Physical functioning, fatigability, and their relation with recovery in acutely hospitalized older medical patients

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

Summary

ID

NL-OMON48844

Source
ToetsingOnline

Brief title
SeniorLines - 2.0

Condition

- Other condition

Synonym
fatigability, fatigue

Health condition

kwetsbaarheid, veroudering

Research involving
Human

Sponsors and support

Primary sponsor: centrum voor ouderengeneeskunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fatigability, frailty, geriatrics, performance-based measurements

Outcome measures

Primary outcome

main study parameters are repeated measurements of mobility (assessed by De Morton Mobility Index), and perceived fatigue (assessed with the Pittsburgh Fatigability Scale).

Secondary outcome

Secondary objectives are the capacity of the physiologic system to enhance homeostasis during illness is reflected by the capacity of different organ systems to restore deviating values back to normal values. Physiologic systems are expressed by cognitive, immunological, endocrine, musculoskeletal, cardiovascular, respiratory, and renal responses.

Furthermore, age, sex, educationlevel, depression, comorbidity, medication, pain, in-hospital activity, and the capacity of the physiologic system to enhance homeostasis will be used in the analyses for the first secondary objective.

Finally, in the qualitative interview, feasibility of an intervention to prevent hospital associated decline will be investigated. The use of a wearable (Fitbit) in combination with a digital application will be evaluated using two questions addressing user acceptability.

Study description

Background summary

Hospital admission is a major life event, often leading to deterioration in physical functioning. Physical functioning is of great importance for independent living in older persons. Therefore interventions to prevent functional decline in older adults are important. Since fatigue is the most prevalent symptom during hospitalization, and it is suggested to be a pre-clinical marker for reduced resilience of physiological systems, it may be an interesting marker for hospitalized older patients regarding recovery and adverse health outcomes like functional decline.

Study objective

The primary objective is to identify joint trajectories of mobility and perceived fatigue from hospital admission to 6 months post-discharge in acutely admitted hospitalized older patients.
Secondary objectives are:
(1) to explore associations of potential predictors and clinical markers of the physiological system measured during hospital admission related to each trajectory.
(2) to explore the feasibility of interventions to prevent functional decline during hospital admission
(3) to explore the feasibility of the use of wearables and a digital application for monitoring physical activity after hospital discharge among geriatric patients aged 70 years and older.

Study design

An observational cohort study

Study burden and risks

Participation consists of filling in questionnaires (total duration maximal 35 min.) and performing physical tests (total duration about 35 min.) at four different moments, including two during hospitalization; to wear a tight worn device, the MOX, during their hospital stay; to wear a wrist worn device (Fitbit) during hospital stay up to 3 months pst discharge; and, optional, participating in a qualitative interview regarding opinions and potential barriers and facilitators towards physical activity during hospital admission (total duration maximal 30 min.).
In total, there are four moments of assessments: first within the first 3 days of their hospital stay (questionnaires, physical test, putting on the MOX and Fitbit); second within 24 hours before discharge (questionnaires, physical

tests, collecting the MOX), and the third and fourth moments of assessment are home visits at 3 and 6 months post discharge (questionnaires and physical tests). For the qualitative interview a separate appointment will be made.

Contacts

Public
Selecteer

Hanzeplein 1
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NL
Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

aged 70 years or older;
willing to participate
medically able to participate
providing informed consent.

Exclusion criteria

1. no understanding of the Dutch language;
2. lack of decision making capacity, due to:
a.previously diagnosed dementia;
b. delirium or other conditions that influence decision making capacity;
3. hospital admission for more than 48 hours, due to:
a.transfer from another hospital to the UMCG;
b.transfer from another ward (e.g. Intensive Care Unit (ICU), or rehabilitation center) to an internal medicine ward in the UMCG;
4. expected stay in hospital for less than 48 hours or when the patient is expected to die within <48 hours;
5. any medical condition that prevents the patient to safely participate in assessments that require light physical activities.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2018
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	06-03-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	29-07-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL64465.042.17