Decoding words with 7 Tesla functional MRI

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The overall goal of this study is to assess the detection and discrimination of individual silently or attempted spoken words from the brain area that represents articulation of speech.To address this goal, we defined three primary objectives:1) To...

Ethical review	Approved WMO
Status	Completed
Health condition type	Neuromuscular disorders
Study type	Observational invasive

Summary

ID

NL-OMON52733

Source
ToetsingOnline

Brief title
Decoding words with 7T fMRI

Condition

- Neuromuscular disorders

Synonym
ALS, Amyotrophic Lateral Sclerosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ALS, decoding, fMRI, speech

Outcome measures

Primary outcome

The three study parameters/endpoints are:

1) decoding (classification accuracy) of silently spoken or attempted words from the brain area that represents the articulation of speech in both ALS or PLS patients and healthy controls.

2) The fMRI brain activity pattern related to articulator movements (movement direction and amplitude);

3) The movement trajectories of the articulators during speech production

4) The fMRI brain activity patterns related to the production of phonemes

5) The fMRI brain activity pattern related to different combinations of sequences of the same phonemes within a word.

Secondary outcome

The secondary study parameters are the optimal acquisition parameters necessary to discriminate different words based on fMRI activity from the brain area representing articulation of speech.

Study description

Background summary

People who suffer from neurological disorders that impair their ability to speak and write, such as amyotrophic lateral sclerosis (ALS) or brainstem stroke, are left behind in the current age of information and communication. To bridge this gap, new solutions are devised to retain or restore communication capabilities. As such, Brain-Computer Interfaces (BCI*s) promise to offer a completely new avenue towards helping people with motor disabilities to communicate and interact with their environment. The general goal of BCI research is to connect the brain directly to a computer, and thereby bypass the non-functional nerve system. Current strategies have focused on a particular part of the brain, the hand region of the motor cortex, where attempted hand movements are accompanied by patterns of neuronal activity that can be detected and distinguished from each other. However, to restore communication hand movements might not be the most intuitive approach. Translating silent speech to a speech computer would be a much more intuitive and effective way of communication. In this project we investigate whether silently (or attempted) spoken words can be detected and discriminated from the brain area that represents articulation of speech: the sensorimotor face area. Prior work has suggested feasibility of this, but the concrete aim of extracting words for BCI is yet to be explored. The results of this study will generate important knowledge for the ultimate goal of enabling people with severe communication disabilities to communicate in real time by silently articulating words.

Study objective

The overall goal of this study is to assess the detection and discrimination of individual silently or attempted spoken words from the brain area that represents articulation of speech.
To address this goal, we defined three primary objectives:
1) To compare the classification results of silently or attempted spoken words between ALS or PLS patients and healthy controls.
2) to assess the neural representation of articulator movements (movement direction and amplitude);
3) to assess the influence of the sequence of phonemes within a word in word classification.

Study design

This is an observational study with invasive techniques (functional magnetic resonance imaging, fMRI) with a group of individuals with bulbar ALS and a control group.

Study burden and risks

Although no direct benefits are expected for the subjects of the current study, the study is expected to increase our understanding of the decodability of words from the sensorimotor face area, which, in the long run, may provide people with severe paralysis a method of fast and intuitive communication. There are no known risks associated with fMRI acquisition. The technique does not require any contrast agent or ionizing radiation administration. The Utrecht group has ample experience with fMRI scanning (±400 sessions per year done on the 7 Tesla MRI scanner). The fMRI procedure is painless; however, some discomfort may occur due to peripheral nerve stimulation during scanning and prolonged time lying still with portion of body and head in a confined tunnel-like device. Additional attention to safety measures will be in place in the shape of constant communication with a researcher or caregiver throughout the scanning session. Also, strict inclusion criteria (i.e.: being able to lay flat during the entirety of one hour of scanning session and being able to use one of the hands to press the emergency button in the scanner) assures that included patients have maximum safety and minimum discomfort during the study. A (para)medic that is familiar with the patient population will be present during scanning to provide assistance if necessary.

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

Control group:
- Age 18 or older (between 45 - 75 years for the subgroup of controls that will be compared to the patient group, see chapter 4.1)
- Blank neurological history
- Adequate proficiency in Dutch and/or English language

Patient group:
- Age 18 or older
- A diagnosis with bulbar onset ALS or PLS
- A strongly impaired ability to speak
- Ability to lie flat on the scanner bed for the duration of the fMRI scan (approximately 60 minutes) without respiratory difficulties or significant saliva build-up
- Ability to press emergency button in the scanner with the hand
- A score of at least 70% on the protocol understanding verification questionnaire
- Adequate proficiency in Dutch and/or English language

Exclusion criteria

General:
- Noncompliance with MRI safety check list
- Claustrophobia
- Pregnancy
- Inability to hear the instructions presented orally in the scanner without a hearing aid

Patient group:
- Mechanical ventilation

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:	Completed
Start date (anticipated):	27-10-2020
Enrollment:	81
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-08-2022
Application type:	Amendment
Review commission:	METC NedMec

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	NL73087.041.20