Validation of the Philips Health band, a wrist-worn device for the assessment of energy expenditure, heart and respiratory rate in patients with chronic heart failure, coronary artery disease and recreational athletes

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Ethical review	Approved WMO
Status	Completed
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON50668

Source
ToetsingOnline

Brief title
Validation of the Philips health band

Condition

- Heart failures

Synonym
Chronic heart failure, congestive heart failure

Research involving

Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: vakgroep cardiologie MMC

Intervention

Keyword: Chronic heart failure, Coronary artery disease, Philips Health band, Recreational athletes

Outcome measures

Primary outcome

The main study parameters are the agreement of energy expenditure in

kilocalories per minute, the heart rate and the respiratory rate assessed by

the Philips Health band and by continuous oxygen uptake assessment over the

entire protocol.

Secondary outcome

The agreement of heart and respiratory rate in beats and respirations per

minute throughout the entire protocol between Philips health band and Oxycon

mobile device.

Study description

Background summary

Cardiac rehabilitation (CR) has proven to reduce repeated cardiac events and cardiovascular mortality. One of the most important goals of CR is improving physical fitness and physical activity levels. Currently, exercise training programmes are usually centre based, and evaluation or monitoring of physical activity is not routinely applied. In order to monitor and promote physical activity in cardiac patients successfully, reliable and non-obtrusive devices to assess physical activity energy expenditure need to be available. The aim of the present study is to validate the Philips Health band, a medically

certified, wrist-worn device, for the assessment of energy expenditure, heartrate and respiratory rate, in patients with chronic heart failure, coronary artery disease and recreational athletes.

Study objective

The primary objective of the present study is to determine the accuracy of the Philips health band for the assessment of total energy expenditure in recreational athletes, in patients with chronic heart failure and patients with coronary artery disease during an activity protocol consisting of daily activities, cycling and walking.
The secondary objective of the present study is to determine the accuracy of the Philips health band for the assessment of heart and respiratory rate in recreational athletes, in patients with chronic heart failure and patients with coronary artery disease during an activity protocol consisting of daily activities, cycling and walking.

Study design

This is a single centre validation study with a comparative design. Energy expenditure, heart rate and respiratory rate assessed by the Philips health band will be compared to energy expenditure calculated from oxygen uptake measurement by the oxycon mobile during an exercise protocol containing low-to moderate-intensity activities representative for daily physical activity. The oxycon mobile is a wireless portable cardiopulmonary stress testing device. The device measures breath-by-breath VO2 and VCO2. Using the Weir equation energy expenditure can be calculated. Heart frequency will be measured with a 12-leads ECG that is connected to the oxycon mobile.

Study burden and risks

Although there is no direct benefit for individual patients participating in this study, the results of this study will be used to improve future cardiac telerehabilitation strategies by implementing accurate assessment of daily activity levels. As the activities involved are in the low-to-moderate-intensity domain and are similar to daily activities, the risk of adverse events in these clinically stable patient categories is considered very low. The investigational product (Philips Health band) and the reference measurement method (Mobile oxycon) are both light weighted and easy to wear as they are developed for measurements during exercise and daily activities.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria chronic heart failure patients:
- Minimum age 18 years
- Patients with symptomatic chronic heart failure with reduced or mildly reduced ejection fraction (NYHA Class II-III, LVEF < 50%) due to ischemic or dilating cardiomyopathy
- New York Heart Association Class II to III
- Speaking Dutch language

Inclusion criteria patients with coronary artery disease:
- Minimum age of 18 years
- Stable coronary artery disease regardless of intervention (PCI or CABG)
- Speaking Dutch language

Inclusion criteria recreational athletes:
- Minimum age of 35 years
- Perform at least 30 weeks of sports a year. With a minimum of 2,5 hours of

the same sports or 1,5 hours of different sports a week.
- Have had at least one consultation at the sports cardiologist
- Speaking Dutch language

Exclusion criteria

Exclusion criteria heart failure patients:
- Hemodynamically significant valvular disease
- Atrial fibrillation
- Peripheral vascular, neurological and orthopaedic conditions impairing exercise capacity
- Severe psychological or cognitive impairments
- Severe pulmonary conditions impairing exercise capacity
- Skin conditions or wounds around the wrist area

Exclusion criteria patients with coronary artery disease:
- Left ventricular ejection fraction <50%
- Hemodynamically significant valvular disease
- Atrial fibrillation
- Peripheral vascular, neurological and orthopaedic conditions impairing exercise
capacity
- Severe psychological and cognitive impairments
- Severe pulmonary conditions impairing exercise capacity
- Skin conditions or wounds around the wrist area

Exclusion criteria recreational athletes:
- Left ventricular ejection fraction <50%
- Hemodynamically significant valvular disease
- Symptomatic coronary artery disease
- Atrial fibrillation
- Peripheral vascular, neurological and orthopaedic conditions impairing exercise capacity
- Severe psychological and cognitive impairments
- Severe pulmonary conditions impairing exercise capacity
- Skin conditions or wounds around the wrist area

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-09-2022
Enrollment:	57
Type:	Actual

Ethics review

Approved WMO

Date:	01-12-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL79217.015.21