PILOT STUDY 2: Prevention Of Malnutrition In Senior Subjects (PROMISS)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21853

Source
NTR

Brief title
PROMISS Pilot study 2

Health condition

Protein-energy malnutrition
Community-dwelling older adults
Randomized controlled trial
Pilot study
Feasibility

Energie-eiwit ondervoeding
Thuiswonende ouderen
Gerandomiseerde interventie studie
Pilot studie
Haalbaarheid

Sponsors and support

Primary sponsor: Funding for this paper was provided by the European Horizon 2020 PROMISS Project ‘PRevention Of Malnutrition In Senior Subjects in the EU’, grant agreement no. 678732.

Source(s) of monetary or material Support: European Commission at the 7th Framework Programme (H2020-SFS-2015-2)

Intervention

Outcome measures

Primary outcome

The main study parameter of this pilot study is change in total protein intake (g/day and g/kg aBW/day).

Secondary outcome

Secondary parameters are potential adverse outcomes of the dietary strategies. We therefore examined change in appetite, change in BW and change in micronutrients (vitamin D and vitamin B12).

Study description

Background summary

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. The overall aim of the Horizon 2020 project PRevention Of Malnutrition In older Senior Subjects (PROMISS) is to better understand and ultimately prevent PEM in seniors, by developing optimal, sustainable and evidence-based dietary and physical activity strategies to prevent malnutrition and enhance active and healthy aging.

This pilot study was conducted to optimize the design and intervention strategies for the long-term prevention trial which is part of PROMISS. The main aim of this pilot study was to examine and compare the feasibility of an ‘even’ or ‘peak’ dietary advise strategy to increase protein intake after four weeks among community-dwelling older adults.

Study objective

Participants from both the intervention groups will increase their protein intake more than participants in the control group.

Study design

4 measurements:

- 1 Telephone interview (screening)
- 1 Pre-baseline visit at the university
- 1 Baseline visit at the university
- 1 Follow-up visit at the university

Intervention

This pilot study consists of three groups; two intervention groups and one control group.

Participants (n = 60) were randomized into one of the three groups; two intervention groups (‘even’ or ‘peak’ strategy) and one control group. Participants of both intervention groups received personalized dietary advice and protein enriched food products to increase their protein intake to 1.2 g/kg adjusted body weight (aBW)/day, or with 0.3 g/kg BW/day when current intake was between 0.9 – 1.2 g/kg aBW/day. The ‘even’ group was advised to consume an equal relative amount of protein during each meal and snack while the ‘peak’ group was advised to consume at least one daily meal with 35-45 g of protein.

All groups received a standard brochure of the Netherlands Nutrition Centre with general information about healthy eating habits. The control group (N=20) receives no further intervention.

Contacts

Public
Vrije Universiteit Amsterdam
Ilse Reinders

Vrije Universiteit Amsterdam
Faculty of Science
De Boelelaan 1085, kamer O-526

Amsterdam 1081 HV
The Netherlands
+31205986969
Scientific
Vrije Universiteit Amsterdam
Ilse Reinders

Vrije Universiteit Amsterdam
Faculty of Science
De Boelelaan 1085, kamer O-526

Amsterdam 1081 HV
The Netherlands

+31205986969

Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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)
- Obesity, 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
- Vacation plans for more than 5 days
- Planned to move out of the study area in the next 8 weeks

Study design

Design

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

Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2018
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-11-2017
Application type:	First submission

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
NTR-new	NL6679
NTR-old	NTR6849
CCMO	NL 678732

Study results