Continuous measurements of vital signs, activity variables and exposure to air pollution in patients with COPD

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1) To collect continuous data2) To extract and describe features, patterns and relationships in the data3) To quantify relationships between vital signs and activity variables or exposure to air pollution4) To identify features, patterns and...

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

Summary

ID

NL-OMON46270

Source
ToetsingOnline

Brief title
Continuous measurements in COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive pulmonary disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Vlaamse Instelling voor Technologisch Onderzoek
Source(s) of monetary or material Support: Vlaamse Instelling voor Technologisch Onderzoek

Intervention

Keyword: continuous, COPD, measurements, mHealth

Outcome measures

Primary outcome

1) A dataset of heart rate, arterial oxygen saturation, physical activity,

time-activity patterns (GPS-location in time) and exposure to air pollution

data from 1-week continuous measurements of COPD patients and matched controls

using different types of sensors

2) A description of features, patterns and relationships in time series of

vital signs, activity variables and exposure to air pollution

3) A quantification of the relationships between vital signs and activity

variables or exposure to air pollution

4) An overview of features, patterns and relationships that differ for COPD

patients compared to matched controls

Secondary outcome

/

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is highly prevalent and is considered the fourth leading cause of death worldwide. Exacerbations are typical stressful events in the natural history of COPD and have associations with vital signs, activity variables and exposure to air pollution. mHealth technologies are more and more frequently used in the management of chronic diseases and can be applied to continuously measure these variables. The hypothesis is that these continuous measurements contain useful information

that can provide additional insights in COPD.

Study objective

1) To collect continuous data
2) To extract and describe features, patterns and relationships in the data
3) To quantify relationships between vital signs and activity variables or exposure to air pollution
4) To identify features, patterns and relationships in the data that are COPD-specific

Study design

Observational case-control study

Study burden and risks

The participants will have to wear mobile sensors for 1 week, 24 hours per day: an armband measuring physical activity, a wrist-worn pulse oximeter with finger clip measuring heart rate and arterial oxygen saturation, a black carbon aerosol monitor and a GPS travel recorder. Additionally, a chest strap measuring physical activity and heart rate and an armband measuring physical activity, heart rate and oxygen saturation should be worn for 2 non-consecutive days. Previous studies with these devices did not report any adverse effects. Though participants might experience some discomfort when wearing the sensors.

Contacts

Public
Vlaamse Instelling voor Technologisch Onderzoek

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- COPD as a primary diagnosis, diagnosed by a chest physician
- Clinically stable
- Treated according to the current international guidelines
- Permission for voluntary participation

Exclusion criteria

- Lack of motivation for voluntary participation in this study
- Receiving oxygen therapy
- Making use of a rollator to assist walking

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Mobile sensors
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-09-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-03-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-04-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL58079.100.16

Study results

Date completed: 18-04-2018

Actual enrolment: 29

Summary results
Trial is onging in other countries