Objective physical arm activity assessment

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Primary objective:Study A: Development, validation and reproducibility of a method to assess arm activity.Study B: Investigate the association between muscle effort and arm use during a series of daily activities in COPD patients and healthy age...

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

Summary

ID

NL-OMON34403

Source
ToetsingOnline

Brief title
Objective physical arm activity assessment

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Accelerometer, Activity, Arm

Outcome measures

Primary outcome

Study A:

• Orientation (Mly) and intensity (SMA) calculated from the accelerometer signals of the three acceleromters of the SensorSleeve (ACCwrist, ACCelbow and ACCshoulder).

• Thresholds to define time spent in different activity categories (sec): 1) low orientation and low intensity, 2) low orientation and medium intensity, 3) low orientation and high intensity, 4) medium orientation and low intensity, 5) medium orientation and medium intensity, 6) medium orientation and high intensity, 7) high orientation and low intensity, 8) high orientation and medium intensity, 9) high orientation and high intensity. Time spend in different activity categories will be obtained from the protocol and calculated from the ACCwrist, ACCelbow and ACCshoulder.

Study B:

• Time spent in different activity categories measured using the CAM.

• Burst characteristics of the m. biceps brachii, m. triceps brachii, m. deltoideus and m. trapezius pars descendens.

Secondary outcome

Date of birth, gender, weight, body length.

Study description

Background summary

Physical inactivity in healthy subjects increases the risk of developing a number of chronic diseases, such as chronic obstructive pulmonary disease (COPD). Indeed, physical inactivity is one of the lifestyle-related health determinants. Therefore, guidelines recommend that a minimum of 30 minutes of daily physical activity of moderate intensity is necessary to maintain physical fitness, and those not meeting this standard are considered insufficiently active.

Decreased activity in daily life is likely to play a key role in the development and progression of skeletal muscle weakness and a poor exercise performance in patients with COPD. Indeed, a *downward disease spiral* has been hypothesized, in which advancing dyspnoea leads to a sedentary lifestyle and de-conditioning of the muscles, and thus further daily physical inactivity. Exercise-based pulmonary rehabilitation programs have been shown to effectively improve quality of life, muscle function and exercise capacity in patients with COPD which cannot be attributed to changes in forced expiratory volume in the first second (FEV1). Moreover, studies of skeletal muscle impairment in COPD have demonstrated that upper limb muscles were less affected than lower limb muscles (strength, endurance and exercise capacity). It is unknown whether and to what extent differences in muscle dysfunction between arm and leg muscles reflect a difference in their daily use or an innate difference in the susceptibility to disease.

To evaluate whether and to what extent differences in muscle dysfunction between arm and leg muscles in COPD patients reflect a difference in their daily use, daily physical activity in relation to muscle function needs to be assessed. For this purpose analyses of daily physical activity have to focus on relevant subsystems, e.g. performance in arm or leg tasks; whole body measurements will be too global to pinpoint loci of interest. Compared with whole body or leg activity assessment, arm function presents a complex problem. Although several studies evaluated activity monitors worn on the arm in COPD patients to measure whole body activity or specific arm exercises, none of these studies assessed the use of these monitors to evaluate performance of common daily arm activities. It is unknown what the optimal placement of the monitor is to evaluate daily arm activities and how the monitor output is related to muscle effort. Therefore, the aim of this study is to validate a new arm activity monitor (CAM_arm) in COPD patients with healthy subjects as reference.

Study objective

Primary objective:

Study A: Development, validation and reproducibility of a method to assess arm activity.
Study B: Investigate the association between muscle effort and arm use during a series of daily activities in COPD patients and healthy age matched controls.

Secondary objectives (study A):
1. Evaluate the optimal sensor placement.¬ For this purpose the sensorsleeve will be worn during a pilot study on young healthy volunteers. The sensorsleeve contains three 3-axial accelerometers. These will be worn on the lower arm at the dorsal side, between the ulnar and radial styloid process (ACCwrist), on the upper arm at the dorsal side, just above the olecranon (ACCelbow) and on top of the acromion (ACCshoulder). The optimal sensor placement will be determined as the sensor that reached the highest amount of seconds correctly categorized samples. The sensor of study B will be placed at the optimal sensor placement.
2. Define thresholds for activity classification. For each sensor two thresholds will be defined to categorize three levels of arm orientations (th1 and th2) and two thresholds will be defined to categorize three levels of arm activity intensity (th3 and th4). These four thresholds will be used to classify activities into 9 categories: 1) low orientation and low intensity, 2) low orientation and medium intensity, 3) low orientation and high intensity, 4) medium orientation and low intensity, 5) medium orientation and medium intensity, 6) medium orientation and high intensity, 7) high orientation and low intensity, 8) high orientation and medium intensity, 9) high orientation and high intensity.
3. Test the reproducibility of the accelerometers to categorize activities.

Secondary objectives (study B: main study):
1. For the main study only one 3-axial accelerometer will be worn (CAM_arm). To categorize arm activities the method developed in study A will be used. The objective is to evaluate arm orientation and intensity while performing a series of daily arm activities in COPD patients and healthy subjects.
2. Assess the relation between arm orientation and intensity with muscle effort of the major arm / shoulder muscles (biceps brachii, triceps brachii, m. deltoideus and m. trapezius pars descendens) in COPD patients and healthy age matched controls. COPD patients will consist of a group with and without lung hyperinflation to investigate whether the association between muscle effort and arm use is similar in both groups.

Study design

For the pilot study (study A) students of Maastricht University will be asked to perform a standardized protocol on two separate days in which activities and postures are strictly controlled. The total duration of study A is 30 minutes (two times 15 minutes on separate days).

For the main study (study B), COPD patients and healthy age matched subjects will perform a series of 15 daily activities in a randomized order at their preferred speed and arm orientation. The total duration of study B is 30 minutes. Other variables that will be taken into account are date of birth, gender, weight, body length which will be taken from the patient*s medical recordings. In healthy subjects these variables will be measured. All subjects will be asked how they experienced wearing the CAM.

Study burden and risks

Not applicable

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

Study A:
- Volunteers willing to participate
- Able to perform the standardized arm activity protocol (see document C1; study procedure)
- Fully competent;Study B:
- 10 COPD patients with lung hyperinflation, 10 COPD patients without lung hyperinflation and 10 healthy age matched volunteers
- Patients need to be clinically stable
- Able to walk (either with or without walking aids)
- Fully competent

Exclusion criteria

Study A:
- Not willing to participate
- Unable to perform the standardized arm activity protocol (see study procedure);Study B:
- Not willing to participate
- Apparent neurological disorders.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	20-12-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL33653.068.10