A detailed somatotopic map of the speech articulators: a 7T fMRI study

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

Summary

ID

NL-OMON56567

Source
ToetsingOnline

Brief title
Somatotopic speech articulator map

Condition

- Other condition

Synonym
not applicable

Health condition

niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: CorTec GmbH,Hersenstichting en Health

Holland

Intervention

Keyword: fMRI, Pneumatic stimulation, Somatotopic map, Speech articulators

Outcome measures

Primary outcome

The main study parameter is an fMRI activity map, which describes, for each voxel of the somatosensory cortex, the speech articulators that generate a response in that voxel upon stimulation with air puffs.

Secondary outcome

Not applicable

Study description

Background summary

Communication through speech is an important aspect in our daily life. People with severe motor impairment (Locked-In Syndrome, LIS), caused by neurological disorders such as brainstem stroke or amyotrophic lateral sclerosis (ALS), are unable to speak or communicate effectively. Brain computer interfaces (BCIs) may offer a solution to this problem by using voluntarily induced signal changes in the sensorimotor areas of the brain recorded with implanted electrodes that are converted to control signals for a communication device. These signal changes can be produced by the attempt to move a body part, for example the hand or speech articulators (i.e., the tongue, lips, jaws). An important remaining challenge for sensorimotor BCIs is the long training time needed for reliable and independent control. Somatosensory feedback about the attempted movements, through electrical stimulation of the brain, seems to be a promising step to reduce training time and improve performance of BCIs in people with LIS. To determine where to apply electrical stimulation to the somatosensory cortex for improved BCI training and performance, it is necessary to understand the underlying brain processes of tactile perception. Previous research found that the hand and fingers are represented in the somatosensory cortex in an orderly manner. However, the organization of the speech articulators, another important BCI control strategy, remains unknown.

Study objective

The overall goal of this study is to investigate the detailed representation of the speech articulators in the somatosensory cortex.

Study design

This is an observational study in healthy volunteers, involving 7 Tesla (7T) functional magnetic resoncance imaging (fMRI) with pneumatic stimulation of the speech articulators using a device that produces air puffs.

Study burden and risks

The risks and burden of this study are minimal. There are no known risks associated with fMRI acquisition. The technique does not require any contrast agents or ionizing radiation administration. The Utrecht research group has ample experience with fMRI scanning (approx. 400 sessions per year done on the 7 Tesla MRI scanner). The fMRI procedure is painless, but some discomfort may occur due to peripheral nerve stimulation during scanning and prolonged time lying still with head and upper body in a confined tunnel-like device.

The pneumatic device is developed by the Medical Technology department of the University Medical Center (UMC) Utrecht, based on a previously reported design, which was shown to be safe to use in an MRI environment (Nazarian et al., 2022; Wienbruch et al., 2006). Intensity of air puffs delivered by the pneumatic device will be extensively tested before the start of the study, to prevent any discomfort for the participant. The device uses clean medical air from the UMC Utrecht and bacterial filters to prevent skin or respiratory tract irritation related to the minimal chance of particles detaching from components in the device. After each participant the device will be cleaned and the tip of the tube that stimulates the tongue plus filter, will be replaced for each participant.

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 above 18 years old
- Blank neurological history

Exclusion criteria

- Noncompliance with MRI screening checklist
- Claustrophobia
- Pregnancy
- Sensation deficits
- Inability to hear the instructions presented orally in the scanner without a hearing aid

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-03-2024
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO

Date:	27-12-2023
Application type:	First submission
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	NL84706.041.23