Functional imaging of Brain-Computer Interface control

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

Summary

ID

NL-OMON31579

Source
ToetsingOnline

Brief title
Imaging of BCI

Condition

- Other condition
- Neuromuscular disorders

Synonym
n.a.

Health condition

Het is onderzoek is basaal en betreft alleen gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,NWO

Intervention

Keyword: BCI, brain, EEG, learning

Outcome measures

Primary outcome

The research variables are: 1) Brain Activity maps obtained with functional MRI scans, 2) Brain activity maps obtained with 128-channel EEG, and 3) Performance measures for BCI proficiency (accuracy by which the subject can hit a target by moving the cursor).

Secondary outcome

none

Study description

Background summary

Brainwaves recorded with EEG can be used to control equipment like a computer. This so-called *Brain-computer Interface* (BCI) technique is currently being developed to aid patients who can not move or communicate, due to motor-neuron disease, spinal cord lesion or head trauma. If successful, patients can operate a computer to write or control devices such as a TV or lights, by merely thinking about making movements. For this purpose, electrodes are positioned on the head, close to the motor cortex, and recorded signals are converted in realtime to movements of a cursor on a computer screen. It requires a certain period of training for subjects to achieve BCI control.

Study objective

There are some unresolved issues that we intend to address in this project. We will examine 1) whether with locating the motorcortex with functional MRI, the best location of the electrodes can be predetermined, 2) how brain activity

changes in the course of learning to achieve BCI control, and whether that causes a gradual decline of BCI control, and 3) whether other brain systems than the motorsystem can be used to broaden BCI solutions. These issues are important for further development of clinical BCI.

Study design

Four groups of healthy volunteers will be recruited. All groups will undergo an fMRI and an EEG scan before and after multiple BCI training sessions, which will be compared to determine whether brain activity changes. Group 1 will not perform BCI training, serving as the control group. Group 2 will train to control a cursor in 1 direction, by imagining movements of the right hand. Group 3 will do the same but now in 2 directions, by also imagining movements of the left hand. Group 4 will do the same as group 3, but instead of imagining left hand movements, the subjects will make mental calculations with electrodes recording from the prefrontal cortex. BCI training consists of learning to control the cursor in a special computerprogram. Learning is measured by the accuracy by which the subject can hit a target by moving this cursor.

Study burden and risks

The burden for participants is low: there are no invasive procedures and the scan techniques (fMRI and EEG) are experienced as a light burden. Both are often used for neuroscientific research in humans. The total duration of participation is 20 hours on average. The exact duration depends on the groups that the person is assigned to, and how quickly he/she learns to control the BCI. Minimum duration is 5 hours (control group, no BCI training), and the maximum duration is 29 hours (with 16 BCI training sessions of 90 minutes). There are no risks involved in participation.

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

physically and mentally healthy
right-handed

Exclusion criteria

neurologic or psychiatric disorder

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2007

Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-10-2008
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	ID
CCMO	NL16232.041.07