The (cost) effectiveness of increasing daily protein intake to 1.2 gram per kilo body weight on physical functioning in community-dwelling older adults with a habitual daily protein intake < 1.0 gram per kilo body weight

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

Summary

ID

NL-OMON48815

Source
ToetsingOnline

Brief title
Effectiveness of protein intake on physical funtioning

Condition

- Other condition

Synonym
Physical functioning

Health condition

Fysiek functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: European Union□s Horizon 2020 research and innovation programme;grant n° 678732.

Intervention

Keyword: community-dwelling older adults, effectiveness, physical functioning, protein intake

Outcome measures

Primary outcome

The primary outcome of this study is change in walk time on the 400 meter walk

test.

Secondary outcome

Secondary outcomes are change in dietary intake (including macro- and

micronutrients), malnutrition prevalence, physical performance, mobility

limitations, muscle strength, body weight and body composition, frailty status,

quality of life, and health care costs.

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. Low protein intake is associated with accelerated loss of lean mass, and an increased risk of functional impairments in old age. The long term effect of increasing protein intake to 1.2 g/kg body weight/d on physical functioning in community-dwelling older adults with habitual low protein intake has hardly

been studied.

Study objective

In this RCT with the duration of 6 months we will examine the longterm (cost) effectiveness of increasing protein intake to 1.2 g/kg body weight/d on physical functioning in community-dwelling older adults with a habitual protein intake < 1.0 g/kg body weight/d. Additionally, we will examine the combined effect of increasing protein intake to 1.2 g/kg body weight/d and consuming protein in close proximity with usual physical activity on physical functioning.

Three sub-studies will be conducted, of which the main objectives are to:
1. Examine the effect of persuasive technology on adherence to increasing protein intake to 1.2 g/kg body weight/d, and to the combination of increasing protein intake to 1.2 g/kg body weight/d and consuming protein in close proximity with regular physical activity;
2. Examine the effect of increasing protein intake to 1.2 g/kg body weight/d on faecal microbiota composition;
3. Examine the effects of increasing protein intake to 1.2 g/kg body weight/d on food-stimuli related central nervous system (CNS) satiety and reward responses, measured by functional magnetic resonance imaging (fMRI).

Study design

Randomized controlled trial with the duration of 6 months in two study sites: Amsterdam, the Netherlands and Helsinki, Finland.

Intervention

This RCT consists of three groups; two intervention groups and one control group. Intervention group 1 (N=44 at each study site) will receive personalized dietary advice aimed at increasing protein intake to 1.2 g/kg body weight/d without changing daily energy intake, by regular foods and by provided protein-enriched food products. Intervention group 2 (N=44 at each study site) receives personalized dietary advice similar to group 1 and also receives personalized advice to consume protein rich foods in close proximity of usual physical activity. All groups receive a standard brochure of the Netherlands or Finnish Nutrition Centre with general information about healthy eating habits. The control group (N=44 at each at each study site) receives no further intervention.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
- Participants in both intervention groups will receive personalized advice

from a registered dietician to increase their protein intake to 1.2 g/kg body weight/d. In this advice, food preferences and usual food intake are taken into account. All advice will be energy-neutral to prevent increases or decreases in body weight. Participants will be requested to adhere to this advice for six months.

- Participants in intervention group 2 will receive personalized advice from a registered dietician to increase their protein intake to 1.2 g/kg body weight/d as well as advice regarding the consumption of protein rich food products in close proximity of usual physical activity. Participants will be asked to not change their usual physical activity pattern, but only adjust the timing of the consumption of protein rich food and physical activity.

- Participants in both intervention groups will receive protein-enriched food products for free. The contents of the provided protein-enriched food products will be similar to that available in over-the-counter products, thereby presenting no health risks to the participants.

- Participants in the control group will receive a standard brochure of the Netherlands Nutrition Centre with general information about healthy eating habits and a present.

- All participants will be invited to different lectures on topics that are not related to food intake.

- Measurements will take place at baseline, mid-study (3 months) and follow-up (6 months) at the university. This will involve 1.5 hour assessments.

