ProMuscle, A protein supplementation and exercise strategy to promote muscle protein anabolism in frail elderly people

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The present study is designed to investigate whether timed protein supplementation in the presence or absence of a resistance-type exercise training will increase skeletal muscle mass in frail elderly.

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

Summary

ID

NL-OMON33401

Source
ToetsingOnline

Brief title
ProMuscle

Condition

- Muscle disorders

Synonym
Sarcopenia

Research involving
Human

Sponsors and support

Primary sponsor: TIFN
Source(s) of monetary or material Support: TIFN

Intervention

Keyword: Exercise, Frail elderly, Protein, Skeletal muscle

Outcome measures

Primary outcome

The primary outcome measure of this study will be change in skeletal muscle

mass after the 6 month intervention.

Secondary outcome

Physical function

Musclefibre hypertrophy

Intracellulair protein synthesis pathways

Nitrogen balance

3-methylhistidine

Nutritional intake

Physical Activity measurement

Cognitive functioning

Depression

Bloodpressure

Study description

Background summary

Sarcopenia is the age associated loss of skeletal muscle mass and function. Especially frail elders have a high risk for adverse health outcomes, such as institutionalization, falls and hospitalization. Resistance-type exercise training has been shown to represent an effective strategy to augment skeletal muscle mass and strength and improve functional capacity in both healthy and frail elderly people. Food intake and in particular protein intake is essential

to promote net muscle protein anabolism for both young and older subjects. It has been described that 25-30 g of high quality protein each meal (i.e. ~10 g essential amino acids) is sufficient to maximally stimulate skeletal muscle protein synthesis, indicating the importance of the dose and timing of protein supplementation.
Until now, very few studies have investigated both the effects of nutritional supplementation and exercise on body composition in frail elderly people. In fact, only one study has investigated the combined effect of protein supplementation and resistance-type exercise on skeletal muscle mass, showing a increase of 2.7% in fat free mass (FFM) after 9 months. There is no evidence of the possible beneficial effects of timed protein supplementation in the presence of resistance type exercise in frail elderly people. We hypothesize that the supplementation of 15 g of protein at breakfast and lunch will increase skeletal muscle mass frail elderly individuals. Together with the habitual protein intake, the protein supplementation will result in approximately 25 g per meal, which has been described as sufficient to maximally stimulate skeletal muscle protein synthesis. Furthermore, we hypothesize that a sufficient amount of dietary protein, supplemented as described above, will further augment the gain in skeletal muscle mass during resistance-type exercise training in the frail elderly.

Study objective

The present study is designed to investigate whether timed protein supplementation in the presence or absence of a resistance-type exercise training will increase skeletal muscle mass in frail elderly.

Study design

Six month randomized control trial, with 4 arms in parallel (2x2 factorial design). The effect of a daily protein supplementation (2x 15g provided at breakfast and during lunch), in the presence or absence of a concomitant resistance-type exercise training program will be investigated.

Intervention

The proposed intervention is a 6 month randomized control trial, with 4 arms in parallel (2x2 factorial design). In this study, the effect of a daily protein supplementation (2x 15g provided at breakfast and during lunch), in the presence or absence of a concomitant resistance-type exercise training program, will be assessed by measuring the gain in muscle mass in 120 frail elderly volunteers. After screening, the subjects will be randomly assigned to one of the four intervention groups:
1. Protein group
2. Protein + resistance-type exercise
3. Placebo group

4. Placebo + resistance-type exercise

The full study comprises a screening and a 6 month intervention period in which skeletal muscle mass is our primary outcome parameter.

Study burden and risks

Benefits
The subjects will receive a final report of the tests that will be performed. In this report, their own results will be presented. Moreover, the final group results will be presented after the results have been published. Food products will not be restricted during the intervention and the participants are able to maintain their daily activities. All the drinks will be provided during the trial. In the exercise groups the participant will be individually trained by an experienced trainer. It has been well established that exercise improves physical performance in daily live. After 6 months, we think that the skeletal muscle mass is increased and physical performance is improved. The training and testing will be carried out in groups which also has a social aspect. After full completion of the study, the participants will receive ¤250. The subjects can quit the study at any time for any reason if they wish to do so.

Risks
The risks involved in participating in this experiment are minimal. A venapunction is comparable to a normal blood collection and the only risk is that of a small local hematoma. In total 72 ml blood will be collected throughout the entire intervention. (48 ml to obtain plasma (creatinine, glucose and insulin) and 24 ml to collect peripheral blood (PBMC). The incision made for obtaining the muscle biopsy will be done by an experienced physician and will heal completely. The test beverages are made from normal nutritional ingredients and for this reason do not bring any health risks. The exercise training and 1RM measurements might result in feelings of muscle soreness. Therefore, an experienced investigator will supervise all training sessions.

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

• Elderly people: > 65 years
• frail elderly individuals (based on MNA, CES-D Depression Scale and physical inactivity)
• Male and female
• Able to understand and perform the study procedures

Exclusion criteria

•• Type I or type II diabetes (fasted blood glucose level >=7,0)
• No recent history (within 2 years) of participating in any regular resistance exercise training program (general questionnaire)
• Use of anti-coagulation medication (except of Acetyl Salicyl acid)
• Presence of coronary heart disease (ECG)
• Renal insufficiency (creatinine level > 200 mmol/l)
• High blood pressure (>160 mm Hg systolic)
• Allergic or sensitive for milk proteins

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2009
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	11-06-2010
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	ID
CCMO	NL29150.081.09