Comparing the effects of three PROtein-enhancement strategies on exercise-induced Muscle damage in Older adults

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To compare the effects of three different protein-enhancement strategies (whey protein (WP), mixed plant-based protein (BRFP), and use of protein-rich food products (PFP) on exercise-induced muscle damage in older adults compared to isocaloric…

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56728

Source
ToetsingOnline

Brief title
PROMO

Condition

- Other condition

Synonym
exercise-induced muscle damage

Health condition

inspanningsgerelateerde spierschade, sarcopenie

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: TKI subsidie van Ministerie van Economische Zaken & Cosun subsidie

Intervention

Keyword: exercise-induced muscle damage, older adults, protein intake

Outcome measures

Primary outcome

Circulating creatine kinase concentration is the primary outcome.

Secondary outcome

Secondary study parameters are circulating lactate dehydrogenase

concentrations, muscle soreness, and muscle function.

Study description

Background summary

Exercise is an important strategy for the primary and secondary prevention of chronic disease development and can improve general health, but an acute bout of exercise also induces muscle damage. A sufficient and high-quality protein intake is of utmost importance for muscle repair and healthy aging. Nevertheless, more than half of Dutch elderly does not reach daily protein intake recommendations, which underscores the need for protein-enhancement strategies. Traditional strategies focus on animal-based protein due to its high quality, but a high-quality mix of plant-based proteins or use of protein-rich food products may yield similar benefits, while decreasing the ecological footprint and improve sustainability of results.

Study objective

To compare the effects of three different protein-enhancement strategies (whey protein (WP), mixed plant-based protein (BRFP), and use of protein-rich food products (PFP) on exercise-induced muscle damage in older adults compared to isocaloric carbohydrate control.

Study design

This explorative study is a partially-blind randomized controlled trial. Participants are instructed to consume either protein supplements (WP or BRFP), protein-rich food products (PFP) or isocaloric carbohydrate control for 4 subsequent weeks. After two weeks, participants will optionally perform a single bout of walking exercise (30-50km), and after four weeks participants will perform a bout of walking exercise on 4 consecutive days (Nijmegen Four Days Marches). Pre- and post-exercise measurements are performed to investigate the effect on EIMD and muscle soreness.

Intervention

Participants will be randomly assigned to a protein-enhancement group or control group. Participants are instructed to consume 40g of supplement (30g of protein)/control powder per day for five weeks, which can be dissolved in water. The food product-group will be coached on the use of protein-rich food products via a mobile application and receive feedback on their protein intake during the study period.

Study burden and risks

The risks involved in participating in this study are minimal. The protein supplements provided are generally available existing products with no adverse effects. Protein and control supplements will be produced according to the HACCP/ISO22000 regulations in certified facilities and using approved and commercially available ingredients. The burden of this study is solely attributed to site visits (9 visits) and physical examinations. Nevertheless, site visits take primarily place during an exercise and training event, which limits the burden. Furthermore, most study procedures do not involve any risks for the participants. Measurements with a limited burden are blood sampling, since it is associated with a 5% risk of developing haemorrhage, which will fully disappear within 2 weeks and is not associated with any functional limitations. Based on previous studies, participants in protein-enhancement groups may benefit from improved physical performance and reduced muscle soreness. All participants will receive a personal summary of the obtained study results after completion of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 60 years or older
- Registered for the Nijmegen Four Days Marches (i.e., able to walk 30-50 km on consequtive days)
- A habitual protein intake <1.2 g/kg/d (based on the PRO55+ screening tool)
- Able to understand and perform the study procedures
- Able to use a smartphone

Exclusion criteria

- Allergic or sensitive for milk proteins, or lactose or gluten intolerant
- Diagnosed type I or type II diabetes mellitus
- Diagnosed intestinal diseases influencing the uptake of protein (i.e., active inflammatory bowel disease, Crohn*s disease)
- Consumption of other freely available protein supplements during the study period.
- If the subject intends to perform additional exercise bouts that cause muscle damage in the 4 days before the single- and multiple exercise bouts.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-06-2024
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2024
Application type:	First submission
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
Other	ClinicalTrials.gov: in afwachting van identificatienummer
CCMO	NL86007.091.24

Study results

Date completed: 19-07-2024

Results posted: 12-08-2024

Actual enrolment: 199

First publication
01-01-1900