Validation of the *Vital Signs Monitoring System* classification algorithm for assessment of physical activity in hospitalised patients

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To assess the concurrent validity of the FastFocus* Vital Sign Monitoring System classification algorithm that discriminates between lying, sitting/standing, and walking activities, and detects number of walking steps in hospitalised patients under...

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

Summary

ID

NL-OMON56139

Source
ToetsingOnline

Brief title
Validation of the Vital Signs Monitoring System

Condition

- Other condition

Synonym
Physical activity

Health condition

Patiënten met problemen met bewegend functioneren

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Bedrijf: Fast Focus,FastFocus BV

Intervention

Keyword: Hospital, Physical activity, Validation

Outcome measures

Primary outcome

Primary outcome parameter: total time walking (sec.).

Secondary outcome

Secondary outcome parameters: total time sitting/standing (sec.), total time

lying (sec.), total number of steps (n).

Study description

Background summary

Low amounts of physical activity and prolonged periods of sedentary activity are common in hospitalised patients. Objective physical activity monitoring is needed to prevent the negative effects of inactivity. FastFocus has developed a wireless monitoring system (ear sensor), the Vital Signs Monitoring System. This wearable device combines physical activity monitoring with the monitoring of vital signs and is feasible to be used on ambulant patients in a healthcare environment. However, the Vital Sign Monitoring System has not been validated to discriminate between lying, sitting/standing, and walking activities, and detects number of walking steps in hospitalised patients under free living conditions yet.

Study objective

To assess the concurrent validity of the FastFocus* Vital Sign Monitoring System classification algorithm that discriminates between lying, sitting/standing, and walking activities, and detects number of walking steps in hospitalised patients under free living conditions by checking it against

video analysis.

Study design

This single centre, prospective validation study will take place from May 2023 until October 2023 at the department of Physiotherapy at the Maastricht University Medical Centre (MUMC+).

Study burden and risks

The burden and risks of participation in this study are minimal. Wearing the Vital Signs Monitoring System ear sensor should not be a burden to patients. Patients will be informed that they can take the activity monitor off in case they are bothered in any way. Patients and healthcare professionals will be instructed to remove the activity monitor in case of skin irritation or damage. The measurement will be performed during usual care physiotherapy. Participation in the study will take approximately 25 minutes, including the informed consent process, attaching and removing the ear sensor.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Receiving physiotherapy treatment during hospitalisation at the MUMC+
- 18 years or older
- Able to walk
- Willing to participate
- Sufficient understanding of the Dutch language
- Able to provide written informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Admitted to the Intensive Care or Medium Care units.
- A contraindication concerning walking (as reported by the attending medical specialists in the medical record).
- A contraindication to wearing the FastFocus* Vital Signs Monitoring System activity monitor at the ear (i.e.: patients with signs of skin damage on the ear, patients with pierced ears at the sensor application/measurement site, patients with skin conditions that could result in permanent harm when using the EarSensor, patients with limited blood perfusion through the ear due to medical conditions (e.g., cauliflower ears, ischemic ear shells, etc.), patients that are obliged to wear other medical devices for health and/or disability purposes (e.g., hearing aids, oxygen tubes, etc.), and/or patients in which the inner aspect of the ear (cavum conchae) is not large enough to accommodate the hook of the sensor without touching the tragus and/or crus of helix.)
- Impaired cognition (dementia / delirium) as reported by the attending medical specialist in the medical record.
- Incapacitated subjects as reported by the attending medical specialist in the medical record. When any doubt arises, the patient will not be considered eligible
- A life expectancy shorter than 3 months as mentioned by the attending medical specialist in the medical record

- Subjects that are not allowed to leave their hospital room due to isolation measures as reported in the medical record.
- Pregnant or breastfeeding women.
- Inability to give informed consent.
- Previous participation in this study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-08-2023
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Vital Signs Monitoring System
Registration:	No

Ethics review

Approved WMO

Date:	01-05-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL82226.000.22

Study results

Date completed: 08-11-2023

Results posted: 16-07-2024

First publication
16-07-2024

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File