

# Pulmonary Rehabilitation of Asthma: a Trial of sustained Internet based Self-management Support)

Published: 05-02-2013

Last updated: 26-04-2024

To assess the one-year (cost)effectiveness of self-management support via an internet-based service in addition to usual care as compared to usual care alone in a pragmatic trial in patients with severe asthma who are referred for a pulmonary...

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

## Summary

### ID

NL-OMON37280

### Source

ToetsingOnline

### Brief title

PRACTISS Asthma

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

asthma, bronchial hyperreactivity

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

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

## Intervention

**Keyword:** asthma, quality of life, Randomized Controlled Trial (RCT), selfmanagement

## Outcome measures

### Primary outcome

health related quality of life

### Secondary outcome

lung function, physical activity, self-management skills, health education

impact, illness perceptions, exacerbations, patient utilities and costs

## Study description

### Background summary

Patients are not always amenable to optimal self-management in their own environment after completing pulmonary rehabilitation. In order to achieve sustained quality of life improvement we need a dependable system of coordinated health care interventions and communication, and components that include self-management support. Innovative forms of self-management support including an online community, monitoring, communication, an action plan and motivational feedback via internet have high potential to improve long-term outcomes. However, the long-term effectiveness of sustaining self-management support via internet in patients with severe asthma who have completed pulmonary rehabilitation has not been determined yet.

### Study objective

To assess the one-year (cost)effectiveness of self-management support via an internet-based service in addition to usual care as compared to usual care alone in a pragmatic trial in patients with severe asthma who are referred for a pulmonary rehabilitation programme.

In addition, we will identify predictors of successful self-management support and quality of life outcomes and unravel the relationship between patient characteristics, process outcomes and quality of life.

### Study design

Pragmatic Randomised Controlled Trial

## Intervention

Control-group will receive usual care. Intervention group will receive self-management support via internet using the PatientCoach-platform during one-year of follow-up additional to usual care.

## Study burden and risks

Patients in the intervention group will be familiarized with PatientCoach shortly after randomization.

Every three months all participants will digitally receive a set of questionnaires which can be filled out using a personal computer with internet connection.

Throughout the follow-up year patients in the intervention group will be encouraged to wear an activity monitor daily to gain insight in their physical activity pattern.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

## Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Pulmonologist-diagnosed severe persistent asthma

Patients with asthma as the most important limiting factor

Referred for rehabilitation to Davos or Heideheuvel because optimal treatment did not lead to adequate asthma control

Access to internet at home and able to use it

## Exclusion criteria

Serious psychological problems that need referral to a psychiatrist after completion of the rehabilitation program

Relevant co-morbidity that interferes with the study

# 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:       | Recruiting |
| Start date (anticipated): | 31-01-2013 |
| Enrollment:               | 100        |
| Type:                     | Actual     |

## Ethics review

Approved WMO

Date: 05-02-2013

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 09-04-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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**

CCMO

**ID**

NL41595.058.12