Enhancing Muscle POWER in Geriatric Rehabilitation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26761

Source
Nationaal Trial Register

Brief title
EMPOWER-GR

Health condition

Sarcopenia

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam
Source(s) of monetary or material Support: Health~Holland, Agri&Food, Danone Nutricia Research

Intervention

Outcome measures

Primary outcome

- Feasibility (adherence to the RET and ONS intervention, drop-out rate and overall feasibility)
- Skeletal muscle mass (SMM)

Secondary outcome

- Feasibility: participation rate
- Relative muscle mass: fat free mass percentage and relative SMM
- Muscle strength: handgrip strength and leg press 1-repetition maximum (1-RM)
- Physical performance: total Short Physical Performance Battery (SPPB) score and individual chair stand test and gait speed test
- Functional performance: Katz index for ADL and Lawton and Brody scale for IADL
- Mobility: Functional Ambulation Classification (FAC)
- Quality of life: EQ-5D-5L
- Malnutrition: Global Leadership Initiative on Malnutrition (GLIM) criteria
- Dietary intake: three-day dietary record
- Length of stay in geriatric rehabilitation, six-month institutionalization and hospitalization and six-month and two-year 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.

Study objective

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 admitted after a hip fracture and increases muscle mass during the stay in geriatric rehabilitation and after discharge.

Study design

V0 (screening at admission to geriatric rehabilitation), V1 (week 0, randomisation, baseline), V2 (discharge from geriatric rehabilitation), V3 (week 13, end of intervention)

Intervention

The intervention group will receive a combination of three RET sessions per week with a leucine and vitamin D enriched whey protein-based oral nutritional supplement (ONS) twice daily on top of usual care for a total duration of 13 weeks. The control group will receive usual care.

Contacts

Public
Vrije Universiteit
Laure Verstraeten

0611503999
Scientific
Vrije Universiteit
Laure Verstraeten

0611503999

Eligibility criteria

Inclusion criteria

1) Admitted to a geriatric rehabilitation centre for a hip fracture
2) Aged 65 years or older
3) Diagnosed with stage 1 or 2 sarcopenia (sarcopenia probable or confirmed) according to the revised European Working Group on Sarcopenia in Older People (EWGSOP2) definition
4) Written informed consent

Exclusion criteria

1) Palliative care or other adverse prognosis precluding post-intervention follow-up
2) Specific medical history such as:
• Patients with ongoing cancer treatment or radiotherapy/ chemotherapy in the last 6 months.
• Any gastrointestinal disease that interferes with bowel function and nutritional intake (e.g. constipation or diarrhoea secondary to neuropathy, diarrhoea due to chronic inflammatory bowel disease, gastroparesis, (partial) gastrectomy or any other procedure for stomach volume reduction, including gastric banding)
• Other relevant medical history or medication that could prevent participation in the intervention or affect the study outcome as judged by the investigator (e.g. severe dementia, hypercalcaemia)
3) Patients in isolation/quarantaine
4) BMI >40 kg/m2 (morbid obesity)
5) Renal impairment (estimated Glomerular Filtration Rate <30 mL/min/1.73m2)
6) Dietary characteristics: known allergy to cow’s milk and milk products or the ingredients of the study products, known allergy to soy, known galactosaemia, known severe lactose

intolerance, patients requiring a fibre-free diet
7) Current alcohol or drug abuse in opinion of the investigator
8) Unable to provide informed consent (e.g. severe dementia or deliriumpatient and legal representative)
9) Not understanding Dutch
10) Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements
11) Participation in any other study involving investigational or marketed products concomitantly or within four weeks prior to baseline

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-05-2021
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
The data generated during this study will be made available on reasonable request, within the acceptable and existing privacy legislations. For sharing of the data, a data sharing committee will be appointed (after database lock) with a member of VU, VUmc, Cordaan and Danone Nutricia Research. Requests for data will be submitted to this committee, which will decide on sharing data for the requested research question/purpose.

Ethics review

Positive opinion

Date:	27-04-2021
Application type:	First submission

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
NTR-new	NL9444
Other	METC VUmc : 2020.0621

Study results