Physical Activity as a crucial Patient Reported Outcome in COPD

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

Summary

ID

NL-OMON34731

Source
ToetsingOnline

Brief title
PROactive

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, functional status

Outcome measures

Primary outcome

The development of a conceptual model of physical activity and, subsequently,

the development of a Patient Reported Outcome (PRO) to assess physical acticity

in COPD patients.

Secondary outcome

not applicable

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 diseaes progression. The inability to participate in daily activities is an important consequence of COPD experiened by patients on a daily basis. Improvement of the ability to participate in physicial activity with minimal symptoms 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 is maximally reflects the experience of COPD patients.

Study objective

The purpose of this study is to explore and expand the understanding of the patient's experience of physical limitations in COPD from the perspective of the patient. The information will be used to support the development of a conceptual model of physical activity in people with COPD and develop a Patient Reported Outcome to assess physical activity in patients with COPD.

Study design

The qualitative study consists of 3 steps:

1) In-depth interviews to explore and expand the understanding of the patient experience of physical limitations as a results of having COPD.
2) Focus groups to derive items capturing relevant dimensions of physical activity.
3) Cognitive debriefings to assess potential redundancy, patients' understanding of the instructions and items, and potential relevance of the identified items.

Study burden and risks

The results of this study might lead to optimise care for patients with COPD in the future. The focus of this study is to develop a Patient Reported Outcome (PRO) to assess physical activity in patients with COPD. The involvement of a representative (i.e. heterogeneous) population of patients with COPD in this study is crucial. Only based on the experiences of patients themselves the final tool will be helpful for future purposes in research and daily clinical practice. Participation in this study will only take some extra time for the patients. Two visits to the hospital (one for interview or focus group meeting and one for clinical testing) will be scheduled. Since there will be no intervention, no direct benefits of participating in this study. Some patients, however, may appreciate the extensive clinical testing. There are no foreseeable risks in participating. No invasive clinical tests (apart from routine tests) will be conducted.

Contacts

Public
Universitair Medisch Centrum Groningen

Postbus 196
9700 AD Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Postbus 196
9700 AD Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients (males and females) with physician diagnosed COPD (confirmed by pulmonary function testing), across the various GOLD stages from mild to very severe COPD.
- age > 40 years
- adequate oral fluency to enable participation in an interview
- willing and able to provide written informed consent

Exclusion criteria

- institutionalised patients (nursing home or psychiatric unit)
- patients with documented dementia or other mental impairment such that they are unable to provide informed consent or complete the required tasks
- patients in palliative care
- patients who don't speak and write the local or country language
- participants with major co-morbidities, which in the physician's opinion could have significant impact on physical activity. These include recent myocardial infarction, stroke, other cardiovascular conditions, rheumatologic disease (including arthritis and other musculoskeletal pain that affects their ability to exercise), neurological illness (including severe neuropathic pain that affects their ability to exercise), or traumatic injury, lung cancer, concurrent asthma, history of drug or alcohol abuse.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2010
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2010
Application type:	First submission
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	NL31238.042.10