Enhancing Muscle POWER in Geriatric Rehabilitation

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26761

Bron
NTR

Verkorte titel
EMPOWER-GR

Aandoening

Sarcopenia

Ondersteuning

Primaire sponsor: Vrije Universiteit Amsterdam
Overige ondersteuning: Health~Holland, Agri&Food, Danone Nutricia Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

- Skeletal muscle mass (SMM)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Vrije Universiteit
Laure Verstraeten

0611503999

Wetenschappelijk

Vrije Universiteit
Laure Verstraeten

0611503999

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-05-2021
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

Ethische beoordeling

Positief advies

Datum:	27-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9444
Ander register	METC VUmc : 2020.0621

Resultaten