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The effects of facial electrical stimulation on visual perception

Submission date 10/08/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/08/2023	**Overall study status** Completed	
Last Edited 14/08/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The research explores a technique called non-invasive transcranial alternating current stimulation (NITACS), which uses weak electrical currents applied to the face or scalp to influence brain activity. A key focus is understanding how this method can make people see light patterns, called phosphenes, without any actual light entering their eyes.

Who can participate?
Healthy volunteers aged 22-60 years

What does the study involve?
During the study, participants sit in a dimly lit room, electrodes are placed around their eyes, and weak currents are applied. They then report any light patterns they perceive.

What are the possible benefits and risks of participating?
Participating might offer insights into how the brain processes visual information and could pave the way for future visual aid technologies. However, there's a slight chance of discomfort from the electrical currents.

Where is the study run from?
Toronto Metropolitan University (formerly Ryerson University) (Canada)

When is the study starting and how long is it expected to run for?
September 2018 to September 2020

Who is funding the study?
Natural Sciences and Engineering Research Council of Canada

Who is the main contact?
Prof. Alexandre Douplik, douplik@torontomu.ca

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Spatial resolution of phosphenes within the visual field using non-invasive transcranial alternating current stimulation

Acronym
NITACS

Study objectives
The study's hypothesis suggests the possibility of generating spatially encoded phosphenes via electrical stimulation of the facial skin. Phosphenes are visual experiences that are not caused by light entering the eye.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 24/10/2019, Toronto Metropolitan University (Formerly Ryerson) (350 Victoria St, Toronto, M5B 2K3, Canada; +1 (0)416 979 5000 ext. 552491; rebchair@torontomu.ca), ref: 2019-324

Study design
Single-centre interventional experiment without allocation or masking

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Laboratory, University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Mapping and perception of phosphenes in healthy human volunteers using EEG electrode stimulation

Interventions
The device is a custom-made cutaneous superficial stimulator that administers charge-neutral current waveforms across multiple electrode combinations. "Phosphotron" was the name coined by Steven Beck in 1979, referring to a device that stimulates phosphenes. This name is the closest thing that describes the device used in this study.

In the proposed interventional study, healthy volunteers are equipped with an electrode dressing consisting of eight EEG gold cup electrodes placed around the orbital sockets. Participants undergo a procedure to determine their phosphene stimulation threshold by gradually increasing the stimulation current intensity until a phosphene is perceived, ensuring the intensity remains below 500 µA for safety. Following this, stimulation sites, named stimulation and control channels, are activated in a pseudo-randomized sequence. During each stimulation event, only two electrodes are active, and participants are instructed to sketch the perceived phosphene shape on a smartboard. The control channel involves no stimulation waveform across any electrode. The sketches are subsequently processed and analyzed to spatially resolve phosphenes in the visual field.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Phosphotron

Primary outcome measure
Phosphene perception and spatial localization are measured using Receiver Operating Characteristics (ROC) analysis of drawings on a smartboard, post-stimulation for each of the 64 stimulation events.

Secondary outcome measures
1. Stimulation threshold for phosphene perception measured using gradual current intensity increase until phosphene detection, determined at the beginning of each participant's session. Thus, finding optimal stimulation settings.
2. Phosphene stimulation efficacy for each channel measured using the percentage of channel-specific trials where phosphene perception was reported, assessed post-stimulation for each of the 64 stimulation events.
3. Spatial orientation of the overall phosphene distribution measured using a complete summation of all phosphene drawings, assessed post-stimulation for each of the 64 stimulation events.
4. Safety and comfort of participants measured by monitoring for signs of discomfort or adverse effects, continuously observed throughout each participant's session.

Overall study start date
01/09/2018

Completion date
01/09/2020

Eligibility

Key inclusion criteria
1. Healthy individuals: participants should not have any known neurological disorders or visual impairments
2. Age range: participants should be within the age range of 22-60 years
3. Consent: all participants must provide informed consent before participating in the study
4. No prior experience: participants should not have prior experience with non-invasive transcranial alternating current stimulation (NITACS) to ensure unbiased reporting of phosphenes
5. Ability to follow instructions: participants should be able to sit still, focus on a central point, and report their experiences accurately during the stimulation sessions
6. No known allergies or sensitivities: participants should not have allergies or sensitivities to any of the materials used, such as the Ten20 electrode paste or the gauze pad
7. History: no past history of recreational/prescription drug use (specifically hallucinogens, stimulants, anti-psychotics, anti-anxiety, SSRIs, cannabinoids, and tranquillizers), panic attacks, migraines, and agoraphobia

Participant type(s)
Healthy volunteer

Age group

Adult

Lower age limit
22 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
8

Total final enrolment
8

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
24/10/2019

Date of final enrolment
24/12/2019

Locations

Countries of recruitment
Canada

Study participating centre
Toronto Metropolitan University (formerly Ryerson University)
350 Victoria St
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Sponsor information

Organisation
Toronto Metropolitan University

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Sponsor type
University/education

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ROR
https://ror.org/05g13zd79

Funder(s)

Funder type
Research council

Funder Name
Natural Sciences and Engineering Research Council of Canada

Alternative Name(s)
Conseil de Recherches en Sciences Naturelles et en Génie du Canada, NSERC, CRSNG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Two to-be-peer-reviewed-and-published manuscripts are written.

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan

The gathered drawings will be thoroughly de-identified and anonymized, removing any information that could identify the source participant. These illustrations will be saved in JPG format and kept on a secure local drive. Researchers interested in accessing the data can reach out to the lab supervisor (email mentioned in the bespoke publications). Once requested, the de-identified data will be sent via email to the requester.
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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			14/08/2023	No	Yes