Flavour processing in healthy males, investigated with fMRI.

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Investigating the neural mechanisms underlying the intensity and pleasantness coding of flavours in healthy volunteers would provide 1) dissociation of the brain activity patterns related to flavour intensity and pleasantness and 2) insight into how…

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

Summary

ID

NL-OMON41200

Source
ToetsingOnline

Brief title
Flavour processing

Condition

- Other condition

Synonym
n.v.t.

Health condition

Er wordt geen aandoening bestudeerd.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Friesland Nutrition,Nutricia,Top Institute Food and Nutrition

Intervention

Keyword: Flavour, fMRI, Intensity, Males, Pleasantness

Outcome measures

Primary outcome

The main study parameters are: the flavors administered to the subjects (two flavors, one pleasant one unpleasant, plus one neutral), flavor intensities (five concentrations, plus one neutral), the perceived pleasantness and intensity of each flavor solution, the brain activity corresponding to each flavor intensity and pleasantness during administration. In addition the brain activity corresponding to exposure to each IAPS image as well as the ratings of reward and disgust at exposure to these images is used.

The outcome of the study (endpoints) will consist of:

- The neural activity patterns associated with flavor intensity and valence;

- A comparison of the reward and disgust networks found in response to flavors and images.

Secondary outcome

NA

Study description

Background summary

The neural processing of a food is influenced by various factors including but not exclusively to the perceived intensity, perceived pleasantness, tactile sensations, complexity, how it looks and possibly caloric content. How these attributes influence the activation patterns of the brain when we taste a flavour is not yet fully clear. Here, we refer to flavour being a taste stimulus, which contains both a taste and an odor. Although taste experiments often used basic tastes (e.g. sweet, salty, sour or bitter), we encounter flavours more often in daily life.

In recent studies we have isolated activation patterns in the insula specific to valence and intensity of basic taste processing and have found separate networks for pleasure and disgust in complex flavours. The regions involved in both disgust and reward processing show similarities with regions found that respond to human facial expressions, emotions and visual stimuli. In the upcoming study we hope to separate intensity and valence coding on a whole brain level in complex flavours. In addition we expect to be able to show that the disgust and reward networks we have identified are not specific to food but universal processing networks for disgust and reward.

Study objective

Investigating the neural mechanisms underlying the intensity and pleasantness coding of flavours in healthy volunteers would provide 1) dissociation of the brain activity patterns related to flavour intensity and pleasantness and 2) insight into how food reward and disgust processing relates to the processing pictures containing emotional content.

Study design

This study will combine fMRI and behavioral measurements. Subjects will undergo one fMRI scanning session in which they will be shown various images from the International Affective Picture System (IAPS) set, which is a frequently used method to study emotion, and they will also experience four repetitions of lemonade solutions; one pleasant and one unpleasant. The unpleasant stimulus will be created by diluting the lemonade with fish sauce. We will balance the lemonade that will be assigned as unpleasant over participants. The stimulus solutions exist of five intensities ranging from not intense at all to extremely intense of two kinds of lemonade. The lemonades will be diluted in tap water. Furthermore tap water will be used for rinsing. Each lemonade flavor will be presented in a run containing 5 consecutive trials with an increasing intensity. These flavor runs will be pseudo-randomized as well as balanced and counter-balanced between subjects. Each individual flavor trial will include both a flavor stimulus and a rinsing stimulus. The behavioral measurement will include subjective pleasantness- and intensity ratings from the participant for

each administered flavor during the fMRI experiment. The analysis of the fMRI data will take into account the behavioral data as a covariate. The pleasantness rating will show what brain activation can be associated with liked and disliked stimuli for each participant individually. Using the intensity ratings the whole brain response to varying degrees of intensity can be determined. The IAPS dataset will be used to determine whether responses to rewarding and disgusting drinks are food specific or whether these responses are universal to disgusting and rewarding stimuli. Furthermore, heart rate and respiratory data will be logged. This data is used to remove any heart rate and respiratory induced artifacts. The design of this study is single-blind; at the moment of the flavor administration, the healthy volunteers do not know which taste he or she is experiencing. The subjects will be informed about the nature of the stimuli, before inclusion into this study.

