Feasibility of a 13-week resistance exercise and protein supplementation intervention in sarcopenic geriatric rehabilitation inpatients: EMPOWER-GR

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The objective of the study is to investigate the feasibility of a combined resistance exercise training (RET) and protein supplementation (ONS) intervention and explore the effect on muscle mass and other parameters compared to standard of care in…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON55274

Source
ToetsingOnline

Brief title
EMPOWER-GR

Condition

- Muscle disorders

Synonym
low muscle mass and muscle strength, Sarcopenia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Nutricia,publiek-private samenwerking (PPS) toeslag van kennis instituten Health~Holland en Agri&Food

Intervention

Keyword: dietary supplement, geriatric rehabilitation, resistance training, sarcopenia

Outcome measures

Primary outcome

Feasibility (adherence to intervention and drop-out rate) and effect of the

intervention on muscle mass.

Secondary outcome

Effect of the intervention on muscle strength, physical and functional

performance, quality of life, mobility, nutritional status, nutritional intake,

length of stay in geriatric rehabilitation, institutionalisation/

hospitalisation and mortality.

Study description

Background summary

Sarcopenia and (risk of) malnutrition are estimated to be present in 56% and 47% of geriatric rehabilitation patients respectively. Resistance exercise training (RET) combined with protein supplementation has been recommended to increase muscle mass and strength in older adults. However, feasibility and efficacy in a geriatric rehabilitation setting remains to be established. The EMPOWER-GR RCT will test the hypothesis that a combined intervention of RET and protein supplementation with an oral nutritional supplement (ONS) is feasible in sarcopenic geriatric rehabilitation inpatients and increases muscle mass during the stay in geriatric rehabilitation and after discharge.

Study objective

The objective of the study is to investigate the feasibility of a combined resistance exercise training (RET) and protein supplementation (ONS) intervention and explore the effect on muscle mass and other parameters

compared to standard of care in sarcopenic geriatric rehabilitation inpatients at discharge and at week 13.

Study design

Feasibility, single-centre, randomised, controlled, open-label, parallel-group study.

Intervention

The intervention group will receive a combined RET (3x per week) and protein supplementation (ONS, 2x per day) intervention on top of standard of care and the control group will receive standard of care for a total duration of 13 weeks. In most cases, the intervention will continue after discharge from the revalidation centre, with a total study duration of 13 weeks for all subjects.

Study burden and risks

The burden of the study on top of standard of care is limited. All subjects will attend a screening visit and 3 study visits (4h each but the majority of the tests are part of standard of care): 2 visits during their stay in geriatric rehabilitation and 1 visit after discharge. All the measurements are commonly used in clinical practice, non-invasive and entail a low burden for the participants. Besides the study visits, subjects will complete a 3-day dietary record at three time points. Also, subjects in the intervention group will follow 3 RET sessions (45min) per week with a physiotherapist (physiotherapists sessions are also part of standard of care) and consume the ONS twice daily. The subjects will benefit from a Comprehensive Geriatric Assessment, providing further insights in their muscle health and other key clinical outcomes.

Contacts

Public
Vrije Universiteit

Van der Boechorststraat 7-9
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit

Van der Boechorststraat 7-9
Amsterdam 1081BT

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Admitted to a geriatric rehabilitation centre of Cordaan.
- Aged 65 years or older.
- Diagnosed with sarcopenia.
- Written informed consent.

Exclusion criteria

- Palliative care or other adverse prognosis precluding post-intervention follow-up
- Rehabilitation after stroke or cancer
- Specific medical history that could prevent participation in the intervention or affect the study outcome as judged by the investigator
- BMI >40 kg/m2 (morbid obesity)
- Renal impairment
- Unable to provide informed consent (patient or legal representative)
- Not understanding Dutch
- Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-05-2021
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	05-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL74989.029.20
Other	NL9444