

Testing the opportunity to reach daily protein intake recommendations of older adults with regular, protein-enriched foods: the Good Meal study.

Published: 07-09-2015

Last updated: 16-04-2024

To study the effectiveness of protein-enriched meals and bread in increasing daily protein intake with at least 14.5g among in-home assisted community-dwelling older adults, in order to reach the daily protein recommendation of 1.2g per kg...

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

Summary

ID

NL-OMON43656

Source

ToetsingOnline

Brief title

Good Meal

Condition

- Other condition

Synonym

Undernutrition

Health condition

Voldoen aan eiwitbehoefte van ouderen ter voorkoming van ondervoeding.

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Dienst Landbouwkundig Onderzoek - Wageningen UR Food & Biobased Research

Source(s) of monetary or material Support: Food Connect BV, Plesmanweg 28, Almelo, Wageningen UR; Ministerie van Economische Zaken; graduate school VLAG.

Intervention

Keyword: Community-dwelling older adults, Enriched regular products, Protein intake

Outcome measures

Primary outcome

Our main parameter of interest is total daily protein intake throughout three weeks.

Secondary outcome

Our secondary study parameters are total daily nutritional intake and product evaluation throughout three weeks.

Study description

Background summary

Undernutrition risk among community-dwelling older adults in developed countries is shown to be as high as 24%, making the aging process unpleasant for many around the world. The main cause of undernutrition was found to be protein-energy wasting among older adults. This wasting is mainly induced by three processes: a reduced capacity to exploit proteins because of impaired anabolic and insulin responses, an increased physiological need for proteins due to a lifelong cumulative physical decline, and a reduced energy and protein intake. Counteracting the reduced protein intake is a strategy that is feasible as well as efficacious to reduce undernutrition in community-dwelling older adults. A promising strategy to increase protein intake among older adults, is to offer solutions that are close to their current daily eating patterns.

Study objective

To study the effectiveness of protein-enriched meals and bread in increasing daily protein intake with at least 14.5g among in-home assisted community-dwelling older adults, in order to reach the daily protein recommendation of 1.2g per kg bodyweight per day. In addition, to study longer-term liking of protein-enriched meals and bread among in-home assisted community-dwelling older adults.

Study design

The study will be performed as a double-blind, randomized, controlled, three-week trial in a real life setting, with one control and one intervention group.

Intervention

The control group will receive ten standard meals and ad libitum standard bread during two weeks within a total trial period of three weeks. The intervention group will receive ten protein-enriched meals and ad libitum protein-enriched bread during two weeks within a total trial period of three weeks.

Study burden and risks

The risks associated with participation can be considered negligible and the burden can be considered minimal. Firstly, the interventional products that we apply are expected to be beneficial for the residents. Secondly, normal food products are used that are produced by food companies, with the use of regular ingredients. Consequently, the regular hygienic and food safety criteria are valid during their production, as the meals and bread are food-grade produced and tested according to the food safety regulations. Therefore, we do not expect any potential risks regarding the products themselves. Thirdly, no invasive measurements will be performed. By a respectful approach, the questions with regard to items eaten during the day may even be perceived as a pleasant social activity. In addition, participants receive meals and bread during two weeks, which yields time because participants do not have to cook and have less groceries to do. This study is group related, since there is no use in testing longer-term acceptability and intake protein-enriched ready meals and bread without participation of the ultimate target group, in-home assisted community-dwelling older adults.

Contacts

Public

Stichting Dienst Landbouwkundig Onderzoek - Wageningen UR Food & Biobased Research

Bornse Weilanden 9
Wageningen 6708 WG
NL

Scientific

Stichting Dienst Landbouwkundig Onderzoek - Wageningen UR Food & Biobased Research

Bornse Weilanden 9
Wageningen 6708 WG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Aged 65 years or over;
- Living independently in a residential care centre;
- Being able to choose their food by themselves;
- Being able to eat by themselves;
- Being able to understand Dutch;
- Having signed informed consent.

Exclusion criteria

- Legally incapacitated;
- Unwilling to give permission to contact their GP regarding their eligibility;
- Mini Mental State Examination score <24;
- Not liking whole wheat bread or not liking at least five of the eight offered meals;
- Having an allergy/intolerance for milk, lactose, soy, or gluten;
- Following a diet that does not allow the use of normal bread or meals (e.g. fluid diet, strong sodium restricted diet);
- Suffering from renal insufficiency (eGFR < 60 ml/min);

- Suffering from a terminal illness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2015
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO	
Date:	07-09-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	
Date:	01-04-2016
Application type:	Amendment
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

CCMO

ID

NL52857.081.15