

Movement registration and analysis for fall risk assessment with older adults: Fall risk assessment in the hospital

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45611

Source

ToetsingOnline

Brief title

BRAVO

Condition

- Other condition

Synonym

fall risk, falls

Health condition

ongevallen en verwondingen (vallen)

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: SIA-Raak, Eagle Vision Systems (levert apparatuur)

Intervention

Keyword: falls, monitoring

Outcome measures

Primary outcome

The accuracy, sensitivity and specificity of the system. (Accuracy is the percentage of correctly detected falls: falls that could have been detected before the fall occurred based on the behaviour of the patient. Sensitivity and specificity also take into account the false positives and false negatives). In addition, the (subjective) evaluation of the system by the nurses and the number of positive examples of when a fall was prevented by the nurses responding to the fall prevention alert.

Secondary outcome

n.a.

Study description

Background summary

Fall incidence among older adults during hospital admittance is a major problem, also in the AMC. The reliability of detecting falls is improving with the current advances in monitoring technology with environmental sensors and learning algorithms.

However, there is a great demand for a reliable fall prevention system: to alert the nurses just before a patient is about to fall. When using such a system, injuries and other negative side effects of falls can be prevented. By analysing the behavioural movement patterns in the period just before a

person fell, the kinematic parameters relevant to make a fall risk assessment can be identified. These parameters, that will be previously obtained in a observational pilot study in the BRAVO project, can directly be used for fall prevention.

Study objective

The objective of this pilot study is to test the accuracy of the fall-prevention module of the BRAVO-EagleEye. This is done by comparing the alerts generated by the system with the observations of the nurses of the particular ward.

Study design

In this intervention pilot study, the effectiveness of the fall prevention module of the BRAVO-EagleEye is tested. This sensor can generate several types of raw data, but also has a fall detection and a fall prevention module (developed in a previous BRAVO pilot).

Study burden and risks

The burden on the subjects is very low (in terms of the examples given above). Administering the fall risk questionnaire will take about 10 min., but that is already common practice at the AMC for patients suspected of an increased risk of falls.

Participants also have to consent to storage and use of their data. The EagleEye optical sensor generates video data, and different types of data derived from that (such as the location or posture of the person). This data will be stored and processed independently of the personal data, to facilitate anonymization. The raw video data will be destroyed 3 months after the end of the project (section 10 of this protocol provides the arguments for this decision).

There are no risks associated with participating in this study. Participants could benefit from the study if potential falls are prevented by the system.

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

increased risk of falling

admitted to neurological or geriatric ward

Exclusion criteria

No consent

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Will not start
Enrollment: 50
Type: Anticipated

Medical products/devices used

Generic name: BRAVO-EagleEye
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 09-10-2017
Application type: First submission
Review commission: METC Amsterdam UMC

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	NL59754.018.16