IS-ACTIVE activity coach: investigating feedback compliance, satisfaction and clinical changes

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON39740

Source
ToetsingOnline

Brief title
IS-ACTIVE

Condition

- Bronchial disorders (excl neoplasms)

Synonym
COPD (Chronic Obstructive Pulmonary Disease)

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: ZonMW (Ambient Assisted Living programma)

Intervention

Keyword: COPD, Feedback, Physical activity, Telemedicine

Outcome measures

Primary outcome

Outcome measures to evaluate the clinical changes are: amount of activity (accelerometer, BPAQ), activity pattern (accelerometer), exercise tolerance (6MWT), fatigue (MFI-20), health status and symptoms (CCQ), and quality of life (EQ-5D).

Secondary outcome

The IS-ACTIVE system will be evaluated among patients in terms of use and usability of the application (registered by system/questionnaire and SUS), feedback compliance (registred by system), and satisfaction with the system (UTAUT).

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a chronic, progressive lung disease. The prevalence and associated costs of COPD are projected to increase the upcoming decades. Symptomatic patients with COPD develop dyspnea and are dyspnoeic even when they perform normal daily activities. This leads to inactivity and subsequently, to physical deconditioning. A vicious cycle develops that greatly affects patients* quality of life. The treatment of COPD aims to reduce risk factors, prevent disease progression and manage exacerbations. Increasing physical participation in everyday activities is among the key goals in COPD treatment.
Home-training programs and self-management have proven to be effective new training methods. Providing feedback to the patient about this physical activity behaviour is important to stimulate self-management. By focused feedback, we can try to positively influence the activity pattern, with the goal to be more physically active in daily life. A prerequisite is that this

should be applied in daily life, so also in the home environment.
The IS-ACTIVE system is an activity coach that promotes an active lifestyle, in daily life. The aim is that patients become aware of their amount of daily physical activity and their daily activity pattern, and can improve their physical activity behaviour. The IS-ACTIVE study was designed because of the limited knowledge about the impact of feedback on the activity level of COPD patients on the long term. Besides the aim is to use a new, more intelligent, type of feedback that promotes COPD patients in having an active lifestyle.

Study objective

The primary objective of this study is to explore the clinical changes on the health status of the patient. The secondary aim of this study is to evaluate the IS-ACTIVE system with COPD patients. We will investigate the use and usability of the application, the application satisfaction, and feedback compliance.

Study design

In a longitudinal intervention study the IS-ACTIVE system will be evaluated. In addition, the changes of the health status by the use of IS-ACTIVE will be explored. The following conditions will be compared: 1) baseline period (without use of IS-ACTIVE), 2) intervention period (with use of the IS-ACTIVE activity coach).

Intervention

The IS-ACTIVE system is an application for promotion of an active lifestyle of COPD patients. The system consists of a smartphone and an activity sensor. The smartphone displays the amount of measured activity in a graph, together with the patient*s reference activity (the amount of activity the patient should aim for) per day. The reference activity is based on the baseline measurement. In addition, the patient receives feedback messages on the smartphone for extra motivation. Besides, the patient can log in to a webportal, to see his measured activity levels. The patient will use this for 3 months, for at least 4 days a week.

Study burden and risks

The risks associated with participation in the study are minimal. The burden for patients is limited to wearing the IS-ACTIVE activity coach (smartphone and sensor). Based on the feedback, the patients are encouraged to be more physically active with a more even distribution over the day. The use of the IS-ACTIVE activity coach is adapted to the physical capabilities of the individual patient, minimizing the risks. Other outcome measures are questionnaires and data registered by the system. Part of the questionnaires is

also frequently used in regular care.

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

- a clinical diagnosis of COPD according to the GOLD criteria, GOLD II-IV
- no exacerbation in the month prior to measurement
- (ex)smoker
- age>40 years
- able to understand and read Dutch
- internet access at home

Exclusion criteria

-serious other disease with a low survival rate
-other diseases influencing bronchial symptoms and/or lung function (e.g. cardiac insuficiency, sarcoidosis)
- severe psychiatric illness
- need for regular oxygen therapy (>16 h per day or pO2<7.2 kPa)
- known alpha1-antitrypsine deficiency
- disorders or progressive disease seriously influencing daily activities (e.g. amputation, paralysis, progressive muscle disease)
- impaired hand function causing inability to use application

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2012
Enrollment:	33
Type:	Actual

Ethics review

Approved WMO Date:	28-02-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	08-07-2014

Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL38996.044.11