Improvements by a Protein-Rich Plant-Based Diet and Resistance Exercise Program for Active Ageing

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

Summary

ID

NL-OMON56082

Source
ToetsingOnline

Brief title
IMPACT

Condition

- Other condition

Synonym
nvt

Health condition

geen

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool van Amsterdam
Source(s) of monetary or material Support: Topconsortia voor Kennis en Innovatie (TKI) en FrieslandCampina

Intervention

Keyword: ageing, plant-based proteins, resistance exercise

Outcome measures

Primary outcome

The primary study parameter is the protein intake after the twelve-week intervention. The protein intake will be measured with 3-day dietary record.

Secondary outcome

The secondary study parameter is the change in appendicular skeletal muscle mass (ASMM) between baseline and after the three-month intervention. The muscle mass is measured with a dual-energy X-ray absorptiometry (DXA) in kg and percentage of total body weight. This study will assess the following parameters explorative: muscle strength and physical performance, body composition, cardiovascular parameters, nutritional status, and environmental outcomes.

Study description

Background summary

Sarcopenia, the age-related decline of muscle mass, strength, and function is associated with the increased chance of physical disability, falls, fractures, mortality, and a lower quality of life. High-protein intake in combination with physical activity are important strategies to reduce this decline. High-protein diets are often high in animal-based products, due to their sufficient amount of high-quality protein. However, animal-based products, especially meat, are

also associated with a larger environmental footprint. Consuming high levels of high-quality proteins to preserve muscle mass is challenging with a (more) plant-based diet. Transitioning towards a more, but not exclusively plant-based diet (i.e., a vegetarian diet) could still decrease the environmental footprint compared to an omnivorous diet and could easier lead to a sufficient high-quality protein intake.

Study objective

The primary objective is to study the protein intake in a three-month high-protein vegetarian diet vs a high-protein omnivorous diet, both in combination with a resistance exercise training program in healthy older adults. To investigate the effects on appendicular skeletal muscle mass (ASMM) is the secondary objective. Muscle strength, physical performance, body composition, cardiovascular parameters, nutritional status, and environmental outcomes will be assessed explorative.

Study design

In a non-blinded randomized controlled trial (RCT), healthy older adults will follow a three-month high-protein vegetarian diet or high-protein omnivorous diet both in combination with a resistance exercise training program (three times per week).

Intervention

The participants will follow a three-month high-protein (>=1.2g/kg/d) vegetarian diet (>=60% plant-based proteins) or high-protein (>=1.2g/kg/d) omnivorous diet (>=60% animal-based proteins) both in combination with a resistance exercise training program (three times per week).

Study burden and risks

The risks associated with participation are minimal. Assessments will be carried out in a private controlled setting and interventions are guided by dieticians (in training), physiotherapists (in training), and researchers. Participation in this study should benefit older adults by improving body composition, increasing knowledge and skills, and providing social aspects and personal health insights. The results of this trial will be used to support evidence-based practice for more environmentally sustainable diets to preserve or increase muscle mass.

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

• Aged 55 years or older
• BMI 18.5-30 kg/m2
• Living independently
• Ability and willingness to comply with the protocol
• Written an informed consent
• Consent of the study physician

Exclusion criteria

• Alcohol abuse (>14 glasses per week (women) or >21 glasses per week (men)) or drug abuse in the opinion of the study physician

• Inability to understand the Dutch language
• Cognitive impairment (MMSE < 25)
• Diagnosed chronic disease that may interfere with protocol (e.g., cardiovascular, gastrointestinal, neurological, renal diseases, and/or diabetes)
• Bariatric surgery
• Current enrolment in an exercise program or other intervention study
• Planned a holiday during the intervention period and is unable to attend training sessions for > 1 week

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2024
Enrollment:	106
Type:	Actual

Ethics review

Approved WMO Date:	17-11-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-01-2025
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
ClinicalTrials.gov	NCT06172725
CCMO	NL84531.018.23