

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

Submission date 30/08/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/09/2025	Condition category 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

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital, University/medical school/dental school

Study type(s)

Treatment, Efficacy

Participant information sheet

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

Pharmaceutical study type(s)

Neuromodulation device

Phase

Phase III/IV

Drug/device/biological/vaccine name(s)

SOTERIX medical 1*1 Low intensity transcranial direct current stimulation

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

06/12/2023

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

50

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

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Sponsor information**Organisation**

Swami Rama Himalayan University

Sponsor details

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Sponsor type

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ROR

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

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

05/12/2025

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