Free-living assessment of Cardiorespiratory Fitness.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37152

Source
ToetsingOnline

Brief title
Cardio fitness

Condition

- Other condition

Synonym
not applicable

Health condition

niet-klinisch onderzoek met gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: accelerometer, heart rate registration, physical fitness

Outcome measures

Primary outcome

• Maximal aerobic capacity (VO2max) as a measure of cardiorespiratory fitness

as assessed by an incremental test on a bicycle ergometer.

• Maximal aerobic capacity (VO2max) as a measure of cardiorespiratory fitness

as estimated by a combination of heart rate recording and movement registration

(accelerometry) in daily life.

Secondary outcome

maximal heart rate

resting heart rate

heart rate recovery

daily physical activity (accelerometer counts)

body composition (% fat mass and fat-free mass)

Study description

Background summary

The assessment of cardiorespiratory fitness is an important health parameter in several settings, such as clinical, sports and research. High cardiorespiratory fitness is associated with a lower risk of developing cardiovascular disease.
The gold standard test to determine cardiorespiratory fitness is maximal oxygen uptake (VO2max) test. This is a test to maximal exertion where the individual

is pushed to reach his/her physiological limit. The measurement of oxygen uptake requires expensive equipment and supervision. Hence, there are many sub-maximal exercise protocols to estimate VO2max. In many of these protocols heart rate (HR) is used to estimate VO2max. However, these tests still require standardized protocols, often in a laboratory setting. Considering the importance of cardiorespiratory fitness assessment and the new possibilities enabled by unobtrusive heart rate monitoring, it is worth investigating the possibility to assess cardiorespiratory fitness (e.g. VO2max) of a person without the need of a standardized laboratory bound test and without the need of maximal exertion.

Study objective

The aim of this study is to develop a new model to assess cardiorespiratory fitness of a subject without the need of a standardized laboratory bound protocol and without the need of maximal exertion. The model will be based on daily life registration of physical activity and heart rate.

Study design

Observational study, methodological study

Study burden and risks

Risks for the participants are minimal since no invasive procedures are included. The exercise protocol can be easily performed by healthy subjects. To make sure subjects are allowed to perform a maximal exertion test, potential participants will be screened using a medical screening questionnaire (see appendix F1). The maximal exertion test will be conducted by an experienced operator and a direct line with the hospital is always available.

Contacts

Public
Philips Research

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Men and women
Aged between 18-45 years
Body mass index between 18.5-27 kg/m2
Informed consent by the participants

Exclusion criteria

Subjects with a chronic disease, such as chronic obstructive pulmonary disease, diabetes, cardiovascular disease or any condition known to affect normal cardiovascular functioning.
Any musculoskeletal condition that would prevent the subject from perfoming the exercise protocol.
Subjects taking medication, except for oral contraceptives.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-10-2012
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	NL41074.068.12