

# A psychological intervention in COPD patients who are hospitalized with an exacerbation: a RCT to improve health related quality of life outcomes and study mechanisms of change

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To test the effects of a short psychological intervention on quality of life, exercise capacity, self-management and health care utilisation.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Bronchial disorders (excl neoplasms)
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33778

### Source

ToetsingOnline

### Brief title

Psychotherapy in COPD.

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

COPD, emphysema

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

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

## Intervention

**Keyword:** COPD exacerbation anxiety psychotherapy

## Outcome measures

### Primary outcome

Quality of life, dyspnea domain (CRQ)

### Secondary outcome

Levels of anxiety and depression, the other CRQ-domains (fatigue, mastery, emotional function), change in illness perception, exercise capacity (step counter) and healthcare use.

Mediating effects, i.e. to see whether improvements in perceived control (Mastery), illness cognitions (IPQ) and self-management tasks are associated with a better outcome on QoL in both groups.

## Study description

### Background summary

COPD-exacerbations have a large impact on exercise tolerance, quality of life and health care utilisation and may lead to higher levels of anxiety and depression. Moreover, anxiety is a strong predictor of future hospitalisations.

Pulmonary rehabilitation is an established treatment modality for COPD with beneficial effects on exercise capacity, quality of life and even readmissions. The main targets of a rehabilitation program are improvements in exercise capacity and self management skills and a program contains both physical and psycho-educational components. The effect of exercise training (endurance- or strength training) is now beyond discussion. The effects of psychological

interventions, however, are less clear. physical

### **Study objective**

To test the effects of a short psychological intervention on quality of life, exercise capacity, self-management and health care utilisation.

### **Study design**

Prospective, randomised, controlled 2-center study. Duration follow-up 6 months.

### **Intervention**

Psychological intervention, aiming at improving problem-solving capability.

### **Study burden and risks**

The intervention group has 6 psychotherapy sessions of 1 hour. Both groups have to fill out questionnaires (5 times) and a diary (whole period), wear a step counter (3 times) and do blood tests (2 times) during the entire study period of 6 months.

## **Contacts**

### **Public**

Universitair Medisch Centrum Groningen

Postbus 30001  
9700 RB Groningen  
NL

### **Scientific**

Universitair Medisch Centrum Groningen

Postbus 30001  
9700 RB Groningen  
NL

## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

COPD, GOLD class 2-4.

age 40-80 y

Patients who are hospitalized with an exacerbation or visit the outpatient clinic of the hospital

### Exclusion criteria

1. comorbidity such as malignancies causing a life expectancy shorter than 1 year.
2. inability to fill out questionnaires or perform exercise tests
3. inability to undergo psychotherapy

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2007

Enrollment: 160  
Type: Anticipated

## Ethics review

Approved WMO  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL16440.042.07