T-REEX: Phase locked TRanscranial Electrical EXcitation

Published: 30-11-2022
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The aim of this study is to demonstrate that accurate brain stimulation is possible in anatomical location and timing.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cranial nerve disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON51691

Source
ToetsingOnline

Brief title
T-REEX

Condition

- Cranial nerve disorders (excl neoplasms)

Synonym
Cognitive disorders

Research involving
Human

Sponsors and support

Primary sponsor: Stichting IMEC Nederland
Source(s) of monetary or material Support: Stichting IMEC Nederland

Intervention

Keyword: brain stimulation, closed-loop stimulation, neuromodulation

Outcome measures

Primary outcome

The main study parameter is the phase difference (error) between the estimated phase of EEG activity and the phase of the delivered stimulation at the target location.

Secondary outcome

Phase change in the brain waves (10 Hz alpha activity) due to different tCS modalities and stimulation parameters used

Amplitude change in the brain waves (10 Hz alpha activity) due to different tCS modalities and stimulation parameters used

Study description

Background summary

Transcranial current stimulation (tCS) is a method in which small currents are applied to different places on the scalp to change the activity of specific brain regions. tCS has been extensively studied for its potential to stimulate brain regions in an accessible, non-invasive and pain-free manner. Potential applications include the treatment of psychiatric or neurological disorders.

Brain activity is characterized by rapid changes. These rapid changes affect the response to tCS and its subsequent effects. It is therefore necessary to consider the timing of the stimulation during tCS, as this provides better control of the tCS effects and helps to better understand these effects. This can be achieved with the so-called "close-loop tCS" approach, where the applied current is changed based on the measured brain activity.

However, current methods for closed-loop tCS suffer from artefacts in the measurements caused by the stimulation itself. Also, some methods estimate brain activity based on predictive models and thus do not rely on the actual measured signals. In both cases, the stimulation is less effective.

This study proposes a novel closed-loop tCS setup that could overcome these drawbacks. The aim of this study is to demonstrate that accurate brain

stimulation is technically possible in space and timing.

In the long term, the current study could contribute to increasing the knowledge about the effects of non-invasive tCS on brain activity and thereby improving tCS treatments.

Study objective

The aim of this study is to demonstrate that accurate brain stimulation is possible in anatomical location and timing.

Study design

Interventional, open label. All participants receive the same interventions.

Intervention

During this study, 3 different types of commonly used stimulation patterns are applied in random order. Each stimulation pattern with a different set of parameters where the amplitude and periodicity of the current delivered varies (9 combinations are tested per stimulation type).

For each stimulation type, the steps described below are repeated 5 times:
Stimulation type 1 (15 minutes)
5 seconds recording of brain activity without stimulation (25 seconds in total)
5 seconds of brain stimulation (25 seconds in total)
10 minutes rest
Repositioning the Electrodes for Type 2 Stimulation (1 minute)
Stimulation type 2 (15 minutes)
5 seconds recording of brain activity without stimulation (25 seconds in total)
5 seconds of brain stimulation (25 seconds in total)
10 minutes rest
Repositioning the electrodes for type 3 stimulation (1 minute)
Stimulation type 3 (15 minutes)
5 seconds recording of brain activity without stimulation (25 seconds in total)
5 seconds of brain stimulation (25 seconds in total)

Study burden and risks

The main burden consists of the time that subjects lose to participate, approximately 1.45 hours.

Like TMS, tCS is considered safe and well tolerated.

However, it can cause some side effects:
Headache
Scalp discomfort at the site of stimulation
Tingling, spasm or twitching of the facial muscles
Dizziness

Other possible side effects are related to increased skin sensitivity or redness around the areas where the electrodes are placed on the scalp.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Signed informed consent
Age between 18 and 64

Exclusion criteria

- Wounded or particular sensitive skin at areas of investigation. For example, skin-rash, discoloration, scars, or open wounds
- Allergies to adhesive or dry electrodes or silver chloride
- Pregnant or lactating
- Any of the following symptoms: fever, tiredness, dry cough, aches and pains, nasal congestion, runny nose, sore -throat, diarrhea.
- Known neurological disorders
- Previous epileptic episodes
- Active implants, such as pacemakers or brain stimulators
- Intracranial metal implants
- IMEC employees

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2023
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	T-REEX
Registration:	No

Ethics review

Approved WMO

Date:	30-11-2022
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL82733.015.22
Other	Studie wordt geregistreerd op www.clinicaltrials.gov voor eerste inclusie