Representation of food preference in the brain in relation to visceral obesity and stress

Published: 17-07-2009
Last updated: 19-03-2025

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

Summary

ID

NL-OMON33020

Source
ToetsingOnline

Brief title
Food preference

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
excess body weight, Obesity

Health condition

viscerale obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Top Institute Food and Nutrition (TIFN)

Intervention

Keyword: Obesity, Reward, Stress

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

na

Study description

Background summary

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.

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.

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 (*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.

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.
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.

As this is a cross-over study, all subjects will undergo the experiment in the stress and rest condition and in the high protein/fat and carbohydrate condition.
The responses of the visceral overweight subjects will be compared to those of the normal weight subjects per condition. Within the subject groups the different conditions will be compared.

Study burden and risks

This research is neither beneficial nor harmful to the subjects. The study consists of 3 times 4 test-sessions per subject of 3.5 h each. All sessions include two blocks of 30 min that will be performed in the fMRI apparatus. fMRI is a non-invasive standard brain-imaging method without any significant risks (See chapter K4A for standardized and approved methods for conducting fMRI experiments involving human subjects). It is a technique that utilizes magnetic fields and low energy radio frequencies to visualize brain structures and brain function. During screening subjects with metallic fragments in their body will be excluded from the study since the fMRI magnet exerts a force on

ferromagnetic objects. The blood sampling in this study (5 blood samples of 5 ml each test-session) does not include any other risks for the subjects, apart from its usual risk of minor bruising. The computer game is a standard memory game with pictures of food items and contains questionnaires regarding the food preference.

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

Inclusion criteria are being right-handed, both genders, age between 18-55 years, 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, liking the tested food items, being able to play a standard memory game, without any metals in the body.

Exclusion criteria

Exclusion criteria are having metals in the body, having a food allergy, not being able to play a standard memory game, being left-handed, diabetics, use of medication (except contraception), extensive alcohol consumption (more than 10 consumptions per week), instable weight, pregnancy, claustrophobia, depression, other serious disorders (for example epilepsy, arrhythmia, parkinsonism, insomnia) and a past history of psychiatric disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	17-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27486
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Binnen 4 weken beschikbaar
CCMO	NL28509.068.09
OMON	NL-OMON27486