A 3-month Multicenter randomized trial to evaluate the efficacy of a Physical Activity Promotion Program on the experience of physical activity in patients with COPD (Mr PAPP)

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

Summary

ID

NL-OMON40168

Source
ToetsingOnline

Brief title
Impact of *telecoaching program* on physical activity in patients with COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: EU Innovative Medicines Initiative (IMI)

Intervention

Keyword: COPD, Questionnaire, telehealth coaching, validation

Outcome measures

Primary outcome

The primary objectives are:

• To assess the impact of a physical activity promotion program on physical activity in patients with COPD in addition to usual care. This will be measured by the PROactive monitors (ActiGraph® and DynaPort®), as the change in average daily number of steps at baseline (during the week prior to visit 101) and at the end of the 3-month epoch (during the week prior to Visit 102).

• To assess construct validity of the daily version of PROactive instrument and its responsiveness to a telecoaching program in addition to usual care in COPD patients.

Secondary outcome

The secondary objectives are to assess change from baseline to 3 months between the intervention group and the control group in:

1-Time spent in at least moderate physical activity

2- Proportion of patients showing an increase of physical activity by >20%

3- Exercise capacity (6-minute walking test (6MWT); Incremental shuttle walk test (ISWT) in a subset of mild patients)

4- Muscle strength (as measured by quadriceps maximal volitional contraction)

5- COPD symptoms and health-related quality of life (as measured by the CAT,

CCQ, HADS, mMRC and SGRQ-C)

6- Change from baseline to 3 months between the intervention group and the

control group in average daily number of steps

7- Satisfaction with the coaching system

Study description

Background summary

In the next decade Chronic Obstructive Pulmonary Disease (COPD) will affect an increasing number of European citizens. Physical inactivity and symptoms during physical activity are a hallmark of COPD and inactivity itself contributes to the disease progression. The inability to participate in daily activities is an important consequence of COPD experienced by patients on a daily basis. Improvement of the ability to participate in physical activity is an important patient centred target in the management of COPD. Despite its importance, currently no Patient Reported Outcome (PRO) captures physical activity in daily life in a way that maximally reflects the experience of COPD patients.

Study objective

The purpose of this study is to test the impact of a physical activity promotion program which is a personalized, semi-automated, coaching program utilizing an smartphone on which an app is installed and coaching by the investigator. The automated telehealth system comprises of a smartphone and a CE marked step counter (Fitbug®). The coaching by investigator is performed during study visits and is aimed to enhance physical activity in patients across a spectrum of COPD severity, in addition to usual care. The study will also validate the PROactive instrument (a combination of a patient reported outcome on a questionnaire and physical activity monitoring tool) developed in Work Package 4 (WP4) of the PROactive project. Limitation in physical activity is an important endpoint reported by COPD patients, which also contributes to the progression of the disease. Despite its importance, there are currently no available measures to capture physical activity in daily life that reflect relevant dimensions of patients* experiences of such limitations.

Study design

This is a 3 month, randomized (1:1 ratio), parallel-group, multicenter trial.

Patients in both groups (control and intervention) will receive information and guidance on the benefits associated with increased physical activity in COPD patients and their health status. Patients in both groups will use two PROactive monitors (ActiGraph® and DynaPort®) and a PDA to complete the PROactive questionnaire. In addition to above, the patients in the intervention group will receive daily coaching by an automated telehealth system, via an app on a smartphone, and coaching by the investigator during study visits.

Intervention

not applicable

Study burden and risks

Central aim of this study is the evaluation of a physical activity promotion program and validation of a questionnaire with which the patient's experience of their physical activity and their limitations in this can be measured. In order to properly reflect the patients perspective it is of vital importance to include a heterogeneous group of COPD patients in this process.

Participation will take patients' time. They will attend three visits to the hospital and they will partake in 2 periods of seven days during which they are asked to complete the PROactive tool (wear a pedometer and complete a short questionnaire).

There are no particular risks associated with this study. As a result of the various clinical assessments, including questionnaires, the patient may experience some tiredness or fatigue, or after the exercise tests muscle soreness. This will quickly pass as usual. Most of the assessments are part of the standard COPD treatment programme .

The results of this study will contribute to future improvement of the treatment of COPD patients.

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

•Written informed consent must be obtained before any assessment is performed.
•Male and female patients >= 40 years of age
•Diagnosis of COPD (GOLD criteria: post bronchodilator FEV1/FVC< 70%)
•Current or ex-smokers with a smoking history equivalent to at least 10 pack years (1 pack year = 20 cigarettes smoked per day for 1 year)
•Patient should have at least 4 days of physical activity data recorded via PROactive monitors during 7 days prior to visit 101.

Exclusion criteria

•Orthopedic, neurological or other complaints that significantly impair normal biomechanical movement patterns, as judged by the investigator. Specifically if the patients* condition/ co-morbidities are such that physical activity cannot be increased.
•Respiratory diseases other than COPD (e.g. asthma)
•Cognitive reading impairment and/or difficulties to manage electronic devices precluding interaction with the healthbase and PDA, as judged by the investigator
•Participating in or scheduled to start a rehabilitation program during the study. If the patient wishes to participate in pulmonary rehabilitation for any reason the patient can be enrolled in the study only at the end of rehabilitation.

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-07-2014
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-01-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL45626.042.13