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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25339

Source
Nationaal Trial Register

Health condition

Sedentary behavior, physical activity

Sponsors and support

Primary sponsor: Mieke Weegels, Head of Product Research Center, Clinical & Consumer Care, Philips Innovation Site Eindhoven
Source(s) of monetary or material Support: Philips

Intervention

Outcome measures

Primary outcome

measurement accuracy of energy expenditure (for both investigational devices)

measurement accuracy of resting heart rate (for the activity and heart rate band only)

Secondary outcome

Secondary parameters include assessment of accuracy of other measures:

- heart rate

- activity type recognition

- step counting

- sleep duration

- respiration rate at rest

- active energy expenditure during exercise

- active minutes

- heart rate recovery

- VO2 max estimate

- interbeat interval

- sedentary behavior indicator on device

Study description

Background summary

Background of the study: 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.

Objectives of the study: The primary objective of this study is to determine the accuracy of energy expenditure (for both investigational devices) and resting heart rate measurement (for the activity and heart rate band). Secondary objectives for the activity and heart rate band include assessment of accuracy of other measures like heart rate, sleep duration, step

counting, activity type recognition, respiration rate at rest, heart rate recovery, interbeat interval and VO2max estimation.

Study design: The study follows a within-person paired measurement design. The study consists of an intake, 3 days free-living monitoring, and measurements in a controlled environment of +/- 2.5 hours. From the free-living measurements, sleep duration measurements can be validated, perception of sedentary behavior detection buzz can be checked, and heart rate recovery and VO2 max assessment can be checked. The measurements in the controlled environment are used for the validation of the energy expenditure estimates and of resting heart rate. They will also be used for secondary purposes.

Study population: The study will take place with 30 volunteers who meet the following inclusion criteria: - Aged 35 years or older. - Body mass index [body weight (kilograms)] / [height^2 (meters)] between 19 and 35 - Functionally capable. If volunteers meet one of the following exclusion criteria, they will be excluded from participation in the study: - 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 - Has a beard (because of the risk of having non-removable hairs in the mask of the K5 system that could compromise functioning)

Intervention (if applicable): During the measurements in the controlled environment, subjects are asked to complete various activities (e.g. walking and cycling). During the measurements, the activity and heart rate band / watch is worn and reference measurements are made.

Primary study parameters/outcome of the study: The primary parameters of the study are: - measurement accuracy of energy expenditure (for both investigational devices) - measurement accuracy of resting heart rate (for the activity and heart rate band)

Secondary study parameters/outcome of the study (if applicable): Secondary outcome parameters for the activity and heart rate band include assessment of accuracy of other measures: - heart rate - sleep duration - step counting - activity type recognition - respiration rate at rest - sedentary behavior alert - heart rate recovery, interbeat interval and VO2max estimation

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

Anticipated clinical benefits: The anticipated benefit from this study is the validation of a new activity and heart rate band and of an update of the energy expenditure algorithm of the activity and heart rate watch that is supposed to improve the accuracy of energy expenditure estimation in daily living. These two devices enable unobtrusive health monitoring in daily life of the general population and could contribute to a more healthy lifestyle.

Anticipated adverse device effects: Not expected.

Residual risks associated with investigational devices: Possibly contact allergy (skin redness, irritation) caused by sensitivity to one of the materials used in the investigational devices or skin irritation due to too tight wearing or dirt / humidity between the devices and the skin during prolonged wearing.

Risks associated with participation in clinical investigation:

- Minimal risks. There is a small risk of falling and/or sprains during the lab protocol because we ask participants to exercise. Risks are mitigated by carrying out exercises under the supervision of an investigator. Furthermore, we ask the subjects to wear clothes (incl. shoes) in which they can exercise.

- Privacy risks are mitigated by separating the personal data from the research data and keeping the informed consents in a secured place.

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 devices will be given to the participants.

- Lab protocol will be executed under the supervision of an investigator.

- Privacy risks are mitigated by separating the personal data from the research data and keeping the informed consents in a secured place.

Study objective

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 design

Participants will receive the activity and heart rate band and instructions for use on day 1. On days 2-4 the band will be worn at home. On day 5 the band is returned and controlled measurements with both investigational devices in the lab are completed.

Intervention

During controlled measurements in a laboratory environment subjects are asked to complete various activities (e.g. walking and cycling). During the measurements the activity and heart rate band / watch are worn and reference measurements are made.

Contacts

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Eligibility criteria

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

The intended use for both investigational devices covers adults at risk for lifestyle-related chronic disease such as cardiovascular disease and diabetes type 2 as well as adults with already existing lifestyle-related chronic disease. Both user groups will be included in this study, if possible.

Examples for risk factors are as follows:

- Age.

- A family history of cardiovascular disease or diabetes type 2.

- Smoking.

- Overweight / obesity.

- Elevated blood cholesterol.

Examples of already existing lifestyle-related chronic disease are as follows:

- 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) 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
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

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

Ethics review

Positive opinion

Date:	07-03-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45332
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6311
NTR-old	NTR6486
CCMO	NL60348.028.16
OMON	NL-OMON45332

Study results

Summary results
Planned, none accepted to date