The Vold-study: The effect of a 12-week self-composed vegan diet with or without concurrent resistance exercise on thigh muscle volume in older adults

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Primary: To assess the effects of a 12-week self-composed vegan diet in comparison to an omnivorous diet on thigh muscle volume (TMV) in community-dwelling older adults. And to assess the effect of a 12-week self-composed vegan diet combined with...

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

Summary

ID

NL-OMON53915

Source
ToetsingOnline

Brief title
Vold-study

Condition

- Other condition
- Bone, calcium, magnesium and phosphorus metabolism disorders
- Muscle disorders

Synonym
age-related muscle loss, Sarcopenia

Health condition

Preventie cardiometabole aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Rijksoverheid

Intervention

Keyword: Aging, Muscle, Protein, Vegan

Outcome measures

Primary outcome

The main study parameter is the difference in change in TMV.

Secondary outcome

- Other body composition indices from MRI-scan: thigh muscle fat infiltration,

liver proton-density fat fraction, visceral adipose tissue, Abdominal

subcutaneous adipose tissue

- Muscle strength

- Muscle fractional synthesis rates

- Bone mineral density

- Bone turnover markers (C-terminal telopeptide of type I collagen [CTX] and

procollagen type I N-terminal propeptide [PINP])

- Insulin-like growth factor 1 (IGF-1) and parathyroid hormone (PTH) levels

- Insulin levels

- Dietary intake

- Metabolic profile

- Blood pressure

- Iron status

- Vitamin B12 status

- Vitamin D status

- Gastrointestinal symptoms

- Gut metabolomics and metagenomics

- High sensitive CRP

- DNA methylation

Study description

Background summary

Consumers are increasingly encouraged to consume more plant-based foods and lower their consumption of foods from animal origin. This shift is driven by environmental and health factors. However, the consequences of such a transition on muscle mass still remains to be explored. This is of particular importance in the older population, where the age-related reduction in muscle mass and strength is highly prevalent. Adequate dietary intake, specifically protein intake, and resistance exercise are well-known strategies in promoting muscle mass in older adults. Plant-based foods are currently considered to be inferior to animal-based foods in their protein quality, and are therefore considered to be suboptimal for the maintenance of muscle mass at an older age. On the other hand, combining plant-based foods may improve the protein quality and thereby the anabolic properties of a vegan meal. Evidence regarding the anabolic properties of vegan diets in older adults is scarce.

Study objective

Primary: To assess the effects of a 12-week self-composed vegan diet in comparison to an omnivorous diet on thigh muscle volume (TMV) in community-dwelling older adults. And to assess the effect of a 12-week self-composed vegan diet combined with twice-weekly resistance exercise (RE) on TMV in comparison to a self-composed vegan diet without resistance exercise in community-dwelling older adults.

Secondary:
To assess the effect of a 12-week self-composed vegan diet in comparison to an omnivorous diet, and to assess the effect of a 12-week self-composed vegan diet combined with twice weekly RE in comparison to a self-composed vegan diet without RE on:

- Other body composition components
- Muscle strength
- Bone mineral density and bone turnover markers
- Cardiometabolic outcome measures
- Vitamin B12, vitamin D and iron status
- DNA methylation

To assess the effect of a 10-day self-composed vegan diet in comparison to an omnivorous diet, and to assess the effect of a 10-day self-composed vegan diet combined with twice weekly RE compared to a self-composed vegan diet without RE on:
- Muscle protein synthesis

To assess the effect of a 12-week self-composed vegan diet in comparison to an omnivorous diet on:
- Gastro-intestinal symptoms
- Gut metabolomics and metagenomics

To assess the nutritional value of a self-composed vegan diet in community-dwelling older adults.

Study design

A randomized controlled intervention trial with three parallel study arms.

Intervention

Self-composed fully plant-based (vegan) diet with or without concurrent RE.

Study burden and risks

The risks of the study are minimal. The diets will be predominantly self-composed by the participants. All products provided by the researchers are commercially available. Only participants with a BMI of >=23 kg/m2, with no more than 4 kg weight loss in the past 3 months will be included to minimize risks related to a potential small decrease in muscle mass. The 12-w duration of the vegan diet excludes the possible risk of vitamin B12 deficiency. Vitamin D supplements will be advised to the participants to minimize the risk of vitamin D deficiency, improve calcium absorption, and thereby minimize fracture risk. Methods used to explore the effects of the intervention have been widely used in other studies and will be performed according to standard operating procedures (SOPs). The MRI-protocol used to assess the primary and secondary outcomes is very short (6-10 minutes) and participants will be screened on eligibility for MRI-scanning at screening and, again, prior to each MRI-scanning session. No serious side effects have been previously observed following the deuterated water protocol that will be used in this study.

Venipuncture and muscle biopsies will be performed by trained health care professionals and may cause some discomfort, but further risks are minor.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Aged >=65 years old;
- Community-dwelling;
- BMI 23-32 kg/m2;
- Habitual diet contains animal-based food products (i.e. dairy, meat and/or fish) at least 5 days per week;

Exclusion criteria

- Following a self-reported entirely vegetarian or vegan diet during the six months prior to the study; - Following a prescribed high (>=1.2 g/kg/d) or low protein diet (below 0.8 g/kg/d), and/or or taking protein supplements on medical advice, during the month prior to the study; - Participating in a structured progressive resistance exercise training program the during three months prior to the study; - >=4 kg of body weight loss during three months before the start of the study; - Being diagnosed with one of the following: diabetes mellitus; severe renal disease (glomerular filtration rate below 30 ml/min) ; neurological or neuromuscular disorders; serious cardiovascular diseases; cancer (with the exception of the following types of skin cancer: basal cell carcinoma, squamous cell carcinoma); (very) severe chronic obstructive lung disease (COPD; GOLD stage III or IV); bowel disease. - Chronic use of medication that affects muscle function as assessed by the research physician; - The use of anticoagulants incompatible for muscle biopsies as assessed by the research physician: acenocoumarol (sintrom); phenprocoumon (marcoumar); dabigatran (pradaxa); apixaban (eliquis); rivaroxaban (xarelto); clopidogrel (plavix); edoxaban (lixiana); combination of acetylsalicylic acid or carbasalate calcium (ascal) with dipyridamole; - Having a contra-indication to MRI scanning (including, but not limited to): o Pacemakers and defibrillators o Infraorbital or intraocular metallic fragments o Ferromagnetic implants o Claustrophobia - Not willing to stop nutritional supplements, with the exception of supplements on medical advice, and vitamin D; - Not willing or afraid to give blood, undergo a muscle biopsy or have an MRI scan during the study; - Unwilling to eat a self-composed vegan diet or an omnivorous diet with daily consumption of animal-based food sources for 3 months; - Unwilling to participate in RE twice a week for 3 months; - Currently a research participant in another trial or participated in a clinical trial during one month before the start of the measurement period; - Not being able to understand Dutch; - Not having a general physician; - Working, or having a direct family member that works at the Division of Human Nutrition at Wageningen University during the study. - Unwilling to be informed about incidental findings of pathology and approving of reporting this to their general physician.

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:	Completed
Start date (anticipated):	18-04-2023
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	23-03-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-11-2023
Application type:	Amendment
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
CCMO	NL82788.091.22