RESilience in Hip frActure Patients measured with the Eforto(R) measurement & monitoring system

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To evaluate the validity of grip work and self-perceived fatigue measured with the eforto® system for monitoring hip fracture recovery and insight in resilience.

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

Summary

ID

NL-OMON49900

Source
ToetsingOnline

Brief title
RESHAPE

Condition

- Other condition

Synonym
ageing; geriatric syndromes, hip fracture

Health condition

geriatrische syndromen; veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: ageing, fatigability, monitoring, resilience

Outcome measures

Primary outcome

Primary exposure:

• muscle fatiguability combined with self-perceived fatigue, measured daily

using the eforto® system.

Primary outcomes:

• delayed length of stay due to a complication

Secondary outcome

Secondary outcome measures of recovery:

• ADL functionality

• Mobility

• Mortality

• Wellbeing

• Complications

• Readmissions

• Discharge destination

• Frailty

Study description

Background summary

Personalisation of treatment requires a balanced judgement of present health risks or diseases and the resilience of the individual to prevent that disease or recover from it. This judgement is now largely based on the clinical judgement of the physician. However, in the context of frailty and multimorbidity, judging the person*s recovery capacity can be challenging. Fatiguability appears to be a useful marker for changes in health and recovery capacity. In this study, we aim to evaluate whether fatiguability measured during hospital admission is a good predictor for recovery capacity in older adults admitted to the geriatric medicine department. Traditionally, fatiguability is measured using an anologue vigorimeter. This method requires a trained professional and is sensitive to measurement error. This makes this method less suitable for recurrent completion in the context of daily care at a busy clinical ward. Therefore, in this
study we use the eforto® system, which comprises of a rubber balloon connected with an app on a smartphone and cloud platform for data storage and monitoring. The healtcare professional/researcher can muscle fatigability easily with eforto(R), because the data will be stored automatically and is presented via the app.

Study objective

To evaluate the validity of grip work and self-perceived fatigue measured with the eforto® system for monitoring hip fracture recovery and insight in resilience.

Study design

This study is a prognostic cohort study, during which we will evaluate if daily measurements of grip work and self-perceived fatigue in patients with an acute hip fracture are a reliable method for monitoring and predicting recovery, and getting more insight in how resilient a patient is. For the current study, daily muscle fatigability measurements and two self-perceived wellbeing and fatigue questions will be added, and for baseline measurements The Older Person and Informal Caregiver Survey short-form (TOPICS-SF) and the Multidimensional Fatigue Inventory (MFI-20) questionnaires will be asked. These measurements will be conducted twice daily during admission supervised by a researcher. The question about self-perceived fatigue is asked twice a day.

Study burden and risks

During this study, we will make use of mostly data that is already being collected as a part of the standard clinical care. In this study, we will add daily fatiguability tests and self-perceived fatigue, which take an additional two times 5-10 minutes per day (duration depends on the time the patient is able to continue to squeeze, thus the tests takes longer for a fitter patient). Next to this, two questionnaires will be administered as a baseline measurement, with an expected duration of 10 minutes per questionnaire. These will not be administered on the same day, so that we will not have sessions that are too long or intense. Moreover, we will ask the questions so they will not have to read it themselves if they do not want to. The questionnaires and tests are administered by the researcher at the patients* ward. For the follow-up measurements, we will use the day during which the patients are already invited back for a regular follow-up measurement as part of the standard clinical care.

Background information (e.g. disease history) will be derived from the medical records to minimise the burden for the patient. Prior research with the eforto® system on our ward showed that patients are capable of, and can endure, completing the test with
supervision of the researcher. Patients appreciated obtaining insight in their physical recovery. The risks are low. In case of an injury (e.g. wrist fracture) or pain (e.g. rheumatoid arthritis) in the hands, the test will be omitted.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

At ZGT,110 patients admitted to the Geriatric Fracture Center will be recruited. Inclusion criteria are: 70+ years, being surgically treated for a hip fracture, being admitted to the geriatrics geriatric fracture center for at least 48 hours, cognitively able to provide informed consent.

Exclusion criteria

Being judged by their treating physician as unable to participate.
Being identified as a patient with palliative treatment regimen at the time of inclusion.
Being physically unable to perform the hand grip measurements.
Severe cognitive impairment.
Unable to communicate sufficiently in Dutch.
Deafness.
A pathological or periprosthetic fracture.
A total hip replacement.
Contact isolation.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2022
Enrollment:	110
Type:	Actual

Medical products/devices used

Generic name:	eforto®
Registration:	No

Ethics review

Approved WMO Date:	01-03-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-01-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-05-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL78347.000.21