TEAMS - Training and protein recommendations for frail older adults (Part I: community-dwelling)

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1. To investigate the impact of various resistance-type exercise variables (i.e. load, repetitions, volume) on skeletal muscle mass, strength and physical performance outcomes in (mal)nourished frail community-dwelling older adults.2. To investigate...

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

Summary

ID

NL-OMON54919

Source
ToetsingOnline

Brief title
TEAMS - I

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
Sarcopenia and malnutrition

Health condition

Ondervoeding & Geriatrische syndromen (zoals sarcopenie)

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: SiA Regie orgaan Praktijkgericht onderzoek,Carezzo,Fonterra ,Fonterra en Carezzo inkind bijdrage in producten: voedingsindustrie

Intervention

Keyword: Older Adults, Protein, Resistance exercise training, Sarcopinia

Outcome measures

Primary outcome

The primary outcome is the change in muscle strength between baseline and

twelve- weeks, and is accessed with a one repetition maximum tests (1-RM).

Secondary outcome

- social demographic characteristics

- medical history / medication use

- cognitive ability

- body composition

- muscle architecture

- inflammation markers, glucose and insulin levels

- physical performance

- handgrip strength

- activities of daily living

- quality of life

- malnutrition

- daily dietary intake

- daily physical activity

- cognitive performance

- psychosocial outcomes

- sleep quality

- cost-effectiveness

- adverse events / medical status

- adherence

- process evaluation

Study description

Background summary

The world population is aging rapidly. As society ages, the incidence of physical limitations and frailty is dramatically increasing, which reduces the quality of life and increases health care expenditures. An important cause of physical limitations and frailty is the age-related loss of skeletal muscle mass, strength and performance also referred to as sarcopenia. Resistance-type exercise training is the most promising intervention to prevent or treat sarcopenia in older adults. Evidence of resistance exercise training is based on well-controlled studies, but the current protocols are difficult to apply in daily physiotherapy practice for this frail community-dwelling population. In addition, about 40% of the frail community-dwelling older adults receiving in-home services are undernourished. More research is warranted on the impact of resistance exercise training and (in)adequate dietary protein intake on training adaptations and sarcopenia in frail older adults.

Study objective

1. To investigate the impact of various resistance-type exercise variables (i.e. load, repetitions, volume) on skeletal muscle mass, strength and physical performance outcomes in (mal)nourished frail community-dwelling older adults.
2. To investigate the impact of various resistance-type exercise variables (i.e. load, repetitions, volume) during (in)adequate protein intake on skeletal muscle mass, strength and physical performance outcomes in frail community-dwelling older adults.
3. To assess the influence of personal characteristics on resistance-type exercise variables and skeletal muscle mass, strength and physical performance

outcomes in frail community-dwelling older adults.

Study design

(Cluster) Randomized controlled trial, with two step randomization and two parallel intervention groups.

Intervention

Control group receiving intervention:
- Resistance exercise training, twice weekly for 12 weeks in which subjects will be randomized by intensity (%1RM)
- Regular health care (+ information flyer)

Intervention group receiving additional dietary protein intervention:
- Resistance exercise training, twice weekly for 12 weeks in which subjects will be randomized by intensity (%1RM
- Dietary protein intervention: combination of 1) blended dietary counselling, 2) protein enriched consumer products

Study burden and risks

The risks associated with participation are minimal. Although muscle injury, soreness, and strain on energy levels might occur due to exercise, the risks are limited. Resistance exercise training takes place in small groups and participants choose their own number of repetitions during exercise. Assessments will be executed in a private controlled setting and interventions are guided by a physical therapist and dietetics. All older adults should benefit from this study (exercise induced performance and body composition benefits, social aspects, personal health insights). The results of this trial can lead to evidence-based practice protocols in physical exercise therapy, dietetics, and geriatrics.

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

* Community-dwelling older adult, receiving in-home care services
* Aged 65 or older
* Physical ability and willingness to execute a resistance exercise program
* Ability and willingness to comply with the protocol
* Willingness that general practitioner will be notified on study participation
* Written informed consent
* Consent of the study physician (ability to comply with the protocol in the opinion of the study physician, to ensure safety for the participants)

Exclusion criteria

* Inability to understand the Dutch language
* Cognitive impairment (MMSE <15)
* Diagnosed unstable coronary heart disease (CHD), decompensated heart failure, uncontrolled hypertension or uncontrolled arrhythmias (e.g. hart failure NYHA >3)
* Diagnosed degenerative neurocognitive disorders
* COPD GOLD >3
* Use of total parenteral nutrition (TPN)
* Active medical treatment interfering with this intervention (e.g. cancer patients following systemic and immune therapy)
* Physical disabled (walking aids or mild visual impairment are not an exclusion criteria)

* Current enrollment in a fixed rehabilitation program or other intervention studies
* Palliative treatment or a life expectancy of <=3 months

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-04-2021
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Physical activity monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2021

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	NL
CCMO	NL74601.029.20