

**Transcranial direct current stimulation (tDCS) in the management of epilepsy: A meta-analysis and systematic review**

INPLASY202460033

doi: 10.37766/inplasy2024.6.0033

Received: 10 June 2024

Published: 10 June 2024

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**ADMINISTRATIVE INFORMATION****Support** - The 1.3.5 project for disciplines of excellence and Brain Science project of West China Hospital, Sichuan University, Grant/Award Number: ZYJC21001.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202460033**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 June 2024 and was last updated on 10 June 2024.**INTRODUCTION**

**Review question / Objective** Primary question: How effective are adjuvant tDCS in reducing the frequency of seizures in these patients.

Secondary questions: Do measures of neuronal correlates measured using methods like EEG, MEG or fMRI that correspond to effects on seizure reduction. Do non-invasive tDCS modulate performance in different cognitive domains in people with epilepsy? Is tDCS safe?

**Condition being studied** Epilepsy is a common neurological disorder that affects 70 million people worldwide, and is one of the top five neuropsychiatric diseases targeted for prevention by the World Health Organization. It is estimated that there are 10 million epilepsy patients in China, and that 400,000 new cases are added each year. The frequency of seizures and the use of multiple

anti-epileptic drugs have significant impacts on health-related quality of life, resource utilization, and costs.

About one-third of the epilepsy patients followed up in clinical centers are considered intractable epilepsy. However, only a few patients with localized white matter lesions are suitable for surgical resection. Surgery, however, may lead to complications, including permanent functional area damage and postoperative neurological deficits. For patients with intractable white matter lesions who are not suitable for surgical resection, non-invasive brain stimulation techniques (NIBS) can be used for treatment. These methods include transcranial electrical stimulation (tES), such as transcranial direct current stimulation (tDCS), and transcranial magnetic stimulation (TMS) Therefore, we conducted the first meta-analysis based on randomized controlled trials and systematically reviewed the literature on the effects of tDCS on neuropsychological function with the aim of

providing new references for clinical decision-making.

## METHODS

**Search strategy** Using the following selected terms, we searched for all relevant studies in the PubMed, Embase, Cochrane Library and web of science published from database : Epilepsy (Medical Subject Heading [MeSH]) and Transcranial Direct Current Stimulation (MeSH) and Randomized controlled trial[Publication Type]. Two authors (CY and OZ ) screened abstracts and titles independently and analyzed studies that met inclusion criteria. We additionally screened the reference lists of included studies to identify additional studies.

**Participant or population** People with epilepsy.

**Intervention** tDCS treatment.

**Comparator** Sham stimulation.

**Study designs to be included** Randomized controlled trials or randomized crossover trials.

**Eligibility criteria** ① Study type: Randomized controlled trials or randomized crossover trials; ② Language of study: English literature; ③ Study subjects: Patients clinically diagnosed with epilepsy according to the ILAE criteria; ④