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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Progressive resistance exercise and increased dietary protein intake enhances physical functioning, quality of life, muscle strength and lean body mass in frail elderly, in a real-life setting, and reduces healthcare costs/utilization.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28702

Bron
NTR

Verkorte titel
ProMuscle in Practice

Aandoening

Physical functioning, community-dwelling older adults

Fysiek functioneren, thuiswonende ouderen

Ondersteuning

Primaire sponsor: Wageningen UR Food & Biobased Research
Overige ondersteuning: Ministry of Economic Affairs, FrieslandCampina, Innopastry

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of this study is the change in physical functioning (Short Physical Performance Battery score).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale and objective:

The age related loss of skeletal muscle mass and muscle function can lead to a decrease in physical functioning, decreased independence, and subsequently increased health care costs. Previous clinical intervention studies have shown that the loss of muscle mass and strength in (frail) elderly can be counteracted using a combination of progressive resistance type exercise training and increased dietary protein intake. In a recent pilot study including both pre-frail and non-frail participants, such a combined intervention has been adapted to real life settings and successfully implemented. Before this adapted intervention program can be widely implemented in real life settings , its (cost)-effectiveness should first be verified and the implementation process should be further optimized to fit within current health care practice. Therefore, the present study aims to study the effectiveness of the adapted intervention and a behaviour maintenance period in (pre)frail community-dwelling elderly, as well as perform an economic and process evaluation in a real-life setting.

Study design: Randomised, controlled, multicentre, phased intervention trial with a parallel design.

Study population: 200 community-dwelling, (pre-)frail elderly (≥ 65 years) living in one of the five intervention municipalities.

Intervention: During the 12 week intervention period, the intervention group receives tailored progressive resistance exercise training twice a week (one hour per training). The trainings will involve small groups and will be guided by physiotherapists. In addition, dieticians will

provide individual dietary advice to increase protein intake to 25 grams of protein per main meal, using protein rich products. During the 12 weeks maintenance period, the intervention group is informed about local exercise- and nutrition facilities supporting maintenance of the new lifestyle. The control group receives no exercise- or nutrition guidance, and no referral to local exercise- or nutrition options during the first 24 weeks.

Main study parameters: The primary outcomes are differences in change in physical functioning between the intervention and control group, at 12 weeks (T1) and 24 weeks (T2). The secondary outcomes related to the effectiveness of the intervention include differences between the intervention and control group in change in muscle strength, muscle mass, quality of life, and social participation, at 12 weeks (T1) and 24 weeks (T2). Care use and Quality of Life is also assessed at week 6 and 18. For the economic evaluation, cost-effectiveness and cost-utility parameters, i.e. costs per effect (SPPB change) and QALY (defined by EQ5D), will be measured. Measures on effect outcomes and costs will also be performed at T3 in the control group. For the process evaluation process indicators including acceptability, applicability, implementation integrity, dose received, and factors for success and failure will be monitored.

Doel van het onderzoek

Progressive resistance exercise and increased dietary protein intake enhances physical functioning, quality of life, muscle strength and lean body mass in frail elderly, in a real-life setting, and reduces healthcare costs/utilization.

Onderzoeksopzet

Parameters are assessed in both intervention groups at baseline, 12 weeks and 24 weeks. Parameters are also assessed at 36 weeks in the control group. Process evaluation parameters are also collected during the intervention.

Onderzoeksproduct en/of interventie

The intervention subjects will receive a 12 week intensive intervention and a 12 week maintenance period. The intensive intervention consists of:

1) Twice weekly1-hour progressive resistance-type exercise training, in groups, supervised by physiotherapists

2) Increased dietary protein intake during the main meals, using protein-rich products, supervised by a dietitian

During the maintenance period the participants will be introduced to local exercise and nutrition facilities. Multiple activities will be organized to stimulate participants to maintain the active lifestyle and an adequate protein consumption.

The control group receives no treatment in the first 24 weeks, and will receive the maintenance period after 24 weeks.

Contactpersonen

Publiek

Bornse Weilanden 9

Esmée Doets
Wageningen 6708 WG
The Netherlands
0317-480262

Wetenschappelijk

Bornse Weilanden 9

Esmée Doets
Wageningen 6708 WG
The Netherlands
0317-480262

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Aged 65 years or over

- Living independently in one of the five selected municipalities

- Able to understand Dutch language

- Pre-frail or frail according to Fried criteria

- Having signed informed consent

- Additional for those not recruited via care organisation: reported loss of muscle strength

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Having an allergy for or being sensitive to milk proteins

- Being lactose intolerant

- Having diagnosed COPD or cancer

- Suffering from diabetes type 1 or type II that is unstable, not well regulated with medication, or not being able to notice when they get hypoglycaemia

- Suffering from hypertension (systolic blood pressure >160 mmHG) that is not well regulated with medication

- Suffering from severe heart failure

- Suffering from with renal insufficiency (eGFR < 60 ml/min)

- Having physical impairment that unable them to participate in the exercise training

- Having cognitive impairments that unable them to understand and complete questionnaires

- Receiving terminal care

- Having a newly placed artificial hip or prosthesis, unless fully recovered

- Having had recent surgery (< 3 months) in whom the exercises might stress the surgery scars

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-09-2016
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-08-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5858
NTR-old	NTR6038
Ander register	: METC-WU (16/12)

Resultaten

Samenvatting resultaten

n.a.