Dietary Fibre Longer Term Study: An intervention to study the effect of 2 weeks of supplementation of a high gelling-high viscous dietary fibre on energy intake

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To study the effects of 2 weeks of supplementation with high gelling-high viscous fibre on energy intake in healthy subjects compared to a placebo with similar texture.

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

Summary

ID

NL-OMON35389

Source
ToetsingOnline

Brief title
FLiTS study

Condition

- Other condition

Synonym
energy balance, satiety

Health condition

verzadiging, energiebalans

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: energy intake, fermentation, satiety, viscous fibre

Outcome measures

Primary outcome

Primary parameter: difference in ad libitum energy intake between 15 days of pectin or placebo supplements.

Secondary outcome

Secondary parameters: differences in 24h feelings of satiety, fasting blood glucose, insulin and leptin, body weight, fermentation, composition of microflora, and differences in acute effects of fibre intake.

Study description

Background summary

Dietary fibre seems to have a relevant role in body weight management. In an acute study we found that high viscous-high gelling pectin increased feelings of satiety. It is hypothesized that, as a consequence of increased feelings of satiety, the fibre may reduce energy intake on a longer term.

Study objective

To study the effects of 2 weeks of supplementation with high gelling-high viscous fibre on energy intake in healthy subjects compared to a placebo with similar texture.

Study design

Double blind, randomized crossover trial with 2 treatments. Each subject will ingests 2 times 15 subsequent days either placebo or pectin supplements on top of their regular diet. The first 2 days and the last 3 days of each treatment period ad libitum energy intake will be measured.

Intervention

The supplements will consist of a low energy dairy product. The supplemented fibre is 10g high-gelling-high viscous pectin. The placebo is gelatin, to provoke a similar texture. Gelatin will be digested in the upper gastrointestinal tract.

Study burden and risks

The intervention is non-therapeutic to the participant. The risk associated with participation is negligible and the burden can be considered as moderate. At screening the following measurements and questionnaires will be taken: inclusion questionnaire (1x), Dutch Eating Behaviour Questionnaire (1x), height, weight (1x), fasting glucose (1x). During the intervention study over 2 periods of 16 days, subjects will take dietary supplements each day once, and come to the university on 5 days in both periods to consume all meals provided by us. Between the 2 periods there is a wash out period of 2 weeks. In both intervention periods the following measurements and questionnaires will be taken: appetite/satiety questionnaires over 1 day waking hours (2x), breath samples over 1 day waking hours (2x), blood samples (3x), fecal samples (2x), body weight (5x), and a pedometer is worn for 5 days.

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: 18-30 year
• BMI: 18.5-25 kg/m2
• Healthy: as judged by the participant

Exclusion criteria

• Weight loss or weight gain of more than 5 kg during the last 2 months
• Using an energy restricted diet during the last 2 months
• Lack of appetite for any reason
• Restrained eater: for men >2.89 and for women >3.39, measured by DEBQ
• Smoking
• Heavy alcohol use: >5 drinks/day
• Reported stomach or bowel disease (e.g. IBS)
• Reported diabetes
• Reported thyroid disease or any other endocrine disorder
• Using medication other than birth control, paracetamol, aspirine, hey feaver and asthma
• Antibiotic use <2 months before the study
• Current dietary fibre supplementation
• Fasting glucose levels >5.8 mmol/l

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2012
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2011
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	03-02-2012
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	ID
CCMO	NL38515.081.11