Effecten van oligofructose (OF) supplementen op lichaamsgewicht en lichaamssamenstelling

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23700

Source
Nationaal Trial Register

Brief title
ENOF

Health condition

Overweight, Obesity

Sponsors and support

Primary sponsor: Wageningen University
Source(s) of monetary or material Support: SENSUS B.V.

Intervention

Outcome measures

Primary outcome

Difference in change of body weight and fat mass between control and oligofructose group after 12 weeks of supplementation.

Secondary outcome

24-h food intake, 24-h appetite, chronic appetite, physical activity

Study description

Background summary

Rationale: Based upon fermentation processes in the intestinal tract, food containing soluble dietary fibres, such as inulin or oligofructose, may limit energy intake and decrease adiposity in humans.
Objective: To study the effect of 12 weeks of supplementation of oligofructose at a dosage of 16 g/d versus placebo on body weight and body composition in overweight and obese men and women.

Study design: A 12 week, double-blind, randomized placebo-controlled parallel study. The study population will be randomly assigned to receive one of two interventions: 1) control granola bar (no oligofructose) or 2) granola bar with added oligofructose (16 g/d). Body weight, body composition, energy intake and appetite will be measured during the study, as well as gastrointestinal function and overall acceptability of the intervention.
Study population: 60 healthy males and females aged 20 – 60 y with a BMI > 25 kg/m2.

Intervention: Subjects receive either 16 g oligofructose or no oligofructose daily for 12 weeks. The dietary supplement will be consumed as a granola bar twice a day (8 g of oligofructose or no oligofructose per bar).

Main study parameters/endpoints: Difference in change of body weight and fat mass between control and oligofructose group after 12 weeks of supplementation.

Study objective

Het lichaamsgewicht van mensen die 12 wk lang hun snacks vervangen voor muesli repen met toegevoegd OF zullen een lager lichaamsgewicht hebben dan mensen die 12 wk hun snack vervangen door een muesli reep zonder OF.

Study design

0, 1, 6, 12 wk

Intervention

Subjects receive either 16 g oligofructose or no oligofructose daily for 12 weeks. The dietary supplement will be consumed as a granola bar twice a day (8 g of oligofructose or no

oligofructose per bar).

Contacts

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Eligibility criteria

Inclusion criteria

Men and women

Age 20 – 60 years

BMI 25-35 kg/m2

Healthy: as judged by the participant

Exclusion criteria

Reported cardiovascular, liver, pancreas, renal, thyroid or gastrointestinal disease

Reported diabetes type 1

Unstable type 2 diabetes, hypertension or dyslipidaemia

Medication that can interfere with the experiment (antibiotics, appetite suppressors, weight loss supplements)

Gain or loss of more > 5 kg in the 3 months prior to study entry

Lack of appetite for any reason

Women: pregnant or lactating

Fasting glucose concentration >6.9 mmol/l

Total cholesterol >6.5 mmol/l

Triglycerides >2.2 mmol/l

Glucose or protein in urine

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2013
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-07-2013

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	NL3878
NTR-old	NTR4075
CCMO	NL45006.081.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A