Fullbrain study: Satiation induced brainstem activity

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The objective of this study is to determine differences in resting state brain activity and brain reactivity to taste, between hungry and progressive satiated states, with a focus on activity within the brainstem.

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

Summary

ID

NL-OMON46480

Source
ToetsingOnline

Brief title
Fullbrain study

Condition

- Other condition

Synonym
body mass index above 30 kg/m2, overweight

Health condition

indirect heeft het onderzoek betrekking tot obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: NWO

Intervention

Keyword: brainstem, energy-intake regulation, satiation, taste

Outcome measures

Primary outcome

Differences in brain activity in rest and brain reactivity (BOLD response) upon oro-sensory exposure to food, between hungry and 50% and 100% sated states (3 repeated measures).

Secondary outcome

The secondary outcome of this study is stomach filling (ml) measured by use of MRI at 4 time points (hungry, after drinking till 50% satiation, at the end of the scanning protocol of the 50% sated state, and during the 100% sated state).

Study description

Background summary

The neural basis of satiation, i.e., the transition from hunger to satiety, is poorly understood. The vast majority of studies compare brain responses in the sated with the fasted state rather than the process of satiation. Satiation evolves by the integration of taste and gastric signals in the brainstem and hypothalamus. These brain areas are therefore highly interesting in relation to satiation but have thus far received little attention due to technical constrains. However, recent developments make it possible to study activity in these brain areas.

Study objective

The objective of this study is to determine differences in resting state brain activity and brain reactivity to taste, between hungry and progressive satiated

states, with a focus on activity within the brainstem.

Study design

The study has a within subject repeated-measures experimental study design and consists of one test day.

Intervention

We will measure resting state brain activity and brain reactivity to taste (chocolate milk) in a hungry state, a 50% sated state and a 100% sated state. Between scan sessions, participants will be asked to drink chocolate milk to arrive at the 50% and 100% satiated states.

Study burden and risks

The study is non-therapeutic to the participants. No immediate benefits for the participants are expected from participation in this study. The risk associated with participation is negligible. The participant*s burden is as follows, regarding time: the training session will take approximately 1 hour and the experimental session will take approximately 2 hours of which 90 minutes will be scanning time but with 5 minutes breaks every ±30 minutes. To undergo an fMRI scan involves: exposure to loud noise, a moderate amount of physical restraint, as well as exposure to a strong magnetic field (3 Tesla) of which the participant is unaware, that is, participants do not *feel* being in a magnetic field. During the scanning session participants will receive taste and tasteless stimuli, administered in liquid form. If the participant is uncomfortable with any aspect of the procedure the study will be terminated.

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

* Right handed
* Between 18-35 years old at the day of inclusion
* Able to understand and speak English fluently or without difficulty
* BMI 18.5-27 kg/m2
* Good general health and appetite
* Willing to comply with the study procedures
* Willing to be informed about incidental findings of pathology and approving of reporting this to your general physician

Exclusion criteria

* Having difficulties with tasting, smelling, swallowing or eating in general.
* Women: Being pregnant or breastfeeding or planning to get pregnant in the upcoming half a year
* Women: Using a IUD as anti-conceptive (with exception of Mirena IUD)
* Suffering from a neurological, endocrine, or eating disorder, gastrointestinal or mental illness or illness of the thyroid gland, respiratory disease or diabetes.
* Having a sight (except glasses) or hearing disorder
* Having non-removable dental braces (with the exception of dental wire)
* Smoking on average one or more cigarettes/cigars a day
* Having a history of, or a current alcohol consumption of, drinking on average more than 21 units per week
* Not willing to stop using drugs during the study period (from inclusion till test session)
* Use of medication that may influence study outcomes
* Allergies or intolerance to any ingredient of the test foods (yoghurt, chocolate milk).
* Not willing to eat the study foods/drinks because of eating habits or believes.
* Followed an energy restricted diet during the last 2 months

* Gained or lost 5 kg of body weight over the last half year
* Participating in another research study
* Employee of Human Nutrition department of Wageningen university
* Thesis student or intern at the chair group of Sensory Science and Eating Behaviour Human Nutrition (WUR).
* Not having a general practitioner
* Intensive exercising more than 8 hours per week
* Not willing to be in an MRI scanner
* Claustrophobic
* Having non-removable metal in or on the body such as piercings, pacemakers, artificial heart valve, metal implants or prostheses.
* High restrained eater according to the Dutch Eating Behaviour Questionnaire (men: score>2.9)*.
* Low score (* 4, neutral) for liking the test food on a nine point likert scale*;After the training :
* Feeling uncomfortable lying in a (dummy) MRI scanner
* Using the weight and height as measured the BMI does not fall within the desired range 18.5-27 kg/m2

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	15-05-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL65187.081.18