- Physical activity will be measured seven days at baseline, mid-study and follow-up by means of an accelerometer.

- Food intake will be measured three days at baseline, mid-study and follow-up by means of dietary recalls supported by food diaries.

- Participants from the intervention groups will have an extra appointment at the university where they will receive a personalized high-protein diet advice and protein-enriched food products at study baseline and at mid-study.

- During the study, we will call all participants frequently to ask for any experienced difficulties with the intervention and provide additional (nutritional) advice if needed. Participants can contact us by mail or telephone at any time during the study.

- In the persuasive technology sub-study conducted in a Dutch sub-sample of participants of the intervention groups (n=24 per intervention group), participants will receive a food storage box that can measure which protein rich food products are taken out and a small-size screen (tablet) that provides

reminders and nudges. We will test if there are differences in adherence to the interventions between participants who took part in this sub-study and participants who did not.

- In the microbiota sub-study (as many subjects as possible) conducted in a Dutch sub-sample of participants from the control group and intervention group 1 (increasing protein intake to 1.2 g/kg body weight/d), tongue swabs and faecal samples will be collected at baseline and follow-up to determine the effect of a long term high-protein dietary intervention on faecal and oral microbiota. Participants will receive a ¤20,- VVV-gift card for participating in this part of the study.

- In the fMRI sub-study conducted in a sub-sample of the Dutch participants that also participate in the microbiota sub-study (control group and intervention group 1) (n=25), blood samples will be drawn and participants will take part in a functional magnetic resonance imaging (fMRI) measurement at baseline and follow-up to determine the effects increasing protein intake to to 1.2 g/kg body weight/d on food-stimuli related central nervous system (CNS) satiety and reward responses. Participants will receive an addition of a ¤80,- VVV-gift card for participating in this part 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

- Age * 65 years;
- Community-dwelling;
- Lower protein intake defined as both a probability score above a certain cutoff on the protein screener (www.proteinscreener.nl) as well as based on actual protein intake assessed by 24-hour recalls. The protein screener was developed and validated using an extended FFQ among Dutch older adults. The cutoff will be chosen based on results of different studies in which we compare the probability scores of the protein screener with protein intake as measured with food diaries and/or dietary recalls. We will then choose the probability score that is most closely associated with a protein intake < 1.0 g/kg body weight/day. This probably score reflects older adults with a higher probability on a protein intake < 1.0 g/kg body weight/d than a general sample of older adults;
- Able to eat independently;
- Willing to eat our provided protein-enriched food products and change food habits;
- Able to speak, write and read the Dutch language;
- Able to walk 400 meter, with or without the help of a walking cane (self-reported).

Exclusion criteria

- Bedridden or wheelchair bound;
- Individuals who do not go outside;
- Individuals with bad hearing (who cannot hear without a hearing aid);
- Diagnosed with diabetes mellitus type I;
- Diagnosed with diabetes mellitus type 2 and starting with insulin;
- Diagnosed with severe kidney disease;
- Diagnosed with Parkinson*s disease;
- Current treatment of cancer (with the exception of basal cell carcinoma);
- BMI < 18.5 kg/m2 (self-reported, and assessed at study baseline);
- Overweight, defined as BMI > 32.0 kg/m2 (self-reported, and assessed at study baseline);
- Vegan;
- Allergies to certain food products (such as peanuts, gluten);
- Alcohol abuse past 6 months (AUDIT-C * 2);
- Diagnosed with an eating disorder (self-reported);
- Current participation to supervised behavioral or lifestyle intervention that intervenes with PROMISS intervention;
- Planning to move out of the study area in the next 6 months;

- Actively trying to lose or gain weight;
- Not able to complete the 400 meter walk test (self-reported, and assessed at study baseline).

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2018
Enrollment:	132
Type:	Actual

Medical products/devices used

Generic name:	Bodystat 1500MDD - bioelectrical impedance analysis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-10-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	ClinicalTrials.gov [not yet assigned] - Release Date: July 2nd, 2018
CCMO	NL65484.029.18

Study results

Date completed:	31-07-2020
Actual enrolment:	132

Summary results
Trial is onging in other countries