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New approaches of transcranial magnetic stimulation in the treatment of addiction and depression

Submission date
24/09/2025

Recruitment status
No longer recruiting

Registration date
30/09/2025

Overall study status
Completed

Last Edited
30/09/2025

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
Depression is a common mental health problem that can affect mood, sleep, and daily life. Alcohol addiction is a chronic condition leading to strong cravings for alcohol and a high risk of relapse. This study tests repetitive transcranial magnetic stimulation (rTMS) combined with brain-computer interface technology. It aims to help people with depression and alcohol addiction by improving their symptoms and reducing relapse risk. We hope to learn how this new treatment affects brain activity.

Who can participate?
1. Patients with depression: aged 16-70 years, right-handed, normal vision and hearing, meeting the ICD-10 diagnostic criteria for depressive disorder, and having been on a stable medication regimen for over 1 month.
2. Patients with alcohol addiction: aged 16-70 years, currently hospitalized for alcohol cessation, voluntary participation, no significant symptoms after the withdrawal period, meeting the ICD-10 diagnostic criteria for alcohol dependence.
3. Healthy volunteers:aged 18-60 years, any gender, no history of mental or major physical illnesses. All participants must be right-handed, have normal or corrected-to-normal vision and hearing, and pass strict safety screening (e.g., no history of epilepsy, no MRI contraindications).

What does the study involve?
Study 1: Participants with depression were randomly assigned to either a real rTMS group or a sham stimulation group. EEG and emotional scales were measured both before and after the treatment.
Study 2: Participants with alcohol dependence were randomly divided into three groups: left-sided rTMS, right-sided rTMS, or sham stimulation. EEG and assessments were conducted before and after the treatment, and MRI scans were performed before the intervention.
Study 3: Participants with alcohol dependence had their brain activity recorded.

What are the potential benefits and risks of participation?
Potential benefits: may improve depressive symptoms or alcohol craving behavior; receive free

professional assessment and intervention; contribute data to support research on mental health treatments.
Potential risks and discomforts: rTMS may cause mild reactions such as headache or scalp discomfort; MRI/fMRI scans may induce claustrophobia; in very rare cases, seizures may occur (this risk is strictly controlled via exclusion criteria).
Safety management measures: stimulation intensity is kept within safe limits; high-risk individuals are excluded; medical personnel and emergency response plans are in place.

Where is the study conducted?
Hefei Fourth People's Hospital (Anhui Mental Health Center) (China)

When does the study start and how long is it expected to last?
January 2023 to December 2025

Who is funding this research?
Anhui Province Key Research and Development Program Project (China)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
PID 205866

Study information

Scientific Title
Using brain-computer interfaces to improve alcohol addiction relapse and probe neuromodulatory mechanisms in deep nuclei

Study objectives
Experiment 1 aims to investigate the regulatory effects of left-right asymmetric repetitive transcranial magnetic stimulation (rTMS) (e.g., 20 Hz left dorsolateral prefrontal cortex [dlPFC] + 1 Hz right dlPFC) on event-related potentials (ERPs) and brain functions in depressive patients under the emotional faces Oddball paradigm.

Experiment 2 aims to explore the resolution of precision dependence on individual-to-standard space registration in traditional analyses through automated specific fiber bundle extraction and a non-rigid registration algorithm based on coherent point drift. It seeks to establish an electroencephalogram (EEG)-based brain-computer interface system, comparing intervention effects between left-side TMS-EEG, right-side control group, and sham stimulation group. The goal is to address high relapse rates in alcohol addiction and provide novel therapeutic targets for prevention and treatment.

Experiment 3 aims to investigate post-physical therapy comparisons between intervention and control groups of alcohol-addicted patients regarding functional near-infrared spectroscopy (fNIRS) changes and alterations in alcohol craving.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/01/2023, Medical Research Ethics Committee of Hefei Fourth People's Hospital (316 Huangshan Road, Shushan District, Hefei, 230026, China; +86 (0)551 6361 6193; 2514331322@qq.com), ref: HFSY-IRB-KYXM-WL(2023001)

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Major depressive disorder and alcohol use disorder

Interventions
Study 1:
Experimenters use a computer to create a series of random number sequences. These numbers are used to designate which treatment group a participant enters. Odd numbers indicate active rTMS group and even numbers indicate sham rTMS group. Bilateral rTMS was applied sequentially to the left dorsolateral prefrontal cortex (dlPFC) at 20 Hz and the right dlPFC at 1 Hz. Active rTMS parameters were set as follows: right dlPFC stimulation at 1 Hz, 100% RMT intensity, with a 2-second inter-pulse interval, totaling 800 pulses over 14 minutes; left dlPFC stimulation at 20 Hz, also at 100% RMT, delivered in trains of 10 pulses with 2 second inter-train intervals, totaling 1500 pulses over 6 minutes. For sham rTMS, the same stimulation protocol and parameters were used, but without actual magnetic field delivery. Instead, electrodes applied to the left or right forehead delivered weak currents to simulate the electric field sensation of real stimulation. The electrical stimulation parameters were set as: monophasic square wave, pulse width 100 μs, and current intensity 4 mA. All participants wore earplugs to reduce acoustic noise during the procedure.

Study 2:
Participants with alcohol use disorder will be recruited and randomly divided into two groups, alongside a healthy control group.
Experimental Group: Participants with alcohol use disorder underwent two single-pulse TMS-EEG sessions (one session per day) targeting the left dorsolateral prefrontal cortex (F3). The stimulation intensity was set at 100% of the motor threshold, with 100 pulses delivered per session.
Control Group 1: The intervention was identical to the experimental group but targeted the right dorsolateral prefrontal cortex (F4).
Sham Stimulation Group: The stimulation site was the same as the experimental group (F3), but a sham coil was used to replicate the sound and sensation without delivering significant magnetic stimulation.
MRI, EEG, and scale data will be collected before the intervention, and EEG data will be collected after the intervention.

