Statement and Filing Application for Correction of Clinical Trials Registration Error

To the Institutional Review Board,

Study Title: Intervention Effect of High Definition Transcranial Direct Current Stimulation (HD-tDCS) on Depressive Disorder

IRB Approval Number: 2020H025

ClinicalTrials.gov Identifier: NCT05286645

Principal Investigator: Kai Wang

During the peer review process and internal registry review, our research team identified that some information registered on ClinicalTrials.gov (including the primary outcome and certain eligibility criteria) is inconsistent with the original protocol approved by the local IRB.

After comprehensive internal verification, we confirm the following:

1. The study has been conducted strictly in accordance with the original IRB-approved protocol throughout participant enrollment, intervention implementation, and data analysis;
2. No substantive changes have ever been made to the study protocol, eligibility criteria, primary outcome, or intervention during the study;
3. The inconsistency currently shown on the registry is due to an initial registration error caused by misunderstanding of certain registry fields, rather than any post-approval protocol amendment;
4. The research team has completed internal verification and confirms that there was no unapproved protocol change, protocol violation, or increase in participant risk.

Based on the above, we respectfully submit this statement to request IRB administrative documentation and acknowledgment of the correction of the ClinicalTrials registration information. We kindly request the IRB to confirm that:

The actual study conduct has always been consistent with the originally approved IRB protocol;
The inconsistency in the registry is due to a registration error;
The research team is permitted to correct the relevant registry information to align with the original IRB-approved protocol.

We hereby confirm that this correction is strictly limited to administrative registry information, does not involve any modification to the study design, intervention, risk level, or participants' rights, and that screenshots of the corrected registry record will be archived for documentation.

Signature of Investigator: Jing Zhang
Signature of Principal Investigator: Kai Wang
Institutional Seal:
Date: 12/25/2025

Kai Wang

Clinical Trials Registration Information Correction Form 2025.12.10.

Correction items	Before correction	After correction
Brief summary	To investigate the intervention effect of high definition transcranial direct current stimulation (HD-tDCS) on suicidal ideation and somatic symptoms in patients with depressive disorder and its underlying neural mechanism by MRI.	To investigate the intervention effect of high definition transcranial direct current stimulation (HD-tDCS) on somatic symptoms in patients with depressive disorder and its underlying neural mechanism by MRI.
Inclusion Criteria	• the patients were diagnosed by more than 2 psychiatrists and met the diagnostic criteria of DSM-5 for depression, and HAMD>17, BSS>6, PHQ-15>5. • the age ranged from 18 to 60 years old, and the length of education was more than 5 years. • the visual acuity or corrected visual acuity is normal, right-handed, can cooperate with the completion of various experimental tests.	• the patients were diagnosed by more than 2 psychiatrists and met the diagnostic criteria of DSM-5 for depression, and HAMD>17, PHQ-15>5. • the age ranged from 18 to 60 years old • right-handed •stable dose of medication for at least 4 weeks or no history of antidepressive drugs before intervention
Exclusion Criteria	• accompanied by severe somatic diseases, such as severe heart, liver, renal insufficiency and so on. • accompanied by other neurological diseases, such as stroke, epilepsy and so on. pregnant and lactating women. • accompanied by other mental disorders, such as drug abuse, schizophrenia, schizophrenic affective disorder, hysteria, autism	• accompanied by severe somatic diseases, such as severe heart, liver, renal insufficiency and so on. • accompanied by other neurological diseases, such as stroke, epilepsy and so on. • accompanied by other mental disorders, such as drug abuse, schizophrenia, schizophrenic affective disorder, hysteria, autism and so on.

	and so on. • patients with MRI taboos or factors affecting imaging quality, such as cardiac pacemaker, cochlear implant, cardio-cerebrovascular metal stent, metal denture, etc. • those who could not cooperate with those who completed the relevant experiments, such as patients with depressive stupor, claustrophobia and so on.	• patients with MRI taboos or factors affecting imaging quality, such as cardiac pacemaker, cochlear implant, cardio-cerebrovascular metal stent, metal denture, etc. • pregnancy and breastfeeding. • previous physical treatment (electroconvulsive therapy or tDCS).
Outcome measures	Primary outcome measures: 1.change of depression symptoms of active treatment group. 2.change of risk of suicide of active treatment group. 3.change of somatization symptoms of active treatment group. 4.change of depression symptoms of sham treatment group 5.change of risk of suicide of sham treatment group 6.change of somatization symptoms of sham treatment group 7.Functional MRI measures 8.Functional MRI measures	Primary outcome measures: 1.the change of somatic symptoms in active group and sham group. 2.the percentage decrease in PHQ-15 scores in active group and sham group. 3.the number of somatic responders in active group and sham group at post-treatment and follow-up visit. Secondary outcome measures: 1.the change of depressive symptoms in active group and sham group. 2.the percentage decrease in HAMD scores in active group and sham group. 3.the number of depressive responders in active group and sham group at post-treatment and follow-up visit.