bRain-triggered Electrical stimulAtioN for Inducing Muscle Activation in individuals wiTh sEvere facial paralysis (REANIMATE)

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

Summary

ID

NL-OMON56911

Source
ToetsingOnline

Brief title
REANIMATE

Condition

- Other condition

Synonym
n/a

Health condition

n/a; fundamental research that contributes knowledge to the development of assistive technology for people with severe face and body paralysis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: brain-computer interfaces, face, facial paralysis, functional electrical stimulation

Outcome measures

Primary outcome

The main study parameter is the accuracy of FES-induced facial expressions. The accuracy will be accessed using a number of different measurements and analyses, including 1) manual and computer-based analysis of video recordings of subjects* facial movements during FES; 2) self-reported perceptual feedback of subjects regarding what facial expression was induced and their certainty estimates about it; 3) ratings of recognizability of FES-induced facial expressions in processed video recordings by external observers; 4) whenever possible, electromyography recordings tracking individual facial muscle movements during FES application.

Secondary outcome

The secondary study parameters or endpoints consist of stimulation parameters, effects of inter-subject variability and the relationship between individual facial muscles and wholistic facial expressions.

Study description

Background summary

Communication is an integral part of being a human. Communication means 1) the

transfer of conceptual information, or meaning, conveyed verbally or visually, and 2) the transfer of affective information, or emotion, conveyed by connotation (e.g., usage of positively or negatively loaded words), prosody (rhythm, tone, pitch, and volume of the voice), and non-verbal communication signals (e.g., facial expressions, posture, gestures, eye contact, spatial distance, and physical touch). Unfortunately, individuals with severe facial and whole-body paralysis are unable to use their facial expressions, body language and even speech for communication. State-of-the-art Augmentative and Alternative Communication (AAC) technology, including communication boards, motion tracking devices and Brain-Computer Interfaces (BCIs), generally focuses on restoring people*s ability to transfer conceptual information. The transfer of affective information via AAC technology has so far been limited to words with positive and negative connotations, for example, reflecting people*s emotional state. It has not been possible for individuals with severe facial or whole-body paralysis to use prosody and non-verbal communication signals to convey emotion.

A potential technology that could make non-verbal communication of affective information possible could detect a user*s intention to move their face, for example, for producing a facial expression, bypass impaired motor pathways and trigger external functional electrical stimulation (FES) of facial nerves to activate target facial muscles and thereby induce the intended facial expression on the user*s own face. Such a technology would constitute a *BCI-FES neuroprosthesis* for restoring facial expressions thereby enabling naturalistic communication of person*s emotions.

So far, it has been shown that intended distinct facial expressions can be detected in neural activity for a potential use in BCI, and that FES applied on individual facial nerves can lead to inducing individual facial movements of the mouth, eye, forehead, and cheeks. It remains unclear whether wholistic facial expressions that require simultaneous stimulation of multiple facial sites can be induced with FES. It is also unclear to what extend the accuracy of FES-evoked facial expressions may differ between FES setups (surface FES with electrodes placed on top of the skin versus percutaneous FES with needles piercing the skin). Overall, more research is needed to assess the potential of BCI-FES to induce facial expressions for non-verbal communication.

Study objective

The present study aims to test the feasibility of evoking basic facial expressions, as standardly identified in psychological research, with surface FES (stimulation via electrodes placed on top of the skin) and percutaneous FES (stimulation via needles placed under the skin in closer contact with target nerve-muscle connections).

Study design

Two experiments and a survey study will be conducted: 1) Experiment I with healthy participants and surface FES to induce individual facial muscle movements and facial expressions. 2) Experiment II with patients who undergo a brainstem surgery or a neuromuscular conflict surgery, during which percutaneous FES is used for clinical purposes. During that time, an additional FES session for research will be conducted to induce facial expressions. 3) a Survey study will be conducted with a new group of healthy participants (not part of Experiment I) to collect recognizability ratings of FES-induced facial expressions captured with video recordings during Experiments I and II.

Study burden and risks

All hardware used for stimulation is CE-marked or MTKF-approved, and is safe to use for the purpose of the present study. In Experiment I, the risk level is minimal since standard stimulation protocols based on published literature (e.g., Ilves et al., 2019 and Volk et al., 2020) will be followed to ensure subjects* well-being and comfort during FES recordings. Besides, in Experiment I, detailed monitoring of subjects* level of discomfort and pain will be carried out. For Experiment II, clinical and research FES are applied while the participants are under general anesthesia. The risk level is this case is minimal since stimulation parameters are defined in consultation with the neurosurgeon and neurophysiologist and follow the settings of the clinical procedure. There is no immediate benefit to the subjects as the study aims to gain scientific knowledge that in the long term can be applied to develop assistive technology for individuals with severe facial and/or whole-body paralysis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Experiment I with healthy volunteers:
• Age 18 years and higher

Experiment II with patient participants:
• Age 18 years and higher
• A clinical indication for undergoing a surgery, such as a brainstem stroke or a neurovascular conflict

Survey study with healthy volunteers:
• Age 18 years and higher

Exclusion criteria

Experiment I with healthy volunteers:
• A history of electrical stimulation on the face for clinical reasons
• Impairment in facial muscle movement

Experiment II with patient participants:
• Indication of longer than average (6 hours for brainstem surgery and 4 hours for neurovascular conflict surgery) duration of the procedure (estimation by the neurosurgeon).
• The neurosurgeon or neurophysiologist decides that a certain patient is not eligible to participate in the study (e.g., for medical or surgical reasons).
• Reported function loss that prohibits the accurate performance of the required tasks.

Survey study with healthy volunteers:
• Participation in Experiment I.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	75
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-07-2024
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	NL85351.041.23