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+).

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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

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

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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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2014
Enrollment:	100
Type:	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	ID
CCMO	NL43226.072.14