PILOT STUDY 1 'Prevention Of Malnutrition in Senior Subjects (PROMISS)'

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In this pilot study among community-dwelling older adults with lower protein intake (< 1.0 g/kg/body weight), we hypothesize that personalized dietary advice will increase protein intake in close proximity of usual physical activity.

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

Samenvatting

ID

NL-OMON22482

Bron
Nationaal Trial Register

Verkorte titel
PROMISS Pilot study 1

Aandoening

- Protein-energy malnutrition (PEM)

Ondersteuning

Primaire sponsor: Vrije Universiteit Amsterdam
Faculty of Science
De Boelelaan 1085
1081 HV Amsterdam
the Netherlands
Overige ondersteuning: European Commission at the 7th Framework Programme (H2020-SFS-2015-2)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters of this pilot experiment are:

1) the feasibility of a) the consumption of protein rich food products; b) the consumption of protein rich food products in close proximity of usual physical activity;

2) participants’ appreciation regarding the provided protein rich food products.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: With the European population growing older, the challenge is to keep an increasing number of seniors across all European countries healthy and active. In Europe, between 13.5 % and 29.7 % of older adults living at home are (at risk of) protein energy malnutrition (PEM), which results in serious health problems. This pilot study will be conducted to optimize the design and intervention strategies for the long term prevention trial which is part of the Horizon 2020 project PRevention Of Malnutrition In older Senior Subjects (PROMISS).

Objective: In this pilot study among 45 community-dwelling older adults aged ≥ 70 years with lower protein intake (< 1.0 g/kg/body weight), we will investigate: 1) Which strategy is most feasible to consume provided protein rich food products use; and 2) which strategy is most feasible to consume provided protein rich food products use in close proximity of usual physical activity by a) providing protein rich food products only; b) providing protein rich food products and to link timing protein rich food product intake to usual activity; or c) providing protein rich food products and to link timing of physical activity to protein rich food product intake; and 3) How are protein rich food products appreciated by community-dwelling older adults with lower protein intake.

Study design: A pilot study: randomized controlled trial with the duration of three weeks.

Intervention: This pilot study consists of three groups; the first group will be instructed to comply with the dietary strategies (i.e. consume provided protein rich food products); the second group will be instructed to comply with the dietary strategies and in addition link their daily food intake pattern to their daily physical activity pattern (for example, consume a specific protein rich food product after walking the dog instead of coffee); the third group will be instructed to optimize their physical activity pattern to their daily dietary pattern (for example, postpone walking to the dog just before consuming a specific protein rich food product). Participants from all groups will receive protein rich food products and personalized advice, taken into account participants food preferences, usual food intake and body mass index (BMI) in order to prevent food waste and under- or overfeeding.

Main study parameters/endpoints: The main study parameters of this pilot study are the feasibility of dietary and physical activity strategies, and the preferences of both the strategies and the provided protein rich food products of community-dwelling older adults.

Doel van het onderzoek

In this pilot study among community-dwelling older adults with lower protein intake (< 1.0 g/kg/body weight), we hypothesize that personalized dietary advice will increase protein intake in close proximity of usual physical activity.

Onderzoeksopzet

The pilot experiment consist of 5 timepoints:

1) (three weeks prior to study baseline): Telephone screening;

2) (two and a half weeks prior to study baseline): Home visit;

3) (study baseline): Clinic visit;

4) (one week after study baseline): Telephone interview;

5) (end of study): Clinic visit.

Onderzoeksproduct en/of interventie

The pilot study is a 3-week, parallel, randomized controlled trial with three intervention arms. Community-dwelling older adults will be randomly assigned to one of the three intervention arms, stratified by sex:

Group 1: Participants will be provided with selected protein rich food products;

Group 2: Participants will be provided with selected protein rich food products and personalized advice to link protein rich food product intake to usual activity;

Group 3: Participants will be provided with selected protein rich food products and personalized advice to link timing physical activity to protein rich food product intake.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 70 years

- Community-dwelling

- Lower protein intake (< 1.0 g/kg/body weight) based on a short food list that is developed and validated using an extended FFQ among Dutch older adults (data available on request)

- Able to eat independently

- Willing to eat our provided products

- Able to speak, write and read the Dutch language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Bedridden or wheelchair bound

- Individuals who do not go outside

- Diagnosed severe kidney disease

- History of active malignancy (with the exception of basal cell carcinoma);

- Low cognitive status (MMSE score < 18)

- Overnutrition, defined as BMI > 30.0 kg/m2

- Vegans

- Allergies to certain food products (such as peanuts, gluten)

- Current participation to supervised behavioral or lifestyle interventions that intervene with PROMISS interventions;

- Planned to move out of the study area in the next 3 weeks

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	25-09-2017
Aantal proefpersonen:	45
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	24-11-2017
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	NL6737
NTR-old	NTR6915
CCMO	NL 678732

Resultaten