A double-blind, randomized, placebo-controlled, crossover study on the effect of a dietary oil composition on food intake

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The primary objective of the present study is to investigate the effect of the fat emulsion on energy intake at lunch.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON35155

Source
ToetsingOnline

Brief title
Effect of a dietary oil composition on food intake

Condition

- Appetite and general nutritional disorders

Synonym
food intake, satiety

Research involving
Human

Sponsors and support

Primary sponsor: DSM Nutritional Products
Source(s) of monetary or material Support: bedrijfsleven

Intervention

Keyword: dietary oil, food intake, satiety

Outcome measures

Primary outcome

The primary objective of the present study is to investigate the effect of the

fat emulsion (6 gram and 12 gram) versus placebo on energy intake at lunch

Secondary outcome

Secondary objectives are to investigate the effect of the fat emulsion (6 gram

and 12 gram) versus placebo on:

• Energy intake at dinner (MJ)

• Energy intake at lunch and dinner (MJ)

• Energy intake at the second day (MJ) (self-reported)

• Hunger and satiety (self reported)

Study description

Background summary

Overweight and obesity are global problems. Weight loss or prevention of weight gain can be achieved by reducing energy intake or increasing energy expenditure. Food ingredients that influence the mechanisms that regulate satiety may play a role in weight management. One of the ingredients that are associated with short term reductions of food intake and appetite suppression is a fat emulsion of dietary oils. It is used as a food ingredient and claimed to reduce appetite and food intake. The main hypothesis tested is that this mixture reduces energy intake at lunch.

Study objective

The primary objective of the present study is to investigate the effect of the fat emulsion on energy intake at lunch.

Study design

The study is designed as a randomized, double-blind, placebo-controlled, cross-over study.

Total study duration will be 3 weeks. In total 40 subjects will visit TNO 4 times. At 3 visits they will stay in the research facility during ca. 10 hours, and at the fourth visit they will hand in the food diary of the day following the 3rd visit.
The first three visits are every week on the same day of the week: day 01, day 08, and day 15.

Intervention

The study comproises three treatments:
* 6 gram vegetable fat emulsion;
* 12 gram vegetable fat emulsion; and
* a placebo.

The vegetable fat emulsion has been studied already in various doses in several studies,. In the present study the product will be used as powder that needs to be dissolved in water. The product will be consumed as breakfast in the morning of each testday, after consumption of 250 g yoghurt.

Study burden and risks

Healthy volunteers will not particularly benefit from participation in this study. By participation a volunteer will contribute to gaining knowlegde about efficacy of the testsubstance on energy intake.

Volunteers will be asked to come 3 times a whole day to TNO for intake of the testsubstance at breakfast. They will also consume lunch and diner at TNO. They are free to consume as much as they like, and therefore the burden is considered to be low. They are asked to fill in several questionnaires and diaries, which demands a certain level of disciplin. However, these are considered to be at an acceptable level and the financial compensation takes this into acccount.

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

1. Healthy as assessed by the TNO health & lifestyle questionnaire and limited physical examination
2. Male or female, age * 18 and * 30 years at Day 01 of the study
3. Body Mass Index (BMI) * 20 and * 27 kg/m2
4. Normal Dutch eating habits; consuming mostly three main meals per day
5. Non restrained eater, defined as the following scores on cognitive restraint according to the Dutch Eating Behaviour Questionnaire: men with a DEBQ-restraint score of <=2.37; women (BMI <26 kg/m2) DEBQ-restraint score <=3.24; women (BMI >=26 kg/m2) DEBQ-restraint score <=3.41)
6. Voluntary participation
7. Having given their written informed consent
8. Willing to comply with the study procedures
9. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years
10. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned

Exclusion criteria

1.Having a history of medical or surgical events that may significantly affect the study outcome, including metabolic or endocrine disorders, gastro-intestinal disorders, eating behaviour disorders.
2. Any prescribed medication with the exception of incidental use of pain killers and use of (oral) contraceptives
3. Intolerance or allergy to milk products
4. Alcohol consumption > 28 units/week for males or > 21 units/week for females
5. Smoking
6. Coffee consumption of > 8 cups/day
7. Reported unexplained weight loss or weight gain of > 2 kg in the 2 months prior to start of the study
8. Reported slimming or medically prescribed diet
9. Reported vegan, vegetarian or macrobiotic diet
10. Pregnant or lactating or wishing to became pregnant during the study period
11. Participation in any clinical trial including blood sampling and/or administration of substances up to 30 days before Day 01 of this study.
12. Participation in any clinical trial including blood sampling and/or administration of substances during the conduct of this study.
13. Personnel of TNO, location Zeist, their partner and their first and second degree relatives
14. Not having a general practitioner
15. Not willing that one*s physician will be informed about participation in this study
16. Not willing to accept information-transfer concerning information regarding a subject*s health (laboratory results, findings at anamnesis or physical examination and eventual adverse events) to and from a subject*s general practitioner.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-12-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	14-11-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL38612.028.11