Exploring relationship between sleep monitoring parameters, through wearables, and delirium score in elderly patients hospitalized for hip fracture

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The primary objective is to explore whether sleep monitoring data correlate with DOS score in patients admitted for hip fracture.

Ethical review	Not approved
Status	Will not start
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON48351

Source
ToetsingOnline

Brief title
Exploring relationship between sleep monitoring parameters and delirium

Condition

- Bone and joint injuries
- Deliria (incl confusion)
- Bone and joint therapeutic procedures

Synonym
confusion, delerium

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: het ziekenhuis (RdGG) en eigen onderzoeksgelden

Intervention

Keyword: delirium score, hip fracture, sleep-tracking, wearables

Outcome measures

Primary outcome

Main endpoint: Relationship between sleep tracking parameters and DOS score

Main parameters:

* Gender

* Use of cardiac medication

* Alcohol use prior to fall

* DOS score

* Duration and total percentage of sleep stages: 1) sleep; 2) awake; 3) deep;

4) REM

* Time to fall asleep

* Duration and total percentage of restlessness

* Heartbeat

* Number of movements

Secondary outcome

Not applicable.

Study description

Background summary

Delirium occurs in 25% to 61.3% of geriatric hip fracture patients, depending on the measurements methods and criteria used (Brännström et al., 1989; Milisen et al., 2001; Williams et al., 1985) and is associated with two to five times higher mortality risk (Tess, 1991). Early recognition of delirium and treatment of older hip fracture patients has been shown to affect its severity and its duration (Milisen et al., 2001) and may contribute to a positive clinical outcome (Cole et al., 1994; Williams et al., 1979). A possible link between delirium and sleep disturbances has been hypothesized in terms of a common pathophysiologic pathway, shared mechanisms, and a potential cause-effect relationship (Figueroa-Ramos et al., 2009). In addition sleep tracking with wearables has been introduced and gone through verification and validation, however within a healthy population (de Zambotti et al., 2016, 2018; Washington et al., 2016). This research hypothesizes the ability of wearable sleep tracking to improve hospital care among elderly hip fracture patients. Moreover, sleep disturbances for whatever cause may point into the direction of delirium caused by numerous possible stressors. This study aims to detect differences of sleeppatterns which correlate with clinical outcome measures, i.e. DOS (Delirium Observation Screening) scoring (Scheffer et al., 2011* Schuurmans et al., 2003) of delirium in hip fracture patients (80+).

Study objective

The primary objective is to explore whether sleep monitoring data correlate with DOS score in patients admitted for hip fracture.

Study design

This study is an exploratory prospective trial, aiming to explore the relationship between sleep monitoring data and DOS score. The sleep monitoring data and delirium score of the eligible patients will be registered during their hospital stay. The sleep data will be collected by means of a wearable bracelet and the delirium status will be scored with the DOS score. The DOS will be applied three times a day, at each shift, by qualified nurses. Potential relationship between sleep monitoring parameters and DOS scores will be assessed by applying correlation and regression methods (linear mixed models) on the collected data.

Study burden and risks

The patient will be supplied with a tracking device at the wrist. A so-called Fitbit Charge 3 tracker with a display of a clock. The tracking devices will be disinfected before use. There is no risk of harm by wearing this measurement device.

Contacts

Public
Reinier de Graaf Groep

Reinier de Graafweg 5
Delft 2625AD
NL
Scientific
Reinier de Graaf Groep

Reinier de Graafweg 5
Delft 2625AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* A hip fracture
* 80 years and older
* Admitted to the hospital
* Mentally competent
* Informed consent obtained

Exclusion criteria

* Mentally incompetence
* Nickel allergy

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:	47
Type:	Anticipated

Ethics review

Not approved

Date:	02-09-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL70878.098.19