Pulmonary Rehabilitation of COPD: a trial of sustained internet based self-management support

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Research QuestionWhat is the long-term effectiveness and cost-effectiveness of self-management support via an internet based service in addition to usual care as compared to usual care alone in patients with COPD who have completed pulmonary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON39845

Source
ToetsingOnline

Brief title
PRACTISS

Condition

- Respiratory disorders NEC

Synonym
chronic obstructive airway disease - 'smokers lung'

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Astmafonds

Intervention

Keyword: cost-effectiveness, e-health, quality of life, randomized controlled trial

Outcome measures

Primary outcome

o health related quality of life

Secondary outcome

o clinical control;

o exercise capacity;

o actual activity;

o lung function;

o self-management skills and health education impact;

o illness perceptions;

o patient utilities;

o exacerbations;

o costs.

Study description

Background summary

The effectiveness of pulmonary rehabilitation on exercise capacity and quality of life is well-established in COPD1. Pulmonary rehabilitation should be part of an integrated care process and include self-management support. Changing patient behaviour and ensuring maintenance are complex processes and require time. Currently, most programs take between six and 12 weeks and a longer duration is associated with greater improvements in physical and psychological functioning2. However, there are sparse data on whether the benefits are sustained beyond completing pulmonary rehabilitation and patients are not always amenable to
optimal self-management in their own environment after completing pulmonary

rehabilitation1. Identification of patients who may have difficulty maintaining and implementing appropriate self-management behaviour during and after the rehabilitation program may offer clues to improve long-term outcomes3. In order to achieve a sustained long-term improvement in quality of life 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.
Recently, a pilot randomised trial in stable, optimised COPD patients who had already completed pulmonary rehabilitation showed that telemonitoring in addition to best care reduced primary care contacts concerning pulmonary complaints4. Another pilot-study showed that cell phone-based exercise persistence and coaching intervention to patients with COPD post-rehabilitation is feasible5. In chronic heart failure (CHF) a recent Cochrane review showed that structured telephone support and telemonitoring reduces the risk of all-cause mortality and CHF-related hospitalisations, improves quality of life and reduces costs6. In asthma, we have recently demonstrated that internet-based self-management support improves quality of life, the number of symptom-free days and clinical outcomes7. To date, the long-term effectiveness of sustaining self-management support via internet in patients with COPD who have completed pulmonary rehabilitation has not been determined yet.

Study objective

Research Question
What is the long-term effectiveness and cost-effectiveness of self-management support via an internet based service in addition to usual care as compared to usual care alone in patients with COPD who have completed pulmonary rehabilitation.

Aim
- To assess the one-year effectiveness and cost-effectiveness of sustaining self-management support via an internet-based service in addition to usual care as compared to usual care alone a pragmatic trial in patients with COPD who have completed pulmonary rehabilitation;
- To identify predictors of successful self-management support and quality of life;
- To unravel the relationship between patient characteristics, process outcomes and quality of life.

Study design

The study is designed as a parallel-group randomised pragmatic trial with 1 year of follow-up. At the end of the rehabilitation program patients will be randomised to either *Internet support strategy* or *Usual care strategy*.

Intervention

In addition to usual care patients in the internet-based self-management support group will be provided with self-management support via PatientCoach up until one year after completion of the multidisciplinary treatment program at the Rijnlands Rehabilitation Centre. The PatientCoach self-management support tools are available to guide discussion between care providers and patient in such a way that the patient determines his or her goal, identifies steps to achieve the goal, identifies barriers to reaching the goal, and plans for overcoming the barriers, including obtaining needed resources12.

Within two weeks after completion of pulmonary rehabilitation in the Rijnlands Rehabilitation Centre patients will attend two PatientCoach educational (individual or group) sessions to become familiarised with PatientCoach.

During follow-up patients will be asked to monitor symptoms twice a week for a limited period by administering the Clinical COPD Questionnaire (CCQ)13. Administering the CCQ aims at gaining insight into one*s own health condition. In addition CCQ-scores will be used to detect exacerbations of COPD. When CCQ score differs relevantly from individual normal CCQ-scores, patients will be directly directed to their exacerbation action plan. This action plan contains additional questions concerning symptoms of an exacerbation based on a validated exacerbation action plan from the *living well with COPD* self-management program14 complemented with the exacerbation plan from RRC and will be provided with an instant feedback function that provides patients with an advice according to the patients* exacerbation action plan which was agreed by the patient and care provider during preliminary pulmonary rehabilitation program.
The exacerbation action plan is also directly accessible and patients who experience worsening of respiratory symptoms are encouraged to use the exacerbation action plan whenever they experience worsening of symptoms and not to wait until they have to fill out the CCQ.

Patients will be equipped with a simple sensor to measure physical activity. PatientCoach will help patients to gain insight in their daily physical activity by providing visual and written feedback on a regular basis.
These sessions might include communication with a pulmonary rehabilitation team member from the Rijnlands Rehabilitation Centre via e-consult who is available for support via the PatientCoach system. It is to be expected that the frequency of these contacts will decrease during follow-up. The team member can also pro-actively contact a patient through e-consult when for instance physical activity patterns are changing or symptoms are worsening.

Furthermore PatientCoach will be provided with the possibility to share information with other participants in the PRACTISS-trial by means of a PatientCoach community. Patients can for instance share their physical

activities or personal goal progress with fellow patients who are using PatientCoach.

Health care providers such as pulmonologists and physiotherapists who are involved in care of patients in the intervention group will be informed that their patient is participating in the PRACTISS-trial and receive additional information and support on PatientCoach.

Study burden and risks

At baseline and after one year of follow-up patients will visit the Rijnlands Rehabilitation Centre where they will perform a shuttle walk test and spirometry. They will wear an acitivity monitor for one week and fill-out the following questionnaires digitally: physical activity questionnaire (SQUASH), MARS (medication adherence), B-IPQ (Illness perception), HeiQ (Health education impact), PIH-NL (Self-management), EQ-5d (Quality of life and utilities)

Every three months patients will fill-out digitally:
CCQ (clinical control questionnaire)
CRQ-SAI (Health related quality of life)
Cost-Q (cost questionnaire)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

pulmonologist-diagnosed COPD (FEV1/FVC < 0.7)
patients with COPD as the most important limiting factor
having completed the rehabilitation programme in the RRC

Exclusion criteria

not being able to use a computer correctly
serious psychological problems that need referral to a psychologist after completion of the rehabilitation programme

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	03-10-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-09-2013
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	ID
CCMO	NL41538.058.12