Activity and heart rate monitor validation study

Gepubliceerd: 19-10-2015 Laatst bijgewerkt: 15-05-2024

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	Interventie onderzoek

Samenvatting

ID

NL-OMON19960

Bron
Nationaal Trial Register

Aandoening

Sedentary behavior, suboptimal physical fitness
Sedentair gedrag, suboptimale lichamelijke fitheid

Ondersteuning

Primaire sponsor: Joep Rous
Head of Product Engineering
Philips Consumer Lifestyle, Personal Health Solutions
High Tech Campus 37 (HTC 37 1.008)
5656AE Eindhoven
+31 651490001
Overige ondersteuning: Fund=initiator=sponsor

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: Klik voor meer informatie
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.

Objective of the study
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, interbeat 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.

Study population:
The study will take place with 31 healthy volunteers who meet the following inclusion criteria: - Aged more than 18 years old . - Body mass index [body weight (kilograms)] / [height^2 (meters)] between 19 and 35 - Functionally capable If volunteers meeting one of the

following exclusion criteria, will be excluded from participation in de 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 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.

Primary study parameters/outcome of the study:
The primary parameters of the study are: - measurement accuracy of energy expenditure - measurement accuracy of resting heart rate

Secundary study parameters/outcome of the study (if applicable):
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, interbeat interval and VO2max estimation yes/no Additionally the wear comfort of the device will be evaluated with a questionnaire.

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

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

Onderzoeksopzet

Participants will receive the device and instructions for use on day 1. On days 2-4 the device will be worn at home. On day 5 the device is returned and controlled measurements in the lab are completed.

Onderzoeksproduct en/of interventie

During controlled measurements in a laboratory environment 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.

Contactpersonen

Publiek

Postbus 9109
Jos Hendrikx
UMC St Radboud
Geert Grooteplein 8
Afdeling reumatische ziekten (huispost 470)
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3617547

Wetenschappelijk

Postbus 9109
Jos Hendrikx
UMC St Radboud
Geert Grooteplein 8
Afdeling reumatische ziekten (huispost 470)
Nijmegen 6500 HB

The Netherlands
+31 (0)24 3617547

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Aged more than 18 years old . '

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

Functionally capable

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-02-2016
Aantal proefpersonen:	31
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-10-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43960
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5270
NTR-old	NTR5552
CCMO	NL54374.028.15
OMON	NL-OMON43960

Resultaten

Samenvatting resultaten

Planned, none accepted to date