

Functional MRI of food evaluation and choice in normal weight and overweight subjects across the lifespan

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To assess the differences in the brain responses to food presentation and food choice and how these responses are modulated by hunger and gut signals in normal weight and overweight subjects across the lifespan.

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

Summary

ID

NL-OMON41399

Source

ToetsingOnline

Brief title

fMRI of food evaluation and choice in overweight across the lifespan

Condition

- Other condition

Synonym

Overweight

Health condition

overgewicht en obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: fMRI, Food choice, gut hormones, Satiation

Outcome measures

Primary outcome

Neural activation (percentage BOLD signal change) induced by the presentation of pictures of food and food choice.

Secondary outcome

1. Scores on the liking task & perceived caloric content
2. Gut hormone levels during hungry and satiated condition on several timepoints.
3. Neural activation (percentage BOLD signal change) in response the execution of a reward task.

Study description

Background summary

Research of food motivation is becoming of increased interest as the prevalence of overweight and obesity continues to rise in both adults and children. In our daily lives we are continuously exposed to food. During the day we make many choices regarding food consumption. Food evaluation and choice both play an important role in the regulation of food intake and therefore in weight management. For this reason it is important to obtain more insight into the mechanisms that underlie these processes.

Study objective

To assess the differences in the brain responses to food presentation and food

choice and how these responses are modulated by hunger and gut signals in normal weight and overweight subjects across the lifespan.

Study design

Observational study

Study burden and risks

The experiment is non-therapeutic to the subjects and will consist of two study sessions. On each study day subjects are required to fast overnight. Before a 40-min MRI session on day 1 or 50-min MRI session on day 2, subjects will execute a computerized liking task in which the food pictures used in the fMRI tasks are rated on their pleasantness. The MRI paradigm one 15-min, one 5-min and two (or three on day 2) 10 min MRI scans are made while subjects make food choices, view pictures of foods and non-food objects, or execute a reward task. This type of paradigm poses no risk. Functional MRI is a commonly used technique which is considered to be safe. Additionally, subjects will be asked to answer several questionnaires on relevant personality traits and eating behaviour. Furthermore blood will be drawn from the adults and a saliva sample will be collected from all subjects for future DNA analyses. The original LFPQ (Finlayson, King et al. 2007) will be administered at the end of the last visit. The children will have an extra preparatory visit before being scanned. During this first visit they will engage in a practice session in a MR scanner simulator. In summary, the risk associated with participation is assessed as low and the burden as minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

1. Healthy (self-reported)
2. Age group 1: 8-10, group 2: 13-17, group 3: 25-45 and group 4: 65-75 at day 01 of the study
3. Body Mass Index (BMI): between 20 and 25 kg/m² (normal weight adults) or 25.1 and 35 kg/m² (overweight adults). For children and adolescents we calculated BMI ranges based on age and gender by using the growth reference data for 5-19 year olds of the World Health Organization (Butte, Garza et al. 2007). A BMI range of -1SD to +1SD in children equals approximately a BMI of 20-25 in adults; A BMI range of +1SD to +3SD in children equals approximately a BMI of 25-35.0 in adults.
4. Right-handed
5. Having given their written informed consent and in children, written informed consent from children and both parents.
6. Willing to comply with the study procedures
7. Willing to accept use of all anonymized data, including publication, and the confidential use and storage of all data
8. Willing to be informed about chance findings of pathology and approving of the disclosure of this information to the general physician (see Informed Consent)

Exclusion criteria

1. Smoking
2. Having a special diet (e.g. to lose weight, medically prescribed diet in the past 6 months, no meat etc)
3. Highly restraint eating (Van Strien et al., 1986).

4. Having a food allergy
5. Having gained or lost >5 kg of body weight in the past 6 months.
6. Having a history of or current alcohol consumption > 28 units per week
7. Having a history of medical or surgical events that may significantly affect the study outcome, such as metabolic or endocrine disease, or any gastro-intestinal disorder
8. Mental or physical status that is incompatible with the proper conduct of the study
9. Not having a general practitioner
10. Participation in any other clinical trial during this study.
11. Working at the Image Sciences Institute or the Radiology Department of the UMC Utrecht as employee or student.
12. MRI exclusion criteria
 - a) Claustrophobia
 - b) Having metal implants (i.e. pacemaker, metal joints, prostheses, etc.) or metal objects on the body which cannot be removed (i.e. piercing, hearing aid, brace, etc.
 - c) Being pregnant.
13. Task related exclusion criteria
 - a) Unsuccessful satiation of the participant (i.e. hungry after protein shake consumption)
 - b) Nausea
14. Menopause (applies only to women of age group 1 (25-45 years old))

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 29-10-2012

Enrollment: 120

Type: Actual

Ethics review

Approved WMO

Date:	03-05-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	12-07-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	20-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	01-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	27-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	20-04-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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: 26000

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL39563.041.12
OMON	NL-OMON26000