

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

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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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	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 ( $\geq 1.2\text{g/kg/d}$ ) vegetarian diet ( $\geq 60\%$  plant-based proteins) or high-protein ( $\geq 1.2\text{g/kg/d}$ ) omnivorous diet ( $\geq 60\%$  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 dietitians (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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### Scientific

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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/m<sup>2</sup>
- 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

## 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