Study 3:
Participants with alcohol use disorder will be recruited and functional near-infrared spectroscopy (fNIRS) will be measured.

Experimenters use a computer to create a series of random number sequences. These numbers are used to designate which treatment group a participant enters. Odd numbers indicate active rTMS group and even numbers indicate sham rTMS group. Process of allocation concealment:
Sealed Envelope Method: A series of sealed and opaque envelopes are prepared in advance, each containing a slip of paper with the treatment group to which the participant belongs. The envelopes were not labeled in any way, and the exact assignment was known only when opened.
Preparation of envelopes: prepare a sufficient number of envelopes in advance according to the randomization list.
Numbering administration: number each envelope for tracking and administration.
Randomization: when a participant is eligible, the researcher takes the next unopened envelope in order and groups them according to their contents.
Preservation of Envelopes: Envelopes that have been used should be kept in a safe place until the end of the study for verification. Single-blind: only the participant does not know which

treatment he or she is receiving, while the researcher and other relevant people know the grouping information.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Study 1:
Electroencephalography (EEG) data acquired using an Event-Related Potential (ERP) system before and after treatment (within 2 weeks)

Study 2:
1. Magnetic resonance imaging (MRI) data acquired using an MRI scanner before the intervention
2. Electroencephalography (EEG) data measured using an Event-Related Potential (ERP) system before and after the intervention

Study 3:
Brain hemodynamic activity (blood oxygenation) assessed using functional near-infrared spectroscopy (fNIRS) at baseline and after the intervention (within 1 week)

Key secondary outcome(s))
Study 1:
1. Depression severity measured using the Hamilton Depression Rating Scale (HAMD) at baseline and after treatment (within 2 weeks)
2. Anxiety severity measured using the Hamilton Anxiety Rating Scale (HAMA) at baseline and after treatment (within 2 weeks)
3. Psychological symptoms measured using the Symptom Checklist-90 (SCL-90) at baseline and after treatment (within 2 weeks)
4. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and after treatment (within 2 weeks)
5. Positive and negative affect measured using the Positive and Negative Affect Schedule (PANAS) at baseline and after treatment (within 2 weeks)
6. Depression symptoms measured using the Zung Self-Rating Depression Scale (SDS) at baseline and after treatment (within 2 weeks)
7. Anxiety symptoms measured using the Zung Self-Rating Anxiety Scale (SAS) at baseline and after treatment (within 2 weeks)

Study 2:
1. Alcohol craving measured using the Alcohol Craving Scale (ACS) at baseline (prior to intervention)
2. Alcohol use disorder severity measured using the Alcohol Use Disorders Identification Test (AUDIT) at baseline (prior to intervention)
3. Anxiety severity measured using the Hamilton Anxiety Rating Scale (HAMA) at baseline (prior to intervention)
4. Alcohol craving measured using the Penn Alcohol Craving Scale (PACS) at baseline (prior to intervention)

Study 3:
Reaction time and accuracy measured using an alcohol-related paradigm at baseline

Completion date

31/12/2025

Eligibility

Key inclusion criteria
Depressed participants:
1. Aged 18-60 years
2. Normal hearing, normal vision or normal corrected vision
3. Right-handed
4. Have received a stable dose of medication for more than 1 month
5. Diagnosed with a depressive disorder according to the International Classification of Diseases, 10th edition (ICD-10) diagnostic criteria

Healthy participants:
1. Age 18-60 years
2. Normal hearing, normal or corrected vision
3. Right-handed
4. No previous diagnosis of mental or psychological illness
5. No history of major physical illness

Alcohol addiction patients:
1. Aged 16-70 years old
2. Gender: Unrestricted
3. Currently receiving inpatient alcohol abstinence treatment
4. Voluntarily participate in the study and sign the informed consent form
5. Meet the ICD-10 diagnostic criteria for alcohol dependence syndrome
6. Post-acute withdrawal phase (14-30 days after cessation), with no significant withdrawal symptoms (CIWA-Ar score <7 points, MMSE ≥26 points)
7. At least 1 year of continuous alcohol use prior to systematic abstinence treatment
8. Normal vision, color vision, and hearing
9. Right-handed

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria

1. Cardiovascular and neurological diseases
2. History of head trauma with loss of consciousness
3. Physical anomalies
4. History of epilepsy
5. Pregnancy or breastfeeding
6. Treatment with electroconvulsive therapy
7. History of syncope
8. Currently participating in other research projects
9. Unwilling or unable to complete the entire experimental procedure

Exclusion criteria for alcohol addiction:
1. Contraindications to TMS, MRI, and EEG (such as metal implants in the head, claustrophobia, etc)
2. Pregnant or lactating women, or women of childbearing age who are planning to become pregnant
3. Severe/uncontrollable systemic diseases (such as respiratory, circulatory, digestive, nervous and other systemic diseases) or mental illness (severe depression, schizophrenia, etc)
4. Other types of substance or non-substance addiction
5. Unable to sign the informed consent form
6. Illiterate
7. Unable to cooperate in completing the experiment

Date of first enrolment
20/03/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
China

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Hefei Fourth People's Hospital
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Sponsor information

Organisation
Affiliated Psychological Hospital, Anhui Medical University

Funder(s)

Funder type
Government

Funder Name
Anhui Provincial Key Research and Development Plan

Alternative Name(s)
Key Research and Development Program of Anhui Province, Key Research and Development Project of Anhui Province, , Key Technologies Research and Development Program of Anhui Province

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

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 Wan Li (wanli@ahmu.edu.cn) after the publication of the article

IPD sharing plan summary
Available on request