

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

<b>Submission date</b> 12/01/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/03/2021	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## 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

**Contact name**  
Dr Shane Fresnoza

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
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?
<a href="#">Results article</a>	results	21/02/2021	08/03/2021	Yes	No
<a href="#">Protocol file</a>	version v1.1		04/02/2021	No	No