Resting State functional magnetic resonance imaging of human brain responses to nutrient shakes.

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Primary objective of this study is to assess changes in brain connectivity and activity in the Default Mode and Salience Network (hypothalamus, prefrontal cortex, nucleus accumbens, Ventral Tegmental Area) after different sugars and sweeteners.

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

Summary

ID

NL-OMON43766

Source
ToetsingOnline

Brief title
rsfMRi of the brain response to nutrient shakes

Condition

- Appetite and general nutritional disorders

Synonym
Feeding behavior, Response to feeding

Research involving
Human

Sponsors and support

Primary sponsor: Unilever
Source(s) of monetary or material Support: Unilever R&D Vlaardingen

Intervention

Keyword: Resting state fMRI, Sugars, Sweeteners

Outcome measures

Primary outcome

Changes in brain connectivity and activity, as measured by rsfMRI.

Secondary outcome

Psychophysical ratings of hunger, taste and sweetness

Study description

Background summary

The central role of the brain in regulating food intake and steering feeding behaviour is increasingly recognized. It is currently well accepted that the brain is the target organ to measure the effects of pleasantness, reward and energy homeostasis in order to change feeding behaviour to reduce the rising prevalence of obesity. The effects of food on the brain are multiple and complex. In addition to primary aspects of food such as taste, texture, looks and smell, secondary aspects such as energy regulation are as much important in the entire *eating experience*. Using functional magnetic resonance imaging (fMRI) we have previously measured the hypothalamic function during nutrient ingestion.
In the present study we use resting state fMRI (rsfMRI) to detect changes in connectivity in the default mode and salience network after consumption of four different *milkshakes* with added sugars and sweeteners. Our overall hypothesis is that sugar ingestion demonstrates the most extensive changes in rsFMRI since both taste and energy homeostasis are being activated. Whereas sweeteners are only expected to trigger the taste system. Secondary points of interest are the (subtle) differences between the different sugars and sweeteners.

Study objective

Primary objective of this study is to assess changes in brain connectivity and activity in the Default Mode and Salience Network (hypothalamus, prefrontal cortex, nucleus accumbens, Ventral Tegmental Area) after different sugars and sweeteners.

Study design

The study design is a randomized crossover observational study in healthy male volunteers.

Intervention

Four different *milkshakes* of 165ml with added sugars and sweeteners.

Study burden and risks

The study will consist of four occasions. There will be an interval of at least one week between the occasions. On all occasions, the subject will be admitted to the Clinical Research Unit of the LUMC. After anthropometric measurements (weight), rsFMRI will be performed after an ingestion of 165ml of a *milkshake* with added sugars or sweeteners. Before and after the MRI the participants will indicate their feelings of hunger and flavour and sweetness of the test product on a VAS scale.

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

Signed informed constent
Age between 18 and 25 years
Bodyweight of at least 70 kg
BMI between 20 and 23 kg/m2

Exclusion criteria

-Diabetes or history of other disturbances of glucose metabolism (eg impaired glucose tolerance, hypoglycemia).
-Any genetic or psychiatric disease (e.g. fragile X syndrome, major depression) affecting brain
-Any significant chronic disease
-Any known food allergies or intolerances
-Renal or hepatic disease
-Recent weight changes or attempts to lose weight (> 3 kg weight gain or loss, within the last 3 months)
-Smoking (current or last 6 months)
-Alcohol consumption of more than 21 units per week or use of recreational drugs at present or in the last year
-Recent participation in other biomedical research projects (within the last 3 months), participation in 3 or more biomedical research projects in one year
-Contra-indication to MRI scanning

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL55440.058.15