Development of fMRI tasks and scan protocols

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Development of (f)MRI tasks and scan protocols and to define the optimal parameters in preparation of a (f)MRI study

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

Summary

ID

NL-OMON43885

Source
ToetsingOnline

Brief title
(f)MRI development

Condition

- Other condition

Synonym
eating behaviour, smell and taste perception

Health condition

sensoriek (reuk en smaakvermogen) en eetgedrag

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3 Tesla, fMRI, protocol, scan sequence

Outcome measures

Primary outcome

The main study parameters are high resolution anatomical MRI scans and/or the

blood oxygen level dependent (BOLD) signal (fMRI scans).

Secondary outcome

Behavioral correlates to differences in sensory rating/evaluation.

Neuropsychological parameters (reaction times and error rates).

Other study parameters

Additional parameters will be obtained during the screening procedure,

including for example measurements on eating habits and food preferences

(questionnaires), and demographic variables like age, gender, weight, Body Mass

Index, etcetera.

Study description

Background summary

For many functional MRI studies, tasks have to be created to activate specific brain regions. The quality of the task can be determined to some extent during the design of it, by using models to compute the outcome in terms of sensitivity and selectivity. Sensitivity is determined largely by the contrast between activation and relaxation of brain areas involved in the task. Selectivity can be estimated by assessing the chance that brain processes that are not of interest and confound the result of imaging. Both properties have to be tested in real fMRI experiments. One may, for instance, create a mathematically very well designed task with high sensitivity and selectivity, but upon testing in an fMRI scanning session it may very well fail to produce

significant brain activity. Quite often it turns out that the task is too tightly controlled, i.e. that brain functions cannot be *switched off* during control conditions. In general, it is difficult to predict whether a particular task with particular stimuli, instructions and temporal sequencing of events, will manipulate the brain as intended.
Finding the right parameters for a task often takes several fMRI tests in individual subjects. Once results are satisfactory, the real experiment can commence. It may however take weeks before this point has been reached, and in some cases the project is abandoned. It is, therefore, important to assess whether a task produces the required results before submitting a protocol to the ethics committee, rather than wait with piloting until approval for the whole study has been obtained.
A second element that sometimes needs piloting is the scan protocol itself. Notably, parameters of the (f)MRI scan sequence sometimes need to be altered, for instance to enhance signal in in the brain near the nasal cavity, and this requires fine-tuning in human volunteers.

Study objective

Development of (f)MRI tasks and scan protocols and to define the optimal parameters in preparation of a (f)MRI study

Study design

We intend to include a maximum of 60 subjects per year for pilot work (i.e. a maximum of 10 pilot studies of maximum 6 subjects each). Each subject will spend a maximum of 90 minutes per session and will be paid according to the standard payment regiment at the Division of Human Nutrition (i.e. 7 euro per 15 minutes in the scanner, plus 7 euro per hour outside the scanner (e.g. filling out questionnaires), plus travel costs). All subjects will sign an informed consent form and all records will be kept just like with other ethics protocols.

Study burden and risks

Functional MRI is an eminently safe technique; there aren't risks that have been associated with the acquisition of fMRI data per se. Above certain limits, warming and/or a hitching/tingling feeling (stimulation of peripheral nerve terminations) are possible. However, the intensities used in pilot studies are amply below these limits. Subjects will be exposed to a magnetic field of 3 Tesla. This field is routinely used in fMRI and MRI research; it is maybe worth to mention that scanners supporting a magnetic field more than twice as powerful (7 Tesla) are used in The Netherlands for research purposes. No harmful side effects have been reported.

Contacts

Public
Wageningen Universiteit

Biotechnion, Bomenweg 2
Wageningen 6703 HD
NL
Scientific
Wageningen Universiteit

Biotechnion, Bomenweg 2
Wageningen 6703 HD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* 18 years and older
* normal (or corrected to normal) vision and hearing, without reported dysfunctions of taste and smell, signed informed consent.

Exclusion criteria

* non matching any of the inclusion criteria
* contra-indication for (f)MRI, such as claustrophobia, presence of metal objects inside the body, pregnancy (for women).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-11-2011
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

Approved WMO

Date:	18-08-2016
Application type:	Amendment
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	NL37059.081.11