Activity and heart rate monitor heart rate algorithm validation study

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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,...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29620

Bron
Nationaal Trial Register

Aandoening

sedentary behavior, physical activity

Ondersteuning

Primaire sponsor: Philips Innovation Site Eindhoven
Overige ondersteuning: Philips Innovation Site Eindhoven

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

measurement accuracy of energy expenditure
measurement accuracy of resting heart rate

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study: 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.

Objectives of the study: The objective of this study is to show equivalence between the monitor featuring the currently implemented firmware and the monitor featuring a new firmware containing an update of the heart rate algorithm regarding the heart-rate-related measurements.

Study design: The study follows a within-person paired measurement design. The study consists of an intake and measurements in a controlled environment of +/- 2.5 hours.

Study population: The study will take place with 11 volunteers who meet the following inclusion criteria:

- Aged 18 years or older.

- Body mass index [body weight (kilograms)] / [height^2 (meters)] between 19 and 35 kg/m2.

- 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.

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, two activity and heart rate monitors (one with the old, the other one with the new firmware) are worn.

Primary study parameters/outcome of the study: The primary outcome parameters of the study are:

- accuracy of energy expenditure estimation

- accuracy of resting heart rate estimation

Secondary study parameters/outcome of the study (if applicable): assessment of accuracy of heart rate measurements

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 an update of the heart rate algorithm of the activity and heart rate monitor that is supposed to improve the accuracy heart rate measurements and of resting heart rate estimation in daily living. The device enables 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 device or skin irritation due to too tight wearing or dirt / humidity between the device 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 device 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.

Doel van het onderzoek

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 prerequisite is that it measures the basic parameters in an accurate manner.

The objective of this study is to show equivalence between the monitor featuring the currently implemented firmware and the monitor featuring a new firmware containing an update of the heart rate algorithm regarding the heart-rate-related measurements.

Onderzoeksopzet

1 lab session of approx. 2.5 hours per participant during which a standardized rest-activity protocol is executed.

Onderzoeksproduct en/of interventie

During controlled measurements in a laboratory environment subjects are asked to complete various activities of daily living (e.g. walking and cycling). During the measurements, the activity and heart rate monitor is worn.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Aged greater or equal to 18 years old

- Body mass index [body weight (kilograms)] / [height^2 (meters)] between 19 and 35 kg/m2

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Suffer 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	30-01-2017
Aantal proefpersonen:	11
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-01-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42837
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6074
NTR-old	NTR6221
CCMO	NL59416.028.16
OMON	NL-OMON42837

Resultaten