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Noninvasive brain stimulation for attention deficits after traumatic brain injury

Submission date
11/10/2020

Recruitment status
No longer recruiting

Registration date
15/10/2020

Overall study status
Completed

Last Edited
02/06/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
After a traumatic brain injury, disturbances in the attentional processes have a direct negative effect on functional recovery and on return to complex activities. To date, there is no good attention remediation treatment available. Transcranial direct current stimulation (tDCS) involves constant, low direct current being delivered via electrodes on the head. The aim of this study is to assess the feasibility of using tDCS to improve attention disorders in patients with mild complicated to severe subacute traumatic brain injury, hospitalized in an inpatient rehabilitation facility.

Who can participate?
Male and female over 18 years old with attention disorders after a mild complicated to severe subacute traumatic brain injury

What does the study involve?
All participants will receive a 20-minute tDCS stimulation three times a week for 3 weeks. An evaluation will be performed before and after the intervention. Participant characteristics, as well as information about satisfaction, tolerability and adverse effects, will be collected.

What are the possible benefits and risks of participating?
Participants will possibly improve their attention with the proposed intervention. Possible side effects of tDCS are fatigue, pain, tingling, skin redness and a burning sensation. Seizures are the most concerning adverse events. If compensatory safety steps are taken, experts agree that the expected benefit justifies the increased risk.

Where is the study run from?
Institut universitaire sur la réadaptation en déficience physique de Montréal (Canada)

When is the study starting and how long is it expected to run for?
November 2017 to January 2020

Who is funding the study?
The Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR) (Canada)

Who is the main contact?
Dr Eve Boissonnault
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CRIR-1337-0518

Study information

Scientific Title
Brain stimulation, an innovative approach for the treatment of attention deficits after traumatic brain injury during the inpatient phase of rehabilitation: a feasibility study

Study objectives
It is hypothesized that anodal transcranial direct-current stimulation (tDCS) applied on the left DLPFC has the potential to enhance attention in patients with mild complicated to severe TBI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/06/2018, Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR) Research Ethics Board (6363, chemin Hudson, bureau 061, Pavillon Lindsay de l' IURDPM, Montréal QC H3S 1M9, Canada; +1 (0)514 340-2085 (4778); administration.crir@ssss.gouv.qc.ca), ref: CRIR-1337-0518)

Study design
Single-centre literature review and feasibility study

Primary study design
Interventional

Secondary study design
Non-controlled study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Attention deficits after traumatic brain injury

Interventions
Participants will receive the tDCS protocol, which consists of 20 minutes tDCS active stimulation three times a week for 3 weeks for a total of nine sessions. The tDCS will be applied by experienced researchers. The skin at the site of the electrodes will be cleaned with alcohol. Two saline-soaked electrodes of 25 cm^2 each (5 x 5 cm) will be placed on the scalp: an anode (excitatory electrode) overlying the left DLPFC, and a cathode (reference electrode) above the right supraorbital area. The electrodes will be inserted into 5 x 5 cm sponges soaked in saline and fixed with two elastic bands. tDCS will be delivered using a battery-driven tDCS stimulator (Model 1300A; Soterix Medical, New York, NY, USA). Current delivery will be monitored throughout the testing. Participants will undergo 20-minute sessions of tDCS at an intensity of 2 mA and a current density of 0,08 mA/cm^2. Participants will sit in a quiet room during stimulation and will be asked to remain inactive.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Battery-driven tDCS stimulator (Model 1300A; Soterix Medical, New York, NY, USA)

Primary outcome measure
Tolerance, adverse effects and safety measured using a customized questionnaire adapted from those provided by Brunoni et al. at the end of each stimulation

Secondary outcome measures
1. Selective attention measured using the Test of Everyday Attention and the Stroop from the Delis-Kaplan Executive Function System at baseline and after the last stimulation session
2. Sustained and selective attention measured using the Ruff 2 &7 Selective Attention Test at baseline and after the last stimulation session
3. Visual sustained attention, vigilance, impulsivity and inattentiveness measured using the Conners Continuous Performance Test 3rd Edition at baseline and after the last stimulation session
4. Visual sustained attention, vigilance, impulsivity and inattentiveness measured using the Conners Continuous Performance Test 3rd Edition at baseline and after the last stimulation session
5. Working memory measured using the Digit Span subtest from the Wechsler adult intelligence scale–Fourth Edition (WAIS-IV) at baseline and after the last stimulation session
6. Processing speed measured using the Coding subtests from the WAIS-IV Edition at baseline and after the last stimulation session
7. Ability to analyze and synthesize abstract visual stimuli measured using the Block Design subtest from the WAIS-IV at baseline and after the last stimulation session

Overall study start date
01/11/2017

Completion date
01/02/2020

Eligibility

Key inclusion criteria
1. Current hospitalization
2. Age 18 years old or more
3. Diagnosis of mild complicated, moderate or severe TBI
4. Attentional impairment as per qualitative clinical assessment
5. French or English speaking
6. Tolerance to 45 to 60 minutes neuropsychology evaluation
7. Capacity to consent in accordance with the Nova Scotia Hospitals Act

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
5

Total final enrolment
6

Key exclusion criteria
1. History of neurological disease not resulting from the current TBI (e.g., stroke, multiple sclerosis, neurodegenerative disorders)
2. Psychiatric illness (e.g., depression, schizophrenia, anxiety disorders)
3. Aphasia and compromises in understanding instructions
4. Significant deafness or blindness
5. Contraindication to tDCS (e.g., seizure, extensive cranial vault lesion, pregnancy or breastfeeding, pacemaker, cochlear implants or cerebral metal implanted device or clip)
6. Scar or skull deformity at the site of electrodes placement
7. Epileptogenic medication
8. Penetrating TBI

Date of first enrolment
01/09/2018

Date of final enrolment
01/01/2020

Locations

Countries of recruitment
Canada

Study participating centre
Institut universitaire sur la réadaptation en déficience physique de Montréal (IURDPM)
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Sponsor information

Organisation
Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal

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Sponsor type
Research organisation

Website
https://crir.ca/

Funder(s)

Funder type
Research organisation

Funder Name
Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available upon request from Ève Boissonnault (eve.boissonnault@umontreal.ca). The data is available already, since 24/03/2020. Original data on paper sheets will be kept by Johanne Higgins at the IURPDM, in a locked closet for a 5-year period. The anonymized data and statistical analysis will be kept by Ève Boissonnault in Excel spreadsheets for a 5-year period as well. The data will be destroyed afterwards. The anonymized data is available on reasonable request. It was specified in the consent form signed by every participant.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/05/2021	02/06/2021	Yes	No