# Protect, The impact of a high protein diet on the preservation of muscle mass during caloric restriction in overweight middle-aged to elderly people

Published: 08-03-2012 Last updated: 01-05-2024

To investigate the effects of a high protein diet vs. standard protein diet for 12 weeks on preservation of muscle mass during caloric restriction in overweight and obese middle-aged to elderly people.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

# Summary

### ID

NL-OMON37859

**Source** ToetsingOnline

**Brief title** Protect

# Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Muscle disorders

**Synonym** loss of muscle mass during weight reduction

#### **Health condition**

obesitas

1 - Protect, The impact of a high protein diet on the preservation of muscle mass du ... 14-05-2025

# Research involving

Human

### **Sponsors and support**

**Primary sponsor:** TI Food and Nutrition **Source(s) of monetary or material Support:** TIFN

#### Intervention

Keyword: Caloric restriction, Muscle mass, Overweight, Protein

### **Outcome measures**

#### **Primary outcome**

Difference in Skeletal muscle mass after 12 weeks

#### Secondary outcome

Secondary outcome measures:

- BMI
- Body weight
- Total fat mass (DXA)
- Bone mineral density (DXA)
- Leg strength (1RM leg press/extension)
- Handgrip strength
- Physical performance (SPPB, 400 m walk test)
- Activities of daily living
- Muscle fiber/type size, satellite cells (biopsy)
- Fasting glucose level
- 2-h plasma glucose level (assessed by OGTT)
- HbA1c
- Insulin

2 - Protect, The impact of a high protein diet on the preservation of muscle mass du ... 14-05-2025

- Lipid profile
- Habitual physical activity (Accelerometer)
- Microbial composition and metabolite profiles.
- Gene expression in adiopose tissue

# **Study description**

#### **Background summary**

Weight loss can have substantial health benefits in overweight and obese adults. It is well established that caloric restriction leads to weight loss. This weight loss is commonly accompanied with a reduction of lean body mass. The loss of lean body mass with weight loss may have adverse outcomes such as poor physical function, sarcopenia, deleterious metabolic consequences, and frailty. It has been reported that high protein diets leads to a loss of body weight and preservation of lean body mass in young adults. In middle aged to older adults, however, the benefits of a high protein diet on muscle mass preservation during caloric restriction is unclear.

#### **Study objective**

To investigate the effects of a high protein diet vs. standard protein diet for 12 weeks on preservation of muscle mass during caloric restriction in overweight and obese middle-aged to elderly people.

#### Study design

Randomized, controlled, double-blind, parallel-group intervention trial in overweight and obese middle-aged to elderly people.

60 men and women of 55-70 years will be included and followed for 12 weeks. Muscle mass iwill be measured at the beginning and at the end of the dietary intervention. After baseline measurements, participants will enroll into the run-in week to get aquinted study procedures and to achieve weight/energy balance. During the run-in week, all foods will be supplied. After the run-in week, subjects will receive a diet which is completely supplied by the university.

To investigate the effect of a high protein diet compared to a standard protein diet, the participants are at random divided in 2 groups, namely:

- 1. High protein diet with caloric restriction
- 2. Standard protein diet with caloric restriction

#### Intervention

All subjects consume a caloric restricted (25%) diet for 12 weeks. Subjects are at random divided in 2 groups:

High protein diet with caloric restriction
g/kg BW/d protein

Standard protein diet with caloric restriction
protein, 55% carbohydrates, 30% fat
g/kg BW/d protein

#### Study burden and risks

Burder in time:

- Screening: 2 hours
- 2 days of measurements of 4 hours, 2 days of measurements of 1 hour
- diner every weekday: 30 minutes a day
- Total: 45 hours

#### Benefits

The subjects will receive a final report of the test that will be performed. In this report, their own results will be presented. Moreover, the final group results will be presented. Participants are free to withdraw from further participation for any reason and at any time during the trial. After full completion of the study, the participants will receive x200, excluding travel costs. A total of x50 or x100 will be provided to compensate for the travel cost (x50:<5km and x100: >5km). In addition to the \*cash-reward\*, during the 13 weeks of the study, subjects receive all their foods and drinks for free (~8.5 Euros a day x 91 days = 773 Euros). Besides this, the participants will have dinner in a group, which also has a social aspect. The participants are able to maintain their daily activities. And finally, during this intervention, the subject may benefit from losing weight under professional supervision, which might result in health benefits.

#### Risks

The risks involved in participating in this experiment are minimal. A catheter is comparable to a normal blood drawn and the only risk is that of a small local hematoma. In total, 140 ml blood will be collected throughout the entire intervention. No noticeable effects will be expected. The incision made for obtaining the muscle biopsy will be done by an experienced physician and will heal completely. The meals for this study are made from normal nutritional ingredients and are not expected to bring any health risks. The physical measurements (1RM, SPPB, 400m, handgrip strength) can result in feelings of muscle soreness.

The voluntary adipose tissue biopsy will be performed by an experienced physician and will heal completely. It can occasionally cause a local haematoma or bruise and some participants may report pain or discomfort.

# Contacts

**Public** TI Food and Nutrition

Nieuwe Kanaal 9A 6709 PA Wageningen NL Scientific TI Food and Nutrition

Nieuwe Kanaal 9A 6709 PA Wageningen NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age

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

### **Inclusion criteria**

- Overweight or obese (BMI 27-35 kg/m2)
- Waist circumference male: >=102 cm, female: >=88cm
- Age in between 55-70 years
- Willingness and ability to comply with the protocol

# **Exclusion criteria**

- Renal insufficiency (MDRD eGFR > 60ml/min/1.73 m2)
- Type 1 or type II diabetes (fasting glucose level >=7 mmol/l)
- Cancer
- COPD
- Participation in weight loss program 3 months before the intervention
- Participation of any heavy resistance-type exercise training (>1 wk) the last 2 years
- Intentional or unintentional weight loss (>3 kg in the last 3 months)
- Severe loss appetite
- Diagnosed allergy to milk products
- Gastric bypass
- Supplements or medication use for weight loss
- Participation in any other intervention trial
- For women: last period >= 1 year ago

# Study design

# Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2012
Enrollment:	60
Туре:	Actual

# **Ethics review**

#### Approved WMO

6 - Protect, The impact of a high protein diet on the preservation of muscle mass du ... 14-05-2025

Date:	08-03-2012
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	20-08-2012
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

# **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** CCMO

ID NL39309.081.11