Feasibility study: Introduction of sleep and activity wearables in hip fracture patients (75+) applied during hospitalization

Published: 27-05-2020
Last updated: 15-05-2024

Feasibility study on the use of wearables during the entire hospital stay (with a maximum of 7 days) among elderly (75+) hip fracture patients. Feasibility is defined by three components: 1) Macro feasibility - the percentage of the entire…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON55262

Source
ToetsingOnline

Brief title
Feasibility study: Introduction of wearables in hip fracture patients (75+)

Condition

- Bone and joint injuries
- Sleep disorders and disturbances
- Bone and joint therapeutic procedures

Synonym
breaking hip, hip fracture

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: Elderly, Hip fracture, Hospitalization, Sleep & activity wearables

Outcome measures

Primary outcome

There are 3 end points:

1) The percentage of the entire population of hip fracture patients (75+)

enrolled in the study (> 70%);

2) Patient satisfaction with the wearable (>= 70%);

3) Successful logistics process that is tested by storing the wearable data per

included patient (> 80%).

Secondary outcome

not applicable

Study description

Background summary

The use of wearable technology aimed at health and sport is constantly increasing. Such equipment is referred to as "wearable" or "activity tracker". However, the medical application of such equipment is still in its infancy. All kinds of physiological parameters can be measured with it, such as the number of steps, the distance, physical activity, energy metabolism and sleep. The validation of movement activity recorded using this type of equipment has already taken place (1). One of the manufacturers, Fitbit, produces the Charge® wearable. The Charge® was validated in measuring sleep components and correlations with the gold standard, polysomnography (PSG), were found to be good (1-5). This study was done in healthy individuals. The survey among the

elderly has also taken place (6). Two exploratory studies have also been conducted on critically ill patients during admission to intensive care (7,8). The results are encouraging but only the beginning of a new path in clinical research.
Our main aim is to establish the feasibility of using wearables in the hospital. We focus on the hip fracture patient, who is usually nursed at the hospital's Geriatric Trauma Unit (GTU). Feasibility is split into three main focus areas. First, whether this approach leads to a high enough percentage (> 70%) of participating patients from the entire population of hip fracture patients (75+). Secondly, whether the use of wearables is acceptable or is experienced as non-disturbing by patients, and thirdly, whether the signal that the wearable registers is not lost in the complex logistics of staying in a nursing ward of the hospital.
The intended patient group is extremely heterogeneous and often particularly vulnerable. The request for permission to grant scientific research immediately upon entering the emergency room is not a feasible option. Deliberate granting of permission to participate is only possible after the operation has taken place, the pain is under control and the first phase of mobilization has taken place. The request for subsequent authorization to participate in medical scientific research is a researched ethical dilemma that has been extensively discussed by Jansen et al (15). This research group drew up a new concept that can be presented to an METC per intervention. It concerns "deferred consent". It is hereby stated that any scientific influence with a very low impact on welfare can and may without prior permission. In that case, one must still ask for permission from the letter of GCP. If a patient is unable or unwilling to participate, participation in the study should be stopped immediately.
In the present situation, the patient wears a wearable on the wrist without permission. The registered data may be kept, but in the absence of permission afterwards, the data must be stored, but may not be used. If a patient subsequently gives permission to participate but withdraws this permission during the study, the data obtained must be stored and this data can be used for the study. A patient reserves the right to withdraw from the study at any time. Even if members of the medical and nursing team find it irresponsible, the investigation will be stopped immediately.

Study objective

Feasibility study on the use of wearables during the entire hospital stay (with a maximum of 7 days) among elderly (75+) hip fracture patients. Feasibility is defined by three components:
1) Macro feasibility - the percentage of the entire population of hip fracture patients (75+) included in the study (> 70%);
2) Patient satisfaction with the wearable (>= 70%);
3) Successful logistics process that is tested by storing the wearable data per included patient (> 80%).

Study design

A prospective exploratory study in which patients with a hip fracture who are admitted to our hospital (Reinier de Graaf Gasthuis) are successively included. The term of inclusion is a maximum of 1 year, but ends when 68 patients giving permission to participate. Patients with a hip fracture are admitted to the RDGG via the SEH. Every hip fracture patient (75+) is given a tracker on the wrist. At most 8 patients simultaneously receive a wearable upon admission. The medical and nursing team determines at any time, in accordance with insight and experience, whether the patient is able to wear the tracker. When in doubt, the tracker is not put on or taken off immediately and the patient does not continue to participate in this research activity. This counts as an exclusion criterion. A second exclusion criterion is that the patient is nursed in a department other than the GTU.

Study burden and risks

The patient receives a wearable (Fitbit Charge® 3) on his/her wrist. No adverse event is expected. Participants will also not benefit from it directly.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

Patients who are admitted due to a hip fracture
75 years and older

Exclusion criteria

• Patients who refuse to wear the wearable or whose medical and nursing team object to the course of events
• Patients at others wards but the GTU
• Patients who are unable or unwilling to grant permission in the deferred consent setting
• No more than 8 patients in parallel can be accommodated in the 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):	12-09-2022
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	27-05-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-11-2021
Application type:	Amendment
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

ID: 26551
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL72900.058.20
OMON	NL-OMON26551

Study results

Date completed:	01-12-2023

Actual enrolment:	73