Controllability of cognitive brain signals and the effects on the frontostriatal network: A 7T fMRI study.

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The primary objective is to investigate the effect of training on a neurofeedback task targeting the DLPFC, on the frontostriatal network. As a secondary objective, we investigate whether such training changes mental effort.

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

Summary

ID

NL-OMON40199

Source ToetsingOnline

Brief title Controllability of cognitive brain signals

Condition

• Other condition

Synonym

NA

Health condition

The research is fundamental in nature and only healthy subjects are studied. The knowledge that will be gained could eventually be used for medical interventions (e.g. new treatment methods for psychiatric disorders). Furthermore, the results are interesting for those who are developing brain-computer interfaces.

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** NWO

Intervention

Keyword: Dorsolateral prefrontal cortex, fMRI, Frontostriatal, Neurofeedback

Outcome measures

Primary outcome

The main study parameter is the change in BOLD activation patterns of the

frontostriatal system after training to self-regulate brain activity of the

DLPFC (comparing the post and pre-training count-back network activation task).

Secondary outcome

The secondary study parameters are the feedback performance and brain

activation patterns during the feedback task with distracters, relative to that

without distracters.

Study description

Background summary

The frontal lobes of the brain play an important role in human behavior. Abnormal function of specific areas in the frontal lobe, but also of specific subcortical areas, is thought to underlie a range of psychiatric conditions, such as schizophrenia, addiction, ADHD, depression and obsessive compulsive disorder (OCD). In recent years the focus of scientific endeavor in this field has shifted towards dysfunctional circuits as opposed to specific regions. New treatments are thus sought in methods to restore normal activity levels in whole networks, and methods to achieve this are being explored, such as cortical stimulation with Transcranial Magnetic Stimulation or even with implants for Deep Brain Stimulation. Multiple parallel neural circuits have been uncovered involving specific areas in the frontal lobe and subcortical structures, each associated with a different motor or cognitive domain. In the current study, we will focus on one of those circuits: the dorsolateral prefrontal circuit. We will investigate the possibility of changing network activity in this circuit by training healthy subjects to control activity levels in one region.

Neurofeedback is based on the feedback of information about brain activity, for example in the process of training to voluntarily regulate brain activity in a certain area. Several studies have suggested that it is not only possible to learn to self-control the activity in certain brain areas, but also that this control may have therapeutic potential. In the current study, we want to train people to voluntarily control activity in the dorsolateral prefrontal cortex (DLPFC), one of the cortical areas of the frontostriatal circuitry, and determine how this affects the entire network.

Study objective

The primary objective is to investigate the effect of training on a neurofeedback task targeting the DLPFC, on the frontostriatal network. As a secondary objective, we investigate whether such training changes mental effort.

Study design

The study is an interventional 7T fMRI study with two groups (experimental and control).

Intervention

Subjects will be included for a real time feedback study in an fMRI setup. Subjects will train to gain control over the brain activity of the DLPFC. The effects of training on the activation of the frontostriatal system will be determined by comparing the activation pattern of a count-back network activation task, which will be performed before and after training. In addition, subjects will try to perform the feedback task while distracters are being presented on the screen. Data from the feedback task with and without distracters will give information about whether or not training reduces mental effort and whether self-regulation of the target area persists in the presence of distraction.

Study burden and risks

There are no known risks associated with fMRI acquisition. The technique does not require administration of any contrast agent or ionizing radiation. The Utrecht group has ample experience with fMRI scanning (300 sessions per year on the 7T MRI scanner). The fMRI procedure is painless. Slight discomfort may occur due to peripheral nerve stimulation during scanning, or due to lying still with the head and part of the body confined in a tunnel-like device. If a subject experiences claustrophobia during scanning, or is uncomfortable with any aspect of the procedure and wants to quit, the session will be terminated. The subject is provided with earplugs to protect him from scanner noise. Also MR compatible clothing is provided for the time in the scanner. An intercom is available in the scanner to remain in contact with the subject during the whole session and an emergency button is placed with the subject, with which he can indicate to stop the procedure immediately. The scanner is handled by trained personnel and subjects are screened for metal before entering the scanner. No immediate benefits are to be expected from participation in this study for the subjects. The research is fundamental in nature, but the knowledge that will be gained could eventually be used for medical interventions (e.g. new treatment methods for psychiatric disorders) or in the development of brain-computer interfaces.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Right-handed

- Age 18-45

Exclusion criteria

- History of psychiatric illness
- Pregnancy
- Metal objects in or around the body (braces, pacemaker, metal fragments)
- Claustrophobia

Study design

Design

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

Recruitment

| NL | |
|---------------------------|---------------------|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-05-2014 |
| Enrollment: | 30 |
| Туре: | Actual |

Ethics review

Approved WMO

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| Date: | 11-06-2013 |
|-----------------------|---|
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 18-03-2014 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

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 CCMO

ID NL43312.041.13