PRACTISS Asthma.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19899

Source
Nationaal Trial Register

Brief title
PRACTISS

Health condition

Severe asthma in patients who have participated pulmonary rehabilitation in specialized asthma clinics

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Netherlands Asthma Foundation (LongFonds)

Intervention

Outcome measures

Primary outcome

Health related quality of life (Asthma Quality of Life Questionnaire).

Secondary outcome

Lung function, physical activity, self-management skills, health education impact, illness

perceptions, exacerbations, patient utilities and costs.

Study description

Background summary

Background of the study:

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.

Objective of the study:

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.

Study population:

Patients with severe asthma who are referred for a rehabilitation programme at the high-altitude center Davos or asthma center Heideheuvel and own a personal computer with an internet connection are eligible to take part in this study.

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.

Primary study parameters/outcome of the study:

Health related quality of life.

Secondary study parameters/outcome of the study:

Lung function, physical activity, self-management skills, health education impact, illness perceptions, exacerbations, patient utilities and costs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Study objective

We hypothesize that selfmanagement support via an internet based service in addition to usual care will improve health related quality of life in patients with severe asthma who have participated pulmonary rehabilitation in specialized asthma clinics.

Study design

Duration 12 months.

Questionnaires at 0, 3, 6, 9, 12 months.

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. This self-management support (PatientCoach website www.patientcoach.nl) comprises:

1. Asthma control self-monitoring (Asthma Control Questionnaire);

2. Lung function self-monitoring (FEV1 measured by PIKO device);

3. Activities monitoring (measured by FitBit device);

4. Diary;

5. Education;

6. Medical news;

7. Forum.

This support aims to improve health related quality of life.

Contacts

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Eligibility criteria

Inclusion criteria

1. Pulmonologist-diagnosed severe persistent, difficult to treat asthma asthma;

2. Patients with asthma as the most important limiting factor;

3. Participated in rehabilitation to Davos or Heideheuvel because previous optimal treatment did not lead to adequate asthma control, and completed at least two third of the initially determined rehabilitation programme;

4. Access to internet at home and able to use it.

Exclusion criteria

1. Serious psychological problems that may interfere with compliance or reliability of the measurements;

2. Relevant somatic or psychiatric 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)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-02-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-03-2013
Application type:	First submission

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
NTR-new	NL3739
NTR-old	NTR3910
Other	METC LUMC : P12.168
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A