Evolving to an integrated smart self-assessment *Fatigability in Outcomes to monitor Resilience Targets in Older persons* (FORTO) measurement & monitoring platform.

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

Summary

ID

NL-OMON50831

Source
ToetsingOnline

Brief title
FORTO 2.0

Condition

- Other condition

Synonym
ageing; geriatric syndromes

Health condition

geriatrische syndromen; veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Horizon 2020; Active & Assistive Living programme (AAL-2020-7-237-CP)

Intervention

Keyword: ageing, fatigability, monitoring, resilience

Outcome measures

Primary outcome

Primary exposure:

• muscle fatiguability, measured daily using the FORTO system.

Primary outcomes:

• Length of stay copied from the medical record;

• Daily functioning measured using the TOPICS-SF questionnaire, completed at

baseline and 3 and 6 months post discharge;

• mortality; once per year, the status of the participants will be checked in

the governments personal records database.

Secondary outcome

Secondary exposure: muscle fatigability measures twice per week during one

month post discharge.

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. Muscle 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, muscle 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 FORTO system, which comprises of a rubber balloon connected with an app on a smartphone and cloud platform for data storage and monitoring. The app coaches the patient and care professional through the steps of the measurement protocol, displays the test results and automatically stores the data.

Study objective

This study aims to evaluate the predictive ability of the muscle fatiguability test to predict recovery in older adults admitted to the department of geriatric medicine. Recovery is defined as length of stay, daily functioning after 3 and 6 months and mortality.

Study design

The current study is an extension to the Bedside Resilience Registry, an ongoing study that aims to develop and validate indicators of resilience in patients admitted to the geriatrics ward. In this ongoing study, questionnaires are completed twice daily on mood, fatigue and mobility. Three and six months after discharge, patients are asked to complete a brief follow-up questionnaire via telephone. For the current FORTO study, muscle fatiguability measurements will be added. These measurements will be conducted twice daily during admission supervised by a researcher.

Patients who possess a smartphone and are able to independently (or with support of a spouse or kin) complete the fatiguability test using the FORTO system, will be asked if they are willing to continue the FORTO measurements at home. If willing, the app will be installed on their phone and they will receive a device to continue the measurements twice per week for one month post discharge.

Study burden and risks

The ongoing registry has been approved as not-WMO compulsory. In that study, we

daily ask participants to complete a questionnaire. The baseline questionnaire takes approximately 30 minutes; the follow-up questionnaires takes approximately 10 minutes each time. For the current project, we add the fatiguability tests, which take an additional 3-8 minutes (duration depends on the time the patient is able to continue to squeeze, thus the tests takes longer for a fitter patient). The questionnaires and tests are administered by the researcher at the patients* ward. Three and six months post discharge, the researcher will contact the patient by phone to complete a brief follow-up questionnaire (approx 15 minutes). General data (e.g. disease history) will be derived from the medical records to minimise the burden for the patient. Continuation of the fatiguability measurements post discharge is optional. Prior research with the FORTO system on our ward sowed 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 Radboudumc,110 patients admitted to the geriatrics ward will be recruited. Inclusion criteria are: 65+ years, being admitted to the geriatrics ward for at least 48 hours, cognitively able to provide informed consent.

Exclusion criteria

Not applicable

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-03-2022
Enrollment:	110
Type:	Actual

Medical products/devices used

Generic name:	FORTO
Registration:	No

Ethics review

Approved WMO Date:	08-02-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-07-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL77879.091.21