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

Submission date
12/06/2024

Registration date
26/06/2024

Last Edited
17/12/2024

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

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

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

Contact information

Type(s)
Public, Scientific, Principal Investigator

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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
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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?
Participant information sheet		31/01/2024	20/06/2024	No	Yes
Protocol file		31/01/2024	20/06/2024	No	No