Monitoring physical activity in acutely hospitalized elderly of 70 years and older

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

Summary

ID

NL-OMON46460

Source
ToetsingOnline

Brief title
Monitoring physical activity

Condition

- Other condition
- Age related factors

Synonym
low physical activity: low mobility

Health condition

geriatric disorders

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: activity monitoring, acutely hospitalized, elderly, physical activity

Outcome measures

Primary outcome

In order to create reference values regarding the amount of time patients are standing and walking per day): mean number of minutes spent physically active (standing and walking) per day (defined as the total number of minutes standing and walking divided by the total number of valid measurement days in the period between inclusion and (intended) discharge).
In order to create a prediction model, this will be dichotomized into a low and high amount of time spent physically active per day during hospitalization. As the estimated event rate of a high amount of time spent physically active per day during hospitalization is 50%, the cut-off value between a low and high amount of time spent physically active will be defined by dividing the cohort at the median.

In order to create reference values regarding the number of breaks in sedentary time per day: mean number of breaks in sedentary time (BST) per day (defined as the total number of BST divided by the total number of valid measurement days in the period between inclusion and (intended) discharge). A BST is defined as any transition from being sedentary (lying or sitting) to being physically

active (standing or walking).

In order to create a prediction model, this will be dichotomized into a low and high number of breaks in sedentary time per day during hospitalization. As the estimated event rate of a high number of breaks in sedentary time per day during hospitalization is 50%, the cut-off value between a low and high number of breaks in sedentary time will be defined by dividing the cohort at the median.

Secondary outcome

The secondary study parameters are:

-SPPB score (summary and component scores)

-AM-PAC Inpatient Basic Mobility short form score

-Age (Categories 70-79, 80-89, *90 years)

-Sex (Male / Female)

-Disability in activities of daily living (ADLs) two weeks prior to admission (Number of disabilities on the Katz Index of Independence in Activities of Daily Living (Katz ADL)

-The use of ambulation assistive devices prior to admission (Yes/No. If yes, specify type of walking aid)

-Clinical diagnosis

-Physiotherapy consulted during hospitalization (Yes/No)

Study description

Background summary

Despite numerous studies supporting adverse outcomes associated with low physical activity (PA), there is insufficient insight in the amount of PA of acutely hospitalized Dutch elderly * 70 years. PA can be objectively measured by accelerometers, but it is time consuming and expensive to provide every patient with an accelerometer. We need to be able to predict which elderly patients are likely to spend low amounts of physical activity during hospitalization. Because of the association between PA and functional decline it is expected that functional assessment tests like the Short Physical Performance Battery (SPPB) or Activity Measure for Post-Acute Care (AM-PAC) can predict the amount of PA of patients during hospitalization. Since age, sex, clinical diagnosis, disability in ADLs 2 weeks prior to admission, the use of ambulation assistive devices and physiotherapy consulted are also associated with the amount of physical activity during hospitalization, these factors will also be taken into account when predicting the probability of low amounts of physical activity during hospitalization for acutely hospitalized elderly * 70 years.

Study objective

The primary objectives of this study are:
1. To assess the amount of physical activity of acutely hospitalized elderly *70 years during hospitalization and to create reference values regarding the amount of time patients are standing and walking per day and the number of breaks in sedentary time (BST) per day, both overall and stratified by sex and age category.
Research question: How much physical activity do acutely hospitalized elderly *70 years get during hospitalization, both overall and stratified by sex and age category?

2. To develop and internally validate a prediction model that can be applied as a tool to predict the probability of a low amount of time spent physically active during hospitalization for acutely hospitalized elderly *70 years. (The amount of time patients are standing and walking per day during hospitalization will be dichotomized into a low and high amount of time spent physically active, defined by dividing the cohort at the median.)
Research questions: In addition to functional assessment tests (SPPB or AM-PAC), which other patient characteristics can predict the probability of a low amount of time spent physically active during hospitalization for acutely hospitalized elderly *70 years? How well does a multivariable prediction model including all relevant predictors discriminate between patients qualified as spending a low amount of time physically active during hospitalization and patients qualified as spending a high amount of time physically active during hospitalization, and how well is that model calibrated?

3. To develop and internally validate a prediction model that can be applied as a tool to
predict the probability of a low number of breaks in sedentary time during

hospitalization for acutely hospitalized elderly *70 years. (The number of breaks in sedentary time per day during hospitalization will be dichotomized into a low and high number of breaks, defined by dividing the cohort at the median.)
Research questions: In addition to functional assessment tests (SPPB or AM-PAC), which other patient characteristics can predict the probability of a low number of breaks in sedentary time during hospitalization for acutely hospitalized elderly *70 years? How well does a multivariable prediction model including all relevant predictors discriminate between patients qualified as performing a low number of breaks in sedentary time during hospitalization and patients qualified as performing a high number of breaks in sedentary time during hospitalization, and how well is that model calibrated?

Study design

This is a single center, observational, prospective cohort study.

Study burden and risks

The burden and risks on patients are minimal. Wearing a small accelerometer should not be a burden to patients. Patients are informed that they are allowed to take it off when they are bothered by it in any way. The SPPB and AM-PAC are suitable to use in the geriatric hospitalized population and are performed under supervision of a trained researcher. Patients are allowed enough time in between scoring items to ensure that the tests are not perceived as too strenuous. No invasive interventions will take place. The additional burden placed on patients will be 30 minutes in which physical activity monitoring is started and a functional assessment takes place.

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

Patients aged *70 years that are acutely hospitalized in MUMC+ in the department of Internal and Geriatric Medicine.
Inclusion criteria:
-70 years or older
-Acutely hospitalized in Maastricht University Medical Centre (MUMC+) in the department of internal and geriatric medicine
-Sufficient understanding of the Dutch language
-Living at home before hospitalization
-Able to walk independently 2 weeks before admission, as scored on the Functional Ambulation Categories (FAC >3)

Exclusion criteria

-A life expectancy of less than three months as assessed by the attending physician
-Incapacitated subjects
-The inability to follow instructions due to cognitive problems or severe agitation
-A contraindication to wearing an accelerometer, fixated by a hypoallergenic plaster, on the upper leg (such as active bilateral upper leg infection, severe edema or bilateral transfemoral amputation)
-(Re)admittance to the intensive care unit
-Presence of contraindications to walking as assessed by the attending physician
-Previous participation to this study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2018
Enrollment:	165
Type:	Actual

Ethics review

Approved WMO

Date:	04-10-2018
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	NL65097.068.18