Neural substrates of anticipatory food reward in healthy males and cancer survivors, investigated with fMRI.

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Investigating the neural mechanisms underlying the anticipation of food reward induced by visual cues related to different foodcharacteristics in healthy males would provide 1) brain activity patterns that can be associated with the anticipation of...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43593

Source
ToetsingOnline

Brief title
Food reward

Condition

- Other condition

Synonym
n.v.t.

Health condition

Er wordt geen aandoening bestudeerd in gezonde mannen; neoplasmata voor de kanker overlevenden.

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: fMRI, Food, Testicular cancer

Outcome measures

Primary outcome

The main study parameters are: the combination of visual food stimuli

administered to the participants (four categories), the reaction

time to choose from the presented combination of visual food stimuli, and the

brain activity corresponding to each choice. The

outcome of the study (endpoints) will consist of 1) the neural activity

patterns associated with anticipatory food reward, and 2) a

description of thechemotherapy-related differences in brain activity patterns.

Secondary outcome

n.v.t.

Study description

Background summary

This study is part of a TI Food and Nutrition project, which aims to understand food choice in cancer survivors and other populations (e.g., elderly). Perceived pleasantness while consuming a food product must be translated into motivation in order to influence subsequent food choice. Such motivation is also known as anticipatory food reward. Visual features that motivate people to choose a specific food product induce anticipatory reward, and are a strong predictor of food choice. Increased Body Mass Index and increased risk of cardiovascular disease are frequently observed as a side effect after treatment

with cisplatin-based chemotherapy in testical cancer. Therefore, in the current study we aim to investigate the neural mechanisms behind the anticipation of reward from food products in these cancer survivors.

Study objective

Investigating the neural mechanisms underlying the anticipation of food reward induced by visual cues related to different food characteristics in healthy males would provide 1) brain activity patterns that can be associated with the anticipation of food reward and 2) a baseline to further investigate if and how these brain activity patterns differ between healthy males and cancer survivors.

Study design

This study will combine fMRI and behavioral measurements. Participants will undergo one fMRI scanning session in which they will perform a computer-based paradigm consisting of visual (anticipatory) food stimuli. All stimuli will vary along two dimensions - taste (sweet or salty) and calorie (high or low). The anticipatory reward to each visual food stimulus will be assessed by a two-alternative forced choice methodology (i.e. an established controlled measure of choice which is widely used to test choice behavior), designed and executed using Matlab. In this task, the participants will be instructed to select the food they *would most like to eat now* in a series of trials in which a visual food stimulus from one of the four food categories will be paired with a stimulus from either the same or another category. Each choice, made via key-press on the keyboard, triggers the next pair of stimuli and so on until all possible combinations (i.e. 10 combinations) are presented 16 times in order to acquire a reliable brain response. The total amount of 160 trials will be divided over four task blocks of 40 trials. The order of all combinations of visual food stimuli will be randomized across all four block as well as balanced and counter-balanced between participants.

A behavioral and neural measure of *anticipated reward* is derived in two ways. First, the brain response derived during each choice can convey information about the degree (on a continuous, interval unit of measurement) to which a chosen visual food stimulus is anticipated to be rewarding relative to an alternative. Second, the analysis of the fMRI data will take into account the reaction times when choices are made to each food category respectively as a covariate. This might show what brain activation can be associated to anticipated food reward for each food category for each participant individually.

The design of this study is single-blind; at the moment of presenting the visual food stimulus, the participants do not know which food category they are experiencing. However, the participants 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: filling in a safety questionnaire before intake (to ensure that all the inclusion requirements are met), Before each scanning

session the subject will be required to fill and sign a safety-specific questionnaire. During the intake session, participants will fill in a reward questionnaire and rate the food images used during the fMRI session on pleasantness and calorie density. The scanning sessions will be between 16:00 and 19:00 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).

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 or treated for testicular cancer with cisplatin-based chemotherapy. Age range: 18-30 year old, fluent Dutch

Exclusion criteria

MR incompatable (posibility of any incompatible metal objects inside the body)
History of psychiatric disorders
Smokers
Alcohol/drug abuse

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-03-2016
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	NL55241.042.15