

The effects of additional protein intake on muscle strength and physical performance in physically active elderly

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We hypothesize that the ingestion of an additional amount of dietary protein (2 x 15g per day) will increase muscle strength and physical performance in physically active elderly (≥ 65 yrs). Moreover, we hypothesize that the ingestion of...

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

Samenvatting

ID

NL-OMON23080

Bron

NTR

Aandoening

sarcopenia, frailty, loss of muscle mass, strength and functionality

sarcopenie, fragiliteit, verlies aan spiermassa, kracht en functionaliteit

Ondersteuning

Primaire sponsor: Radboudumc Nijmegen, Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in maximal voluntary contraction (3 repeated measures (RM) leg extension strength test) and physical performance (SPPB) will be our primary outcome measures.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Sarcopenia is defined as the age-related loss of skeletal muscle mass, muscle strength and muscle function. These declines can lead to a decrease in physical performance, decreased independence and enhanced vulnerability, and subsequently increased health care costs. Previous studies have shown beneficial effects of enhanced protein intake in frail elderly but little is known about the effect of enhancing protein intake in currently healthy physically active elderly. It has been shown that physically active elderly have the same age-related declines in muscle strength as their inactive peers, while protein recommendations are often not met in both groups.

Objective: The present study has been designed to investigate the impact of additional protein intake on muscle strength and physical performance in physically active elderly.

Study design: The proposed intervention is a 13-week double-blind randomized placebo-controlled trial with 2 arms. The effects of daily protein supplementation (2x 15g provided at breakfast and after exercise or on days without exercise: at lunch) on muscle strength and physical performance will be investigated.

Study population: The study population includes in total 120 subjects, aged 65 years and above with a protein intake in the lowest quartile and registered to participate in the Nijmegen Four Days Marches 2017.

Intervention (if applicable): The physically active elderly subjects will be randomly assigned to the intervention or control group, receiving either protein supplementation (30 gram per day) or placebo. It will be assured that baseline protein intake, gender and age is similar between the groups. The daily supplementation consists of a protein product (30 grams of protein) or an placebo (consisting of carbohydrates). It will be given in the form of 2 drinks that need to be consumed during breakfast and after exercise (or on days without exercise, during lunch).

Main study parameters/endpoints: The primary outcomes are differences in change in muscle strength and physical performance between the intervention and control group after 12 week intervention. Changes in muscle mass and total body composition, muscle, joint and bone markers and questionnaires changes will also be assessed. Furthermore, during the Four Days Marches we will assess differences between the protein-supplemented group and the placebo group in recovery of physical performance and muscle strength and in biomarkers (inflammation, muscle, joint and bone health).

Doel van het onderzoek

We hypothesize that the ingestion of an additional amount of dietary protein (2 x 15g per day) will increase muscle strength and physical performance in physically active elderly (\geq

65 yrs). Moreover, we hypothesize that the ingestion of additional protein in physically active elderly will have a beneficial effect on recovery of muscle and joint characteristics during the Four Days Marches.

Onderzoeksopzet

change in maximal voluntary contraction: 2 time points

Change in SPPB: 4 time points

Onderzoeksproduct en/of interventie

Protein supplements will be provided as ready-to-drink products of 250 ml containing 15 gram protein (MPC-80) and will be produced by FrieslandCampina. De placebo supplements will be provided as ready-to-drink products of 250 ml and will be produced by FrieslandCampina. The products will be vanilla flavoured. Caloric content is very similar between the products. The products will be consumed twice a day for 13 weeks.

Contactpersonen

Publiek

Dominique ten Haaf
Philips van Leijdenlaan 15

Nijmegen 6525EX
The Netherlands
+31(0)243613676

Wetenschappelijk

Dominique ten Haaf
Philips van Leijdenlaan 15

Nijmegen 6525EX
The Netherlands
+31(0)243613676

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 65 years or older
- Registered for the Nijmegen Four Days Marches 2017
- Protein intake less than 1.0 g/kg bw/d based on FFQ
- Able to understand and perform the study procedures

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Type I or type II diabetes
- Allergic or sensitive for milk proteins, or lactose intolerant.
- Having diagnosed COPD
- Currently treated for cancer
- Having diagnosed renal insufficiency (eGFR<30 (ml/min*1.73m²))
- Having diagnosed intestinal diseases influencing the uptake of protein (i.e. active inflammatory bowel disease, Crohn's disease)
- Use of statins
- Involved in a heavy resistance type exercise program within the last 2 yrs

Onderzoekopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind

Controle: Placebo

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 13-03-2017

Aantal proefpersonen: 120

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 10-03-2017

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45732

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6313
NTR-old	NTR6488
CCMO	NL60137.072.16
OMON	NL-OMON45732

Resultaten