ProMuscle in Practice: Effectiveness of a combined resistance exercise and nutrition intervention to promote maintenance of physical functioning of community-dwelling elderly in a real-life setting

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

Summary

ID

NL-OMON43073

Source
ToetsingOnline

Brief title
ProMuscle in Practice

Condition

- Other condition

Synonym
frailty, physical impairment

Health condition

fysieke kwetsbaarheid

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: FrieslandCampina,Innopastry,Ministerie van Economische Zaken;FrieslandCampina;Innopastry

Intervention

Keyword: Dietary protein, Older adults, Physical functioning, Resistance exercise

Outcome measures

Primary outcome

Change in physical functioning.

Secondary outcome

Effect evaluation, change in:

- Quality of life

- Muscle strength

- Muscle mass

- Protein intake

- Social participation

- Activities of daily living

- Behavioural determinants

Economic evaluation:

- Cost-effectiveness of the intervention compared to usual care, based on

effect on Short Physical Performance Battery score

- Cost-utility of the intervention compared to usual care, based on Quality Adjusted Life Years (QALY's).

Process evaluation:

The feasibility of the intervention in practice, based on the following process indicators:

- Acceptance of the intervention (both participants and professionals)
- Applicability of the intervention (professionals)
- Integrity of the intervention: extent to which the intervention is implemented as planned (professionals)
- Dose received: Attendance of the training for professionals (professionals), attendance of training sessions and consultations with the dietician, compliance in taking protein products during the intervention and maintenance phase (participants)
- Factors for success and failure

Study description

Background summary

Sarcopenia is the age associated loss of skeletal muscle mass and function. Loss of muscle mass and strength has several health consequences, such as reduced physical functioning, and a possible increased risk of development of chronic diseases. This can lead to difficulties with everyday activities, like walking stairs, rising from a chair and from a bed. Impairments in physical functioning can contribute to loss of independence, a higher chance to develop chronic metabolic diseases and a higher chance of institutionalisation. Those factors are important barriers for social participation and independent living. Research shows that the combination of resistance exercise training and protein supplementation are good strategies to counteract the loss of muscle strength,

muscle mass, and physical functioning in elderly people. Due to changes in the elderly care in the Netherlands the elderly are expected to live longer independently at home. In a previous phase, the experimental intervention has been adapted to fit the real-life setting and was pilot-tested for feasibility. In the current multicentre randomised controlled trial the (cost-)effectiveness and feasibility of an adapted experimental intervention, that combines resistance exercise and extra dietary protein intake, in a real-life setting (care).

Study objective

The primary objective of this study is to study the effectiveness of the adapted experimental intervention in a real-life setting on muscle- and health outcomes, and quality of life of community-dwelling (pre-)frail elderly. Furthermore, effectiveness of the maintenance program, and cost-effectiveness and cost-utility of the intervention will be assessed, compared to usual care. Feasibility and acceptance of the intervention at the different settings will also be extensively studied.

Study design

This study is a randomised, controlled, multicentre, phased intervention trial with a parallel design. The intervention group receives the combined nutrition and exercise intervention for 12 weeks, and subsequently a maintenance period of 12 weeks (in which they will be informed and familiarized with local exercise and nutrition options). The control group receives only usual care for the first 24 weeks, but also receives the 12 week maintenance period after 24 weeks. Effectmeasures, and measures related to care costs will be performed at baseline, after 12 weeks and after 24 weeks in both study groups, and also after 36 week. Follow-up measurements will be performed on healthcare use, quality of life and physical functioning in week 52 (only the first three locations). Process measures will be performed during the complete study period.

Intervention

All intervention-group participants will perform resistance exercise training and will increase their dietary protein intake, during week 1 * 12. The progressive resistance exercise trainings will be twice a week, for 1 hour per training, in a small training group. Participants receive intensive guidance from a physiotherapist during the training sessions; they pay attention to the safe and correct execution of the exercises. The training consists of a warming-up, exercises for the major muscle groups, and a cooling-down. The exercise intensity is tailored to the strength of the individual participants. The protein intake is increased based on advice by a dietician. This dietician advises the participant on increasing the protein intake in the main meals,

using protein rich products, which can be either added to the meal or used as a substitution for other products. The aim of the nutrition program is to achieve a protein intake of at least 25 grams at each main meal. Halfway during the intervention period, an evaluation consultation will be scheduled with the dietician, to evaluate the nutrition program and make adjustments to the advice if necessary.
During the maintenance period (week 13-24 for the intervention group, week 25-36 for the control group), participants are informed about and facilitated towards local exercise- and nutrition possibilities. This is done to help them to independently continue or start with the exercise and consumption of protein rich foods.

Study burden and risks

The study measures are non-invasive. Next to questionnaires and short interviews, a number of tests will be performed to assess muscle strength and physical functioning. Measurements will take some time and effort from the participants. The resistance exercise and maximal strength measures (3 *RM) are supervised by skilled trainers, who ensure safe performance of all exercises. The exercises will be tailored to the participants' abilities. These trainings might result in feelings of muscle soreness, but those will fade in a few days. The protein products are made from normal nutritional ingredients, are subject to strict safety regulations at FrieslandCampina and Innopastry, and will be tested according to the microbial specification for food safety for the specific products.
Since the trainings are twice a week for one hour at a time, subjects are able to continue to engage in their normal daily activities. There is no restriction in food products during the study. The protein products will be provided during the study, and choice will be offered through different types and flavours of products.
During the maintenance period, participants are free to do what they want, they are not forced to continue with the exercise or eating protein rich foods. Participants are free to stop with the study at any time, for any reason, if they wish to do so. Besides a financial compensation, it is expected that participants benefit from the intervention and maintenance period. Previous research showed that the combination of resistance exercise and protein improves muscle strength, muscle mass and physical performance. Being informed with facilities in the local community can help them to maintain a healthy lifestyle. Participants will receive an overview of their personal results on the tests that will be performed at the end of the 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

In order to participate in the study, individuals should be aged 65 years or over, living in one of the five selected municipalities, being able to understand Dutch, be pre-frail or frail based on Fried frailty criteria. Also non-frail elderly who do not fulfill the fitnorm and experience difficulties with activities of daily living will be included.

Exclusion criteria

The General Practitioner of the possible participant will check whether a person can safely participate in the study, based on the following exclusion criteria:;- Allergic or sensitive to milk proteins and/or lactose
- Clients with diagnosed COPD or cancer
- Clients with diabetes type I or type II that is unstable, not well regulated with medication, or who do not notice when they get hypoglycaemia
- Clients with hypertension (systolic blood pressure >160 mmHG) that is not well regulated with medication

- Clients with severe heart failure
- Clients with renal insufficiency (eGFR <30 ml/min)
- Clients with physical impairments that unable them to participate in exercise training
- Clients with cognitive impairments that unable them to understand and complete questionnaires
- Clients receiving terminal care
- Newly placed artificial hip or knee prosthesis, unless fully recovered
- Clients that had recent surgery (< 3 months) in whom the exercises might stress the surgery scars

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	02-08-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	01-12-2016
Application type:	Amendment

Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	14-09-2017
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	NL57373.081.16