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Effect of neuromodulation technique (tDCS) in reducing the craving and dependence in alcohol dependence

Submission date
30/08/2025

Recruitment status
No longer recruiting

Registration date
12/09/2025

Overall study status
Completed

Last Edited
08/09/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Alcohol Dependence Syndrome (ADS) represents a major public health challenge worldwide, contributing significantly to the global burden of disease and injury. Craving is now recognized as a diagnostic criterion in the DSM-5, partly due to its association with alterations in brain reward circuitry. Given the potential benefits and the need for improved treatments, this study was designed to investigate the efficacy of transcranial direct current stimulation (tDCS) in a Northern Indian population. The primary aim was to compare the effect of active tDCS versus sham tDCS on reducing alcohol craving and the severity of dependence among inpatients with ADS.

Who can participate?
Patients aged between 18 and 60 years with a diagnosis of ADS who are being admitted to the psychiatry ward

What does the study involve?
Participants were randomly assigned to either Group A (active tDCS) or Group B (sham tDCS) using a computer-generated sequence, with masking achieved through the device's built-in sham protocol. Both groups underwent ten stimulation sessions over five consecutive days. Group A received bilateral transcranial direct current stimulation (tDCS) at 2 mA for 20 minutes per session, with electrodes placed over the left (cathodal, F3) and right (anodal, F4) dorsolateral prefrontal cortex using saline-soaked sponges. Group B followed the same setup, but received only brief current delivery at the beginning and end of each session to mimic the sensation of active stimulation and maintain blinding.

What are the possible benefits and risks of participating?
Health benefits are seen as a reduction in the craving for substance use.
Notable risks are headache, rash, and tingling sensations, mostly noticed with the use of tDCS.

Where is the study run from?
The Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, India

When is the study starting and how long is it expected to run for?
December 2023 to March 2025

Who is funding the study?
The Swami Rama Himalayan University, India

Who is the main contact?
Dr Shobit Garg, shobit.garg@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparative study of effect of tDCS (Trans cranial direct current stimulation) vs sham tDCS on reducing the craving and severity of dependence among patients of alcohol dependence syndrome

Study objectives
To measure the changes in craving as measured using PACS after treatment with tDCS and comparing it with sham tDCS.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/03/2024, Ethics Committee of the Swami Rama Himalayan University (Swami Ram Nagar, Jolly Grant, Dehradun, 248016, India; +91-135-2471111; research@srhu.edu.in), ref: SRHU /HIMS/ETHICS/2024/36

Study design
Single-centre interventional single-blinded randomized sham-controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Reducing the severity and dependence on alcohol in alcohol use disorder.

Interventions
Participants were randomly allocated to one of two groups: Group A (active tDCS) or Group B (Sham tDCS) using a computer-generated random number sequence. Masking was done using the built-in sham protocol. The current was only delivered for the first 30 seconds (ramping up) and the last 30 seconds (ramping down) of the 20 minutes.

All participants received ten sessions of stimulation over five consecutive days (two sessions per day).
1. Group A (Active tDCS): A weak direct current (2 mA) was delivered for 20 minutes per session. The intervention employed bilateral tDCS, with the cathodal (inhibitory) electrode placed over the left dlPFC (F3 position) and the anodal (excitatory) electrode over the right dlPFC (F4 position). Saline-soaked sponges were used as electrodes.
2. Group B (Sham tDCS): The procedure mirrored the active group, including electrode placement. However, the current was only delivered for the first 30 seconds (ramping up) and the last 30 seconds (ramping down) of the 20 minutes. This method mimics the initial tingling sensations associated with active tDCS, ensuring effective blinding.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
SOTERIX medical 1*1 Low intensity transcranial direct current stimulation

Primary outcome(s)
Change in craving as measured using the Penn Alcohol Craving Scale (PACS) at baseline and after 10 sessions of tDCS at day 6

Key secondary outcome(s))
The role of severity as a mediator for the changes in cravings measured using the Severity of Alcohol Dependence Questionnaire (SADQ) at baseline and after 10 sessions of tDCS at day 6

Completion date
10/03/2025

Eligibility

Key inclusion criteria
1. Age between 18 and 60 years (both genders)
2. A diagnosis of Alcohol Dependence Syndrome according to ICD-10 DCR criteria 14
3. Admission to the psychiatry ward

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
48

Key exclusion criteria
1. Co-morbid substance use disorders (excluding nicotine).
2. Co-morbid psychiatric disorders
3. Uncontrolled or serious medical or surgical illnesses
4. Use of anti-craving or psychotropic medications (except benzodiazepines for withdrawal management) within the past month

Date of first enrolment
10/03/2024

Date of final enrolment
05/03/2025

Locations

Countries of recruitment
India

Study participating centre
Himalayan Institute of Medical Sciences
SRHU, Swami Rama Nagar, Jolly Grant
Dehradun
India
248016

Sponsor information

Organisation
Swami Rama Himalayan University

ROR
https://ror.org/02nw97x94

Funder(s)

Funder type
University/education

Funder Name
Swami Rama Himalayan University

Alternative Name(s)
SRHU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
India

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Shobit Garg, shobit.garg@gmail.com

IPD sharing plan summary

Available on request