Study burden and risks

Functional MRI is an eminently safe technique; there are no risks that have been associated with the acquisition of fMRI data per se. Above certain limits, warming and/or an itching/tingling feeling (stimulation of peripheral nerve terminations) are possible. However, the magnetic intensities used in this research are amply below these limits. Subjects will be exposed to a magnetic field of 3 Tesla and rapidly alternating gradients and radio frequency fields. This field and gradients' changes are routinely used in fMRI and MRI research. It is worth to mention that scanners supporting a magnetic field that is more than twice as powerful (7 Tesla) are used in The Netherlands for research purposes. Also, no harmful side effects have been reported there.
The data collected during the functional and anatomical MRI scans will be used for research purposes only. However, if evident abnormalities in the brain are noticed, then the General Practitioner, who is indicated by the subject, will be notified.

The strong magnetic fields used by fMRI can dislocate ferromagnetic particles inside the brain and the eyes, interfere with the functioning of electronic devices implanted inside a person's body (pacemakers, insulin pumps, etc.), as well as induce heating in artificially metal-rich regions (red tattoos, metallic supports to previously fractured bones, prosthetic implants). In order to stave off the risks involved with such possible conditions, subjects will be required to complete a questionnaire and only if none of the exclusion criteria is met the subject will be allowed to participate in our experiment.

The environmental conditions of being inside an MR scanner and of being partially restrained can induce claustrophobic feelings. Three steps will be taken to reduce this risk: 1) the subject will be explicitly asked about being claustrophobic, 2) the subject will experience a training moment in a dummy scanner and 3) prior to the beginning of the actual experiment, and during pauses between scans, subject will be asked about their well being. Additionally, they will receive an alarm trigger that they will be able to use

at any moment to interrupt the scanning. Finally, an experimenter will be in close proximity of the participant during the session, for the primary reason to present the aforementioned small amounts of liquids. Such proximity will allow a close monitoring of the subject*s well being.

The subject's burden is as follows, regarding time: a screening moment by telephone, to ensure that all the requirements are met and to determine the individual intensity/pleasantness curve needed for the scanning session. Before each scanning session the subject will be required to fill and sign a safety-specific questionnaire.

The scanning sessions will be between 8:00 and 18:00 hours; we will ask the subjects to stop eating at least three hours before the scan to ensure a sufficient state of hunger to induce a stronger BOLD response to the stimuli.

To undergo a fMRI scan involves: exposure to loud noise (addressed with ear protection, by means of both ear plugs and headphones), a moderate amount of physical restraint (the head is inside a fMRI coil; the feeling is similar to wearing a motorbike helmet), as well as to a strong constant magnetic field (3Tesla), and small variable electromagnetic fields (see question E9).

During the scanning sessions the subjects will receive beverages. The individual administrations are the equivalent of small sips (approx. 2 ml), and the total amount of liquid ingested in one scanning session (approx. 30 min) is the equivalent to little more than half a can of cola (180ml). The current study design is largely based on earlier approved study (METc2012/090 and METc2011/151). In this previous study, 80 subjects participated and showed no problems with regard to the 2 ml. taste administrations or with the horizontal position of the body while swallowing. Based on this experience we do not expect the paradigm to be problematic for the current subject group.

The subjects will receive two flavours of lemonade, one with a pleasant taste and one with an unpleasant taste. The solutions are made from consumer grade lemonade and will pose no threat to their health. The caloric content of the solutions will be kept stable by addition of a non-sweet carbohydrate (Fantomalt), this is an over the counter food supplement. Assuming an intake of maximum 100ml of lemonade, the total amount of Fantomalt ingested will not exceed the advised intake of 100g daily. In addition to the lemonade solutions the participants will view images of the IAPS picture set. These pictures range from regularly encountered experiences such as household items to images meant to elicit disgust and pleasure. This set of images is frequently used in experiments studying emotional processing and attention.

No immediate benefits for the subjects are expected from their participation in this study.

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

Caucasian, right handed, normal (or corrected to normal) vision, healthy, BMI 18-25 kg/m2, normal sense of taste and smell, non-smoking, fMRI compatible, no history of neurological or psychiatric disorders, Male, Age range: 18-30, fluent in dutch.

Exclusion criteria

MR incompatable (posibility of any incompatible metal objects inside the body),
History of psychiatric disorders,
History of taste-related disorders,
Allergies against ingredients of the stimuli,
Smokers.

Wearing glasses (lenses are allowed)
Alcohol/drug abuse

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	11-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL50815.042.14