ProMuscle 65PK: feasibility and potential impact of a physical activity and nutrition intervention in practice for community dwelling elderly people receiving home care: A pilot study

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

Summary

ID

NL-OMON42268

Source
ToetsingOnline

Brief title
ProMuscle 65PK pilot study

Condition

- Other condition

Synonym
frailty, Physical impairment

Health condition

Zorgbehoevende (kwetsbare) ouderen

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,FrieslandCampina,Zorggroep Noordwest-Veluwe

Intervention

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

Outcome measures

Primary outcome

The primary study outcomes focus on the feasibility of implementing the

intervention in practice (process evaluation):

- Acceptability of the intervention (participants and professionals)

- Applicability of the intervention (professionals)

- Implementation integrity: Extent to which the intervention is implemented as

planned in the implementation protocols (professionals)

- Dose received: The compliance of the participants to the trainings, and

whether the protein intake during the main meals is increased to 25 grams

(participants)

- Factors for success and failure

Secondary outcome

The secondary study outcomes are the changes after 12 weeks in the following

outcomes (participants):

- Muscle mass

- Muscle strength

- Physical functioning

- Activities of daily living (ADL)

- Quality of life

- Dietary intake

Study description

Background summary

Sacropenia 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, and thus an important barrier for social participation and independent living. Research shows that the combination of resistance exercise 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 the current pilot study it will be tested whether an adapted clinical effective intervention is feasible to implement in practice (care-setting).

Study objective

The primary objective of this pilot study is to study the feasibility of implementation of the ProMuscle 65PK in a real-life setting. Besides that, the potential impact of the intervention will be studied on muscle health and physical performance outcomes, and to verify whether a future effectiveness study should be performed.

Study design

This study is a pilot study of 12 weeks, with a one group pre-test post-test design, with on-going process measures.

Intervention

For twelve weeks, subjects will receive the ProMuscle 65PK intervention. All participants will perform both resistance exercise and increase their protein intake during the study. Subjects perform progressive resistance exercise twice

a week, one hour per training, in small groups. Trainings are supervised by certified physiotherapist; during performance of the exercises there is always one-on-one guidance. The trainings start with a warming-up, followed by exercises for the major muscles, and a cooling-down. The training intensity is always tailored to the individuals abilities. The dietary protein intake will be increased based on an advice of a dietician. The dietician advises how to increase the protein intake during the main meals, using protein-rich dairy products. They aim to reach at least 25 grams of protein during the main meals.

Study burden and risks

The study measures are non-invasive. Measurements will take some time and effort from the participants, but this is only at baseline and after the twelve weeks. The resistance exercise and maximal strength measures (3 -RM) are supervised by skilled trainers, that ensures safe performance of all exercises. The exercises will be tailored to the subjects abilities. These trainings might result in feelings of muscle soreness, but these will fade in a few days. The protein products are made from normal nutritional ingredients, are subject to strict safety regulations at FrieslandCampina, 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. After full completion of the study, subjects receive a small reward in the form of a credit note. The subjects can quit the study at any time, for any reason, if they wish to do so. Previous research showed that the combination of resistance exercise and protein improves muscle strength, muscle mass and physical performance in daily life. Subjects 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 of over, living in the municipality of Harderwijk, being able to understand Dutch, and have a care referral for at least one of the following types of care:
- Domestic care
- Personal care
- Nursing care
- Individual or group support

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 en/or lactose
- Clients with diagnosed COPD or cancer
- Clients with diabetes type I or type II that are unstable, not well regulated with medication, or do not notice when they get hypoglycaemia
- Clients with hypertension (systolic blood pressure >160 mmHG) that is not well regulated met medication
- Clients with severe heart failure
- Clients with renal insufficiency (eGFR <60 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 surgery scars

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	21-04-2015
Application type:	First submission
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	NL51834.081.14