

# Does a program of physical therapy exercises, education and home based walking lead to a change of the activity level at moderate COPD-patients in daily life.

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<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-OMON32588

### Source

ToetsingOnline

### Brief title

Activity-change at moderate COPD-patients.

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

breathingproblems, Bronchitis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Praktijk voor Fysiotherapie

**Source(s) of monetary or material Support:** Usual care ( fysiotherapie ) middels verzekeraar. onderzoek kosteloos als masterthesis gedaan.

## Intervention

**Keyword:** Activity-level, Behaviour, COPD, Physical therapy.

## Outcome measures

### Primary outcome

Primary study parameter will be walkingtime in minutes.

Tested by using the Personal Activity Monitor ( PAM).

Objective measurement.

### Secondary outcome

Secondary study parameter is the change in daily physical activity. Subjective measurement by a questionnaire.

Secondary study parameter is the functional walking/exercising capacity of the therapy-group. Testing by using the six minute walking test.

Also confounders will be measured:

- Quality of Life
- Depression
- Dyspnea
- Self-efficacy

# Study description

## Background summary

1. There is enough evidence on the territory of physical therapy exercises at moderate COPD-patients. There are many benefits: increasing quality of life, less dyspnea and increased functional walking and exercising capacity. The overall benefits at COPD-patients are less exacerbations, less hospitalisation and more life-years.
2. Also there is enough evidence about positive effects by being enough active, also at COPD-patients.
3. Also has come clear that COPD-patients are less physical active compared to healthy people.

After the physical therapy program it is important to know if the COPD-patients are using the positive effects of it and have become more active in their daily life. Has the physical therapy program lead to a higher activity level in their daily life.

## Study objective

The objective of the study is to find out if the COPD-patient how has followed the physical therapy program has lead to a change in activities in daily life. In primary usual care is expected that the patient will follow the advice of being more active at home.

But with COPD-patients there is no knowledge at this point. Objective is to research if the factor home-based walking leads to being more active after the total program. Getting used to the extra- walking schedule could very well make patients more active during daily life and thereby using the benefits of the exercises.

## Study design

Randomised Controlled Trial, singleblinded.

The researcher and the attendant at the filling in of the questionnaires and the instructions at the activity monitor are blinded.

Referral by the general practitioners with after that the patients are being screened and by minimization assigned to the therapy or control-group. The control-group will get no intervention. Both groups will do the spirometry, filling in of the questionnaires and one week wearing the activity monitor before the program. After that there is period of 10 weeks of yes or no therapy and after that the spirometry, the filling in of the questionnaires. Also again the activity monitor will be worn during one week.

## Intervention

The intervention is a program of twice a week during 10 weeks. The program contains: physical therapy exercises, education ( of the possibilities and problems with the sickness ) and home based walking once a week.

The control-group won't get the program.

## Study burden and risks

The therapy-part is usual care.

The burden is with that evidence based physical therapy which leads only to benefits.

Risks are small because patients are being screened by their general practitioner. When there is a doubt, the patient will do a maximum test before. During the therapy, patients are constant under surveillance by using the saturationmeter and borg-score questions are asked. This are all patients with mild complaints.

the research-part before and after the program:

Filling in the questionnaires, blowing into the spirometer and wearing a very small activity monitor for a week has no higher risk than normal daily life.

## Contacts

### Public

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### Scientific

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## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

COPD in Goldclasse 2 <= moderate COPD.

### Exclusion criteria

Severe heartconditions, unstable COPD and overall complaints what makes exercising risky.  
The total list is mentioned in the research protocol.

## Study design

### Design

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

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	27-10-2008
Enrollment:	52
Type:	Anticipated

## Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Amsterdam UMC

## 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	NL24766.018.08