

# The effects of transcranial direct current stimulation on the brain electrical signal changes that happen to nicotine users: an exploratory study

<b>Submission date</b> 12/06/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/06/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/12/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

**Background and study aims**  
Nicotine use disorder, also known as tobacco addiction, is a serious condition that can make it difficult to stop using tobacco products. This study investigates electrical changes in the brain under the influence of direct current brain stimulation (tDCS) to better understand the disorder's basis and provide alternative treatments. tDCS is known to have some benefits according to previous studies in rehabilitation medicine, post-stroke movement disorders, nerve studies and other substance disorders.

**Who can participate?**  
People aged 18-55 years with nicotine use disorder

**What does the study involve?**  
Participants will receive tDCS intervention lasting 20 minutes per session. These sessions will occur 5 days a week, spanning 2 weeks. Participants undergo an electroencephalogram (EEG) recording at 6 weeks.

**What are the possible benefits and risks of participating?**  
There are no direct benefits to participants. However, participation might help to improve our understanding of nicotine use disorder and provide better treatment in the future. The device used is simple and safe. No invasive procedures are involved as the device is applied across the head surface without creating any wounds. There might be an unpleasant tingling sensation, headache, itchiness, or burning sensation during the procedure due to the placement of electrodes.

**Where is the study run from?**  
Hospital Permai (Malaysia)

When is the study starting and how long is it expected to run for?  
January 2024 to December 2024

Who is funding the study?  
Monash University (Malaysia)

Who is the main contact?  
Dr Yee Hway Ann @ Anne Yee, [anne.yee@monash.edu](mailto:anne.yee@monash.edu)

**Study website**  
<https://research.monash.edu/en/persons/yee-hway-ann-anne-yee>

## Contact information

**Type(s)**  
Public, Scientific, Principal Investigator

**Contact name**  
Prof Yee Hway Ann @ Anne Yee Yee

**ORCID ID**  
<https://orcid.org/0000-0002-9835-6798>

**Contact details**  
Jeffrey Cheah Sch of Med & HS  
Monash University Malaysia  
Johore Bahru  
Malaysia  
80100  
+60 (0)198891360  
[anne.yee@monash.edu](mailto:anne.yee@monash.edu)

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
MUM-RP-tDCSN-VER01-31JAN24

## Study information

**Scientific Title**

The effects of transcranial direct current stimulation on EEG changes in nicotine use disorder patients: an exploratory study

## **Acronym**

tDCSN

## **Study objectives**

1. There are EEG changes (alpha, beta delta and theta wave at different regions, including the prefrontal lateral lobe) before and after transcranial direct current stimulation (tDCS) in nicotine use disorder patients.
2. There is efficacy of tDCS in the treatment of nicotine withdrawal.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

1. Approved 17/07/2024, National Institute of Health, Malaysia (Jalan Setia Murni U13/52, Seksyen U13 Setia Alam, Shah Alam, 40170, Malaysia; +60 (0)3 3362 8888; mrecsec@moh.gov.my), ref: RSCH-ID-24-01102-QTS
2. Approved 17/07/2024, Monash University Human Research Ethics Committee (MUHREC) (Monash Human Ethics Office, Wellington Road, Clayton, Victoria, 3800, Australia; +61 (0)3 990 51478; lauren.morris@monash.edu), ref: 44302

## **Study design**

This exploratory research (involve intervention) is focused on examining the impact of transcranial Direct Current Stimulation (tDCS) on subjects diagnosed with nicotine use disorder. The study primarily utilizes Electroencephalography (EEG) to monitor and analyze changes in cortical activities resulting from the tDCS intervention. The objective is to understand how tDCS influences brain function in individuals affected by nicotine dependence.

## **Primary study design**

Interventional

## **Secondary study design**

Non randomised study

## **Study setting(s)**

Hospital

## **Study type(s)**

Other

## **Participant information sheet**

See study outputs table

## **Health condition(s) or problem(s) studied**

Nicotine use disorder

## **Interventions**

Transcranial Direct Current Stimulation (tDCS). Participants will receive tDCS intervention lasting 20 minutes per session. These sessions will occur 5 days a week, spanning 2 weeks. The tDCS will be delivered following standardized protocols to ensure safety and uniformity across treatments. There is no control group, hence, no randomisation is required.

**Intervention Type**

Device

**Pharmaceutical study type(s)**

Not Applicable

**Phase**

Not Applicable

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

Transcranial direct current stimulation device

**Primary outcome measure**

EEG is measured using the standard 64-channel EEG machine at baseline (T0), week 1 (T1) and week 6 (T6)

**Secondary outcome measures**

1. Nicotine dependence assessed using the Fagerstrom Test for Nicotine Dependence (FTND) at baseline (T0), week 1 (T1) and week 6 (T6)
2. Withdrawal symptoms assessed using the Minnesota Nicotine Withdrawal Scale (MNWS) at baseline (T0), week 1 (T1) and week 6 (T6)

**Overall study start date**

31/01/2024

**Completion date**

31/12/2024

## Eligibility

**Key inclusion criteria**

1. Aged 18-55 years
2. Diagnosed with nicotine use disorder as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)
3. Healthy with no history of seizure, epilepsy, head trauma, or head surgery

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

55 Years

**Sex**

Both

**Target number of participants**

10

**Key exclusion criteria**

1. Concomitant psychiatric disorder
2. Polysubstance disorder/uses
3. On psychotropic treatment

**Date of first enrolment**

01/10/2024

**Date of final enrolment**

01/12/2024

**Locations****Countries of recruitment**

Malaysia

**Study participating centre****Hospital Permai**

Jalan Tampoi

Johor Bahru

Malaysia

81200

**Sponsor information****Organisation**

Monash University Malaysia

**Sponsor details**

No. 8, Masjid Sultan Abu Bakar

Johor

Malaysia

80100

+60 (0)35514 6000

mum.business.research@monash.edu

**Sponsor type**

University/education

**Website**

<https://www.monash.edu.my/>

**ROR**

<https://ror.org/00yncr324>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Jeffrey Cheah School of Medicine and Health Sciences, Monash University Malaysia

**Alternative Name(s)**

Jeffrey Cheah School of Medicine & Health Sciences, Jeffrey Cheah School of Medicine and Health Sciences, JCSMHS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Malaysia

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/06/2025

**Individual participant data (IPD) sharing plan**

The datasets will be stored in a non-publicly available repository, however, other authors can request

**IPD sharing plan summary**

Stored in non-publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		31/01/2024	20/06/2024	No	Yes
<a href="#">Protocol file</a>		31/01/2024	20/06/2024	No	No