and after rehabilitation; correlates of CAT scores (i.e., health status questionnaires, co-morbidity, other potential confounders).

## Secondary outcome

N/A

## Study description

### Background summary

Background:

The CAT is a simple eight-item patient-completed questionnaire and could be used in clinical practice.

Objectives:

Study clinical, physiological and psychosocial determinants of CAT in a broad sample of patients with moderate to very severe COPD and the impact of co-morbidities on health status assessed with CAT; assess the effects of pulmonary rehabilitation on CAT scores in COPD patients; formulate reference values for CAT using healthy controls; validate CAT in a broad sample of COPD patients.

Study design:

Cross sectional observational study with a longitudinal part for tertiary care patients.

Study population:

Broad range of COPD patients (100 COPD patients from primary care setting, 100 COPD patients from secondary care and 600 COPD patients of the tertiary care) between 40 and 85 years old and 150 healthy controls.

Primary study parameters/outcome of the study:

CAT scores of COPD patients and healthy controls; change in CAT score before and after rehabilitation; correlates of CAT scores (i.e., health status questionnaires, co-morbidity, other potential confounders).

## Study objective

1. (Previously undiagnosed) cardiovascular disease (heart failure/vascular abnormalities/coronary artery disease), metabolic syndrome and other co-morbidities are additional independent predictors of impaired health status, assessed with CAT, in patients with COPD, irrespective of the severity of airflow limitation;
2. CAT is responsive to a comprehensive pulmonary rehabilitation programme in patients with COPD;
3. COPD patients have worse scores on the CAT than healthy elderly subjects;
4. CAT is a valid instrument to assess health status in patients with mild to very severe COPD;
5. CAT scores correlate well with other questionnaires (i.e., SGRQ-C, CCQ).

## Study design

All participants have one baseline visit to collect the data of the study. Only tertiary care patients have two visits, one before and one after pulmonary rehabilitation.

## Intervention

There is no intervention. Tertiary care patients will receive a regular pulmonary rehabilitation program which is part of their routine treatment.

## Contacts

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## Eligibility criteria

### Inclusion criteria

1. Age 40-85 years;
2. COPD patients: Diagnosis of COPD according to GOLD guidelines;
3. Healthy controls: Healthy, as judged by the investigator.

### Exclusion criteria

1. History of a significant respiratory disease; having undergone lung surgery; any clinically relevant disease which in the opinion of the investigator may influence the results of the study;
2. Moderate or severe exacerbation or pneumonia requiring systemic corticosteroids, antibiotics or hospitalisation during the last 4 weeks;
3. For healthy controls only: COPD, chronic heart failure.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
<b>Control:</b>	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2012
Enrollment:	850
Type:	Actual

## Ethics review

Positive opinion

Date: 02-05-2012

Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 39909

Bron: ToetsingOnline

Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL3263
NTR-old	NTR3416
CCMO	NL38550.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39909

## Study results

### Summary results

N/A