Activity and heart rate band validation Activity and heart rate watch energy expenditure algorithm validation

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

Summary

ID

NL-OMON45332

Source
ToetsingOnline

Brief title
Activity and heart rate band / watch validation

Condition

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

Synonym
sedentary behaviour, sub-optimal physical fitness

Health condition

prevention of non-communicable lifestyle-related chronic disease such as cardiovascular disease or diabetes type 2

Research involving
Human

Sponsors and support

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

Intervention

Keyword: activity monitor, heart rate monitor, validation

Outcome measures

Primary outcome

Validation of the activity and heart rate band:

The primary objective of this part of the study is to determine the measurement accuracy of the activity and heart rate band with regards to medical parameter accuracy of total energy expenditure (TEE) estimation and resting heart rate (RHR) estimation.

Validation of the activity and heart rate watch EE algorithm:

The objective of this part of the study is to validate that a firmware update 17.1.0 for the activity and heart rate monitor has equivalent performance to the current firmware with regards to medical parameter accuracy of total energy expenditure estimation.

Secondary outcome

Validation of the activity and heart rate band:

Secondary objectives include exploratory assessment of accuracy of other measures of the band like step counting, activity recognition, actives minutes, respiration rate at rest and feedback on sleep duration, heart rate recovery,

interbeat interval (IBI) measurement and VO2max estimation.

Study description

Background summary

The purpose of the activity and heart rate band / watch 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 purpose of the study is to validate the measurements of an activity and heart rate band. The primary objective of this study is to determine the measurement accuracy of the activity and heart rate band with regards to the measurement of energy expenditure and resting heart rate. Secondary objectives include assessment of accuracy of other measures of the monitor like steps counting, activity recognition, respiration rate at rest, and feedback on sleep duration, heart rate recovery, interbeat interval (IBI) measurement and VO2max estimation.

Furthermore, it is the purpose of this study to validate a firmware update of the activity and heart rate watch, with respect to the accuracy of the energy expenditure estimate.

Study design

Within-person paired comparison study design

Intervention

Part 1: Intake and informed consent. The activity and heart rate band is taken home.
Part 2: 3 days of free living while subject wears the band day and night.
Part 3: Lab test with rest-activity protocol. Subjects wear the activity and heart rate band and the activity and heart rate monitor.
Duration of individual subject participation: 3 days of free-living monitoring and a laboratory session of approx. 2.5 hours

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
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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

- Aged greater or equal to 35 years old
- Body mass index [body weight (kilograms)] / [height^2 (meters)] between 19 and 35 kg /m2;Any of the following risk factors:
- Age.
- A family history of cardiovascular disease or diabetes type 2.
- Smoking.
- Overweight / obesity.
- Elevated blood cholesterol.
- Elevated blood pressure.
- Manifest diabetes type 2.

Exclusion criteria

- Suffer from severe chronic disease for which a physician has contraindicated moderate intensity exercise without medical supervision. Subjects will be asked to fill in the Physical Activity Readiness questionnaire (PAR-Q (15-17)) during recruitment and also at intake.
o Subjects who answered *yes* to any of the items of the PAR-Q during recruitment will be asked to provide a written statement by their physician that they can safely undergo moderate-intensity exercise without medical supervision as foreseen by this protocol.
- Function/mobility and/or cognitive impairments preventing compliance with the study protocol
- Having a pacemaker or other implantable electronic devices
- Skin issues or wounds in wrist area
- Might be or is pregnant (self-report)
- Has a beard (because of the risk of having non-removable hairs in the mask of the K5 system that could compromise functioning)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Philips health band (Activity and heart rate band);Philips health watch (Activity and heart rate wat
Registration:	No

Ethics review

Approved WMO Date:	06-02-2017
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-05-2017
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: 25339
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60348.028.16
OMON	NL-OMON25339