

Satiety related brain activation and gastric distention

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To find the effects in satiety related brain regions and satiety related scores of additional gastric distention with similar nutrient load and oro-sensory exposure.

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

Summary

ID

NL-OMON42427

Source

ToetsingOnline

Brief title

Cerebro

Condition

- Other condition

Synonym

satiating effect of gastric stretching

Health condition

algemene fysiologie

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: EU F7

Intervention

Keyword: distention, fMRI, gastric, Satiety

Outcome measures

Primary outcome

Increase or decrease of blood perfusion signal of brain regions

Secondary outcome

Satiety related scores based on appetite questionnaires, food image

palatability scores and ad lib intake

Study description

Background summary

The time food resides in the stomach is relevant for the feeling of *being full*. Satiety is related to the amount of food consumed, but it is not completely understood to what extent the effects on satiety exactly stem from gastric stretching independent of oro-sensory and nutrient effects. Several areas in the brain are associated with satiety, but all factors modulating activation in these areas are not yet known.

Study objective

To find the effects in satiety related brain regions and satiety related scores of additional gastric distention with similar nutrient load and oro-sensory exposure.

Study design

Randomized cross-over

Intervention

Meal shake with water

Study burden and risks

Potential participants will be invited for an introductory Q&A session where they can ask questions they may have and get further information on the study. If still interested, the participants are invited for a screening (30min). For the study, participants will visit the MRI facility in Hospital Gelderse Vallei (Ede) two times (duration approx. 70 min). The subjects will scanned using MRI to measure their stomach volume before the treatment, and then be asked to drink a 100mL shake, followed by either a small or a large volume of water. Questions will be asked about their hunger state and fullness. The study is non-therapeutic to the participants. The risk associated with participation is negligible.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- * Male
- * Right handed
- * Age 18 * 35yr
- * BMI 18.5 - 25 kg/m²
- * Being healthy (self-reported)
- * Having given written informed consent (see E2)

Exclusion criteria

- * Not meeting the inclusion criteria
- * Drug use or medical conditions which may interfere with normal functioning of the digestive tract
- * Drug use or medical conditions which may interfere with normal functioning of the circulatory system
- Drug use or medical conditions which may lead to unreliable fMRI results (including, but not limited to neurological conditions)
- * Food allergy to or unwillingness to consume the study products
- * Reported unexplained weight loss or weight gain of > 5 kg in the month prior to pre-study screening
- * Presence of non-removable metal objects in the mouth
- * Personnel of Wageningen University, department of Human Nutrition
- * Current participation in other research from the Division of Human Nutrition
- * Having a contra-indication to MRI scanning
- * Disliking the food items.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2015
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO	
Date:	30-06-2015
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	NL53180.081.15