# Effect a hypocaloric high protein diet and resistance exercise on body composition, muscle strength, physical functioning and quality of life during a weight loss trial in overweight older adults(55+).

Published: 25-04-2014 Last updated: 20-04-2024

The objective of this study is to evaluate the effects of excercise training and/or a high protein hypocaloric diet on improvement of body composition (preservation fat free mass), muscle strength, physical functioning and quality of life in an...

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

# Summary

### ID

NL-OMON40428

**Source** ToetsingOnline

**Brief title** WelPrex

### Condition

Other condition

**Synonym** adiposity, overweight

#### Health condition

overgewicht en obesitas

1 - Effect a hypocaloric high protein diet and resistance exercise on body compositi ... 23-06-2025

## Research involving

Human

### **Sponsors and support**

Primary sponsor: Vrije Universiteit Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

#### Intervention

Keyword: body composition, protein, resistance exercise, weight loss

#### **Outcome measures**

#### **Primary outcome**

fat free mass

#### Secondary outcome

muscle strength

physical functioning

quality of life

# **Study description**

#### **Background summary**

Overweight and obesity are a health problem, also for the elderly. The current CBO guideline for the treatment of obesity in the Netherlands does not differentiate beween adults and elderly. However, weight loss in elderly increases risk of muscle loss and therefore potentially loss of strength and physical functioning. This loss should be prevented. From literature it appears that a high protein diet and resistance training might result in preservation of fat free mass.

#### **Study objective**

The objective of this study is to evaluate the effects of excercise training and/or a high protein hypocaloric diet on improvement of body composition (preservation fat free mass), muscle strength, physical functioning and quality of life in an overweight elderly (55+) population.

#### Study design

2-by-2 factorial design; 100 subjects; 50 subjects receive a hypocaloric high protein diet (the other 50 receive a regular hypocaloric diet) and 50 subjects are enrolled in a resistance training program (the other 50 receive exercise advise according to the CBO guidelines).

#### Intervention

- Regular hypocaloric diet and exercise advise according to the CBO guidelines.

- Hypocaloric high protein diet and eercise advise according to the CBO guidelines.

- Regular hypocaloric diet and resistance training.

- Hypocaloric high protein diet and resistance training.

#### Study burden and risks

Based on available literature, no specific adverse effect of the high protein diet (1.3g/kg) are expected. The study physician will judge on eligibility based on subject's medical history and medication use. To minimize the potential risk of the resistance exercise program, a physiotherapist will carefully assess each subject and decide whether a subject is capable and whether it is safe to participate in the resistance exercise program. Potential benefits are preservation of fat free mass, muscle strength and physical functioning, which are the objectives of this study.

# Contacts

#### Public

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

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

#### **Inclusion criteria**

BMI>28 and/or BMI > 25 with a waist circumference > 88 cm (women) or > 102 cm (men) Age >=55 year

### **Exclusion criteria**

renal failure cardiovascular disease Diabetes Mellitus with insulin exercise asthma dysfunction of joints use of antidepressant (< 1 year) thyroid dysfunction (use of thyroid medication with changed dosage in last 12 months. When stable, subjects can be included.) Participation in a resistance exercise and/or weight loss program three months before starting and during the study Current alcohol or drug abuse in opinion of the sponsor-investigator Known allergy to milk and milk products Known galactosaemia Sponsor-investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements

# Study design

### Design

Interventional
Parallel
Randomized controlled trial
Open (masking not used)
Active
Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2014
Enrollment:	100
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Date:	25-04-2014
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

# **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

ССМО

**ID** NL43226.072.14