Cortical Representations of Attempted Hand Movements in Amputees Using 7 Tesla MRI

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

Summary

ID

NL-OMON41759

Source
ToetsingOnline

Brief title
Attempted Hand Movements in Amputees

Condition

- Other condition

Synonym
Not applicable

Health condition

Het onderzoek richt zich op het decoderen van hersenfuncties en zijn van belang voor de ontwikkeling van brein-computer interfaces.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: European Research Council (ERC)

Intervention

Keyword: amputee, decoding, functional MRI, hand gestures

Outcome measures

Primary outcome

The primary study parameter is the fMRI decodability (classification accuracy)

of six different gestures in amputated subjects, compared to the classification

accuracy in non-amputated control subjects.

Secondary outcome

Not applicable.

Study description

Background summary

People with the *locked-in syndrome* (LIS) lost nearly all their motor control, as a consequence of which communication is made impossible or is heavily hindered, and people suffering from it rely on assistive devices for their communication, such as eye trackers or head switches.

Brain-Computer Interfaces (BCIs) are able to restore communication in LIS patients by recording brain activity. Often the sensorimotor cortex is targeted for BCI control. The sensorimotor cortex responds to executed movements, but to attempted movements as well.

Previous results have shown that it is possible to decode hand gestures as used in sign language. Decoding these acts of language production can be used to restore communication with a BCI in an intuitive way. For the development of BCIs, it is important to know what happens to the cortical representations of hand gestures after denervation, and whether decoding this information from brain signals is still possible in this situation.

Study objective

In this study we would like to investigate the effects of denervation on the cortical representation of finger articulations. We will assess the decodability of six different hand gestures from the American Manual Alphabet in people with an amputated right or left arm using 7 tesla functional MRI. We will compare the results to the decodability of gestures in a non-amputated control group.

Study design

All subjects will practise the hand gestures at home (10 minutes per day for six days in total). On the scanning day, they will perform the gestures in the MRI scanner according to the instructions presented on the screen. During the scanning session, the subject wears a so-called *data glove* on their left hand, which will record the finger positions. Statistical analysis and classification will be done off-line.

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 7 tesla 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.

The results of this study are important for the brain-computer interface research in the UMC Utrecht. Individual subjects in this study are not expected to have any benefits from the outcome of 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

Age 18 or older
Right-handed (according to Edinburg Handedness Inventory; amputees have to fill in the situation before amputation)
Naive to sign language (American Manual Alphabet)
For experimental group: amputated arm (left or right; above-elbow), longer than 1 year before the study

Exclusion criteria

Damage to the brain
Noncompliance with MRI safety check list (claustrophobia, metal in the body, etc.)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	28-04-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-03-2015
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	NL48033.041.14