Clinical validation of physical activity measured by the Vital Signs Monitoring System in a controlled environment

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The main objective of this study is to validate the accuracy of the device to monitor the physical activity of a subject by comparing the measured values to the golden standard (video recording).

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

Summary

ID

NL-OMON50401

Source
ToetsingOnline

Brief title
Clinical validation of physical activity monitoring

Condition

- Other condition

Synonym
n/a

Health condition

n.v.t.

Research involving
Human

Sponsors and support

Primary sponsor: FastFocus B.V.
Source(s) of monetary or material Support: FastFocus B.V.

Intervention

Keyword: medical device, monitoring, physical activity, wireless

Outcome measures

Primary outcome

The primary outcome is the bias and precision of total time spend on one activity/posture (per activity/posture), number of steps, number of transitions, motion intensity, and main activity per minute as determined by the device under test compared to the golden standard. The activities and postures that can be discriminated between are lying, standing/sitting, walking, stair walking, and bending.

Secondary outcome

N/A

Study description

Background summary

Low physical activity is common during hospital stays. It has been shown that this can increase hospital-related complications and that it can be associated with functional decline after discharge of the hospital. Healthcare professionals can stimulate patients to be more physical active. To provide healthcare professionals with an objective method to monitor physical activity in the hospital, FastFocus developed its second generation of a wireless monitoring system, the Vital Signs Monitoring System. This wearable device combines physical activity monitoring with the monitoring of vital signs (pulse rate, respiratory rate, and oxygen saturation) and is, therefore, feasible to be used on ambulant patients in a healthcare environment. We want to validate the accuracy of the Vital Signs Monitoring System in monitoring the various

parameters related to physical activity, which are based on accelerometry. This is essential to assure its accuracy before bringing the device to the market.

Study objective

The main objective of this study is to validate the accuracy of the device to monitor the physical activity of a subject by comparing the measured values to the golden standard (video recording).

Study design

This study is a method-comparison study in a controlled environment. Healthy volunteers will perform different prescribed activities for approximately 20 minutes while being monitored by two different methods.

Study burden and risks

The hardware that is used is identical to the first-generation wireless monitoring system of FastFocus, Wireless Patient Monitoring System, that is CE marked as a medical device. Activities that must be performed by the subject are normal day activities, like sitting and walking. The subject needs to spend about 30 minutes to participate in the study. Hence, it is concluded that the risk and burden for the subject are negligible.

Contacts

Public
FastFocus B.V.

Gerverscop 9
Harmelen 3481LT
NL
Scientific
FastFocus B.V.

Gerverscop 9
Harmelen 3481LT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult (> 18 years)
Physically able to perform the specified activities

Exclusion criteria

Inability to give informed consent
Pregnant or breastfeeding

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):	04-01-2022
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Vital Signs Monitoring System
Registration:	No

Ethics review

Approved WMO Date:	03-11-2021
Application type:	First submission
Review commission:	METC NedMec

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	NL78761.000.21

Study results

Date completed:	18-01-2022
Results posted:	27-12-2022

First publication
14-11-2022