Activity and heartrate monitor validation study

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The primary objective of this study is to determine the accuracy of energy expenditure and resting heart rate measurement.Secondary objectives include assessment of accuracy of other measures like sleep duration, steps counting, activity recognition...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43960

Source
ToetsingOnline

Brief title
Activity and heartrate monitor validation study

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Appetite and general nutritional disorders

Synonym
Sedentary behavior, suboptimal physical fitness

Health condition

Validatie meeteigenschappen van activiteiten en hartslagmonitor bij gezonde proefpersonen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Activity monitor, Heartrate monitor, Validation

Outcome measures

Primary outcome

The primary parameters of the study are:

- measurement accuracy of energy expenditure

- measurement accuracy of resting heart rate

Secondary outcome

Secondary parameters include assessment of accuracy of other measures:

- heartrate

- sleep duration

- steps counting

- activity recognition

- respiration rate at rest

- sedentary behaviour alert

- heart rate recovery, interburst interval and VO2max estimation yes/no

Additionally the wear comfort of the device will be evaluated with a

questionnaire.

Study description

Background summary

The purpose of the activity and heart rate monitor is to measure and track movement (acceleration) and heartbeat, and derive a number of health-related parameters, which can serve as basis for behavioral change programs leading to e.g. a healthier, more active lifestyle, weight reduction, reduced risk of cardio-vascular disease, reduced risk of diabetes, or can be part of a disease or condition management program. In order for such a measurement/monitoring device to be able to lead to positive health benefits a preliminary requirement is that it measures the basic parameters in an accurate manner.

Study objective

The primary objective of this study is to determine the accuracy of energy expenditure and resting heart rate measurement.

Secondary objectives include assessment of accuracy of other measures like sleep duration, steps counting, activity recognition, respiration rate at rest, heart rate recovery, interburst interval and VO2max estimation. Last wear comfort of the device will be evaluated.

Study design

The study follows a within-person paired measurement design. The study consists of an intake, 3 days free lving monitoring, and measurement in a controlled environment of +/- 2.5 hours. From the free-living measurements data will be collected to estimate the resting heart rate, sleep duration measurements can be validated, sedentary behavior detection buzz can be checked, and heart rate recovery and VO2 max assessment can be checked. The controlled measurement is used for the validation of the energy expenditure measurements and provides reference data for resting heart rate. Both of these datacollections will also be used for secondary purposes.

Intervention

During the controlled measurements subjects are asked to complete various activities (eg. Walking and cycling). During the measurements the activity and heart rate monitor is worn and reference measurements are made.

Study burden and risks

Anticipated clinical benefits :
In the future the device will be used with programs users will have a clinical benefit, we are now testing the accuracy of the measurement device.

Anticipated adverse device effects:
Not expected

Residual risks associated with investigational device:
Possibly contact allergy (skin redness, irritation) or skin irritation due to prolonged wearing.

Risks associated with participation in clinical investigation:
Minimal risks. There is risk on falling during the protocol because we ask participants to exercise. Risks is mitigated because of the use of good research and sporting materials and continuous observation by researchers. Privacy risk are mitigated by separating the personal data from the research data and datastorage in a secured database by an external, certified clinical research organisation.

Possible interactions with concomitant medical treatments:
There are no interactions with concomitant medical treatments

Steps that will be taken to control or mitigate risks:
Information on the device will be given to the participants before start of the study

Contacts

Public
Philips

High Tech Campus 37
Eindhoven 5656AE
NL
Scientific
Philips

High Tech Campus 37
Eindhoven 5656AE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Aged more than 18 years old .
- Body mass index [body weight (kilograms)] / [height^2 (meters)] between 19 and 35
- Functionally capable

Exclusion criteria

- Suffering from severe chronic disease for which a physician has contraindicated moderate intensity exercise without medical supervision
- Function/mobility and or cognitive impairments preventing compliance with the study protocol
- Having pacemaker or other implantable electronic devices
- Skin issues or wounds in wrist area
- Might be, or is, pregnant

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2016
Enrollment:	31
Type:	Actual

Medical products/devices used

Generic name:	Activity and heartrate monitor
Registration:	No

Ethics review

Approved WMO Date:	07-10-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-11-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-12-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-03-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 19960
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54374.028.15
OMON	NL-OMON19960

Study results

Results posted: 06-06-2016

First publication
01-01-1900