Food preference.

No registrations found.

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

Summary

ID

NL-OMON27486

Source Nationaal Trial Register

Brief title N/A

Health condition

Visceral obesity, stress

Sponsors and support

Primary sponsor: NUTRIM, Maastricht University, Maastricht, The Netherlands Top Institute Food and Nutrition, Wageningen, The Netherlands **Source(s) of monetary or material Support:** na

Intervention

Outcome measures

Primary outcome

The main study endpoint is the effect of acute and long-term consumption of highly rewarding foods on the physiological stress response and relevant reward related brain areas, on rewarding value of other foods and food intake in visceral overweight subjects.

Secondary outcome

Study description

Background summary

Rationale:

Obesity is rapidly developing into a great threat of epidemic proportions. Especially visceral obesity is a key component in the development of the metabolic syndrome. Obesity develops due to an exceeding food intake compared to the energy requirements and especially visceral obesity is often correlated to stress. Stress is indicated by an increased 'hypothalamic-pituitary-adrenal-axis' (HPA-axis) activity, represented by an increased concentration of its end product, cortisol. Visceral obese subjects have higher serum cortisol levels in comparison to normal weight people. In stressed conditions they choose foods high in fat and carbohydrates because these foods have a high rewarding value. However, foods high in carbohydrates may increase the stress (cortisol)-response even more in visceral obese subjects thereby inducing a vicious cycle. To break the vicious cycle that stress causes in visceral obesity, the relationship between food choice and stress response (cortisol levels) needed to be clarified and quantified. In order to do this, first the rewarding value of foods needed to be quantified (MEC 07-3-053).

The rewarding value is represented as brain activity in certain brain areas that have been described previously in the literature. To identify the exact brain areas that are involved and to quantify the representation of the rewarding value of foods in the brain, a computer game was played while 'functional magnetic resonance imaging' (fMRI) was performed in different conditions (stress vs. rest) within different subjects (visceral overweight vs. normal weight). The computer game gave us the ability to determine the rewarding value of foods and explain the food choice. The involved brain areas were identified with the fMRI.

First results show that visceral overweight subjects in stress and in the absence of hunger prefer and consume foods that are crispy, full of taste, high in fat and carbohydrate, in contrast to normal weight subjects. Moreover, reward related brain areas such as the putamen show reduced activation. A study completed by Martens et al. (MEC 08-3-076) showed that carbohydrates increased cortisol, while protein and fat did not when compared with control (water). A study by Vicennati et al. (2002) showed that, in contrast to a high protein/fat meal, a high carbohydrate meal significantly increased the cortisol levels in visceral obese subjects. Moreover, Lacroix et al. (2004) showed that in rats high protein/fat foods reduced cortisol levels. Further research aims to determine the effects of consumption of highly rewarding (crispy, full of taste) high protein/fat foods compared with high carbohydrate foods on the stress response and on the representation of rewarding/satiating effects of those foods in the brain, on food preference, food choice and food intake, acutely and in the long-term.

Objective:

This study focuses on visceral overweight and stress, related to intake of highly rewarding foods and food choice. The main objective of the study is determination of the effects of consumption of highly rewarding high protein/fat foods compared with high carbohydrate foods on the physiological stress response (cortisol) and on the representation of rewarding/satiating effects of those foods in the brain, on rewarding value of other foods and food intake, acutely and in the long-term.

Study design:

The study has a 4-arm cross-over design, with randomized conditions. Conditions are rest or stress with the consumption of high protein/fat foods and rest or stress with the consumption of high carbohydrate foods. The subjects are brought in the rest or stress condition and will subsequently play a computer game in the fMRI apparatus. The computer game is used to determine the rewarding value of food while fMRI measures the representation of this rewarding value in the brain. Per condition, the fMRI session consists of two parts (30 min each), one before and one after the meal. Stress and rest conditions are induced with a mathematical test. The rewarding value of food is compared between normal weight and overweight subjects in all the different conditions. Hereby the relationship between visceral overweight and food choice in stress and rest conditions will be quantified. Each test-session 5 blood samples of 5 ml each are taken for cortisol concentration measurements that represent the HPA-axis activity.

Subjects will be tested in stress/rest, in high protein/fat vs. carbohydrate condition, before and after a dietary phase (\geq 4 weeks) of daily protein/fat vs. carbohydrate-consumption as snacks.

In total the study consists of 3 times 4 test-sessions per subject: before and after the dietary phase of daily protein/fat-snack consumption (or carbohydrate) and after the dietary phase of daily carbohydrate-snack consumption (or protein/fat). A complete test-session takes 3.5 h.

Study population:

The study population consists of 40 healthy right-handed subjects, both genders, age 18-55 years, with a normal weight (n=20, 2090cm, women >80cm), that do not have any metals in the body and are able to play a standard memory game.

Study objective

This study focuses on visceral overweight and stress, related to intake of highly rewarding foods and food choice. The main objective of the study is determination of the effects of consumption of highly rewarding high protein/fat foods compared with high carbohydrate foods on the physiological stress response (cortisol) and on the representation of rewarding/satiating effects of those foods in the brain, on rewarding value of other foods and food intake, acutely and in the long-term.

We hypothesize that consumption of high protein/fat foods, in contrast to high carbohydrate foods, does not increase the physiological stress response, the effort for reward and food intake.

Study design

2 years.

Intervention

1. Stressed condition:

The stressed condition is a situation where the subjects are brought in a state of actual mental stress. The control condition is a condition of rest applied to the same subjects. The two conditions will be compared.

2. High protein/fat vs. carbohydrate consumption:

During the test-sessions (meal) as well as on a daily basis (snacks) subjects will consume high protein/fat vs. high carbohydrate foods. The food items will be highly rewarding, i.e. full of taste, creamy and crispy.

For the high protein/fat foods subjects will receive commercial (in the shops available) gouda cheese ('Frico Slankie 20+') and sausages ('salami Plus huismerk'). For the high carbohydrate foods subjects will receive commercial (in the shops available) biscuits: 'Salted biscuits Tuc Pocket Lu' and 'Wasa sandwich cream cheese & chives'.

The amount of foods consumed will be calculated according to the subjects daily energy requirements, 25 % per test-meal during the test-days and also 25% per day during the snack-dietary phase of daily consumption (42). Daily energy requirements are calculated individually for each of the recruited subjects by multiplying the basal metabolic rate (BMR) by an activity index of 1.75. The BMR (kCal/day) is calculated according to the equations of Harris-Benedict (42).

During test days all foods will be presented on plates and prepared in a research kitchen from the Department of Human Biology by one of the researchers. Subjects will consume the foods in a little dining room next to the research kitchen. For the snack-dietary phase subjects will be given the originally packed unopened food items from the shops. The gouda cheese and salami will be conserved in the refrigerator and the biscuits dry in a cupboard, at the research kitchen.

Contacts

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Eligibility criteria

Inclusion criteria

- 1. Right-handed;
- 2. Both genders;
- 3. Age between 18-55 years;

4. BMI between 20 and 25 kg/m2 and between 25 and 30 kg/m2 with a waist circumference for men > 90 cm and for women > 80 cm;

- 5. Liking the tested food items;
- 6. Being able to play a standard memory game;
- 7. Without any metals in the body.

Because of the different brain laterality in left- and right-handed subjects we chose to include only right-handed subjects. Hence the results can be compared between the subjects.

Determining the effect of age is not an aim of this study. For the purpose of simplicity we exclude the effect of ageing and therefore set the age limit at 55 years.

Exclusion criteria

- 1. Having metals in the body;
- 2. Having a food allergy;
- 3. Not being able to play a standard memory game;
- 4. Being left-handed;
- 5. Diabetics;
- 6. Use of medication (except contraception);
- 7. Extensive alcohol consumption (more than 10 consumptions per week);
- 8. Instable weight;
- 9. Pregnancy;
- 10. Claustrophobia;
- 11. Depression;
- 12. Other serious disorders (for example epilepsy, arrhythmia, parkinsonism, insomnia);
- 13. A past history of psychiatric disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2009
Enrollment:	40
Туре:	Anticipated

Ethics review

Positive opinionDate:10-0Application type:Firs

10-07-2009 First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33020 Bron: ToetsingOnline Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1795
NTR-old	NTR1904
ССМО	NL28509.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33020

Study results

Summary results

N/A