# 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

High Tech Campus 34 Eindhoven 5656 AE NL

#### **Scientific**

Philips Research

High Tech Campus 34 Eindhoven 5656 AE

## **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