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The effect of transcranial direct current stimulation (tDCS) on diabetes-related visual impairment (diabetic retinopathy)

Submission date	Recruitment status	[_] Prospectively registered
12/01/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/03/2021	Eye Diseases	

Plain English summary of protocol

Background and study aims
Diabetic retinopathy is a complication of diabetes, caused by high blood sugar levels damaging the back of the eye (retina). It can cause blindness if left undiagnosed and untreated. Proliferative diabetic retinopathy (PDR) is a severe complication of diabetes and the leading cause of preventable blindness.
In the present study, we explored the potential of transcranial direct current stimulation (tDCS) to enhance PDR patients' residual vision.
Transcranial direct current stimulation (tDCS) is a form of brain stimulation that uses constant, low direct current delivered via electrodes on the head.

Who can participate?
Patients clinically diagnosed with PDR who have the capacity to consent participated in this study. They are right-handed and at least 18 years of age during the experiment.

What does the study involve?
Patients were divided into two groups: tDCS and sham group. Patients in the tDCS group received 10 minutes of tDCS stimulation of the part of the brain that process visual information called the visual cortex. Patients in the sham group only received tDCS stimulation for 30 seconds. Visual acuity and ability to discriminate numbers of non-verbal stimuli such as dots (number acuity) were measured before and after stimulation.

What are the possible benefits and risks of participating?
tDCS is a safe and non-invasive method of stimulating the brain. The current is very low (1mA) and will not cause pain or skin burn. Skin irritation is only documented for an extended period of stimulation and higher current intensity. This study expected to improve visual and number acuity of patients who will receive negative current or cathodal tDCS.

Where is the study run from?
Nazareth General Hospital in Dagupan City, Pangasinan (Philippines)

When is the study starting and how long is it expected to run for?
October 2019 to February 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Shane Fresnoza, shane.fresnoza@uni-graz.at

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Visual cortex transcranial direct current stimulation for proliferative diabetic retinopathy patients: an exploratory randomized trial

Acronym
VTDCSPDR

Study objectives

Retinal diseases, including the early stages of diabetic retinopathy, are characterized by high internal noise within the visual pathways which further aggravates impaired visual functions. Cathodal tDCS could reduce neural noise and improve the processing of impaired visual inputs from the damaged retinas of PDR patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The clinic where the study is conducted is located in a private, non-research and non-teaching hospital which do not have a formal ethics committee. The patients included in the study were all private patients, who provided informed consent for participation. The study protocol (STUDY PROTOCOL Version 1.1) was approved by the chief of clinics of Nazareth General Hospital in Dagupan City, Pangasinan, Philippines.

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Study design
Double-blinded randomized sham-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improving the residual vision of proliferative diabetic retinopathy patients

Interventions
Participants were allocated into either the tDCS group or sham group using block randomization (online Study Randomizer Software (https://www.studyrandomizer.com)).
Participants in the tDCS group received 10 minutes 1 mA cathodal tDCS stimulation of the primary visual cortex.
Participants in the sham group were only stimulated for 30 seconds using the same stimulation parameters.

Measures were taken immediately before and after the stimulation, there was no further follow up.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcranial direct current stimulation (tDCS)

Primary outcome(s)

Visual acuity is measured using the logarithm of the minimum angle of resolution (LogMAR) scores before and after stimulation

Key secondary outcome(s))
Number acuity measured before and after stimulation using a numerical discrimination task. (Patients were presented with an intermixed of 60 black and white dots. After the stimulus presentation time of 500ms, patients have to indicate whether there were more black or white dots by key presses)

Completion date
20/02/2020

Eligibility

Key inclusion criteria
1. Clinically diagnosed PDR patients
2. Voluntary participation and capacity to consent
3. Right-handedness (Edinburgh Handedness Test)
4. At least 18 years of age during the experiment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
22

Key exclusion criteria
1. Other co-morbid conditions such as chronic or residual neurological, psychological, and psychiatric disorders (esp. epilepsy, schizophrenia, mania or depression)
2. History of head injury with loss of consciousness
3. Intracerebral ischemia/history of cerebral bleeding
4. Metal implants in the head and neck area (e.g. post-operative clips)
5. Electronic implants (pacemakers, cochlear implant, deep brain stimulator)
6. Pregnancy or breastfeeding
7. Alcohol or drug addiction
8. Local or global aphasia
9. Any legal reason why the candidate cannot participate
10. Participation in another scientific or clinical study within the last 8 weeks

Date of first enrolment
20/02/2020

Date of final enrolment
20/02/2020

Locations

Countries of recruitment
Austria

Philippines

Study participating centre
Nazareth General Hospital
Perez Blvd
Pangasinan
Dagupan City
Philippines
2433

Study participating centre
University of Graz
Institute of Psychology
Universitätsplatz 2
Graz
Austria
8010

Sponsor information

Organisation
University of Graz

ROR
https://ror.org/01faaaf77

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/02/2021	08/03/2021	Yes	No
Protocol file	version v1.1		04/02/2021	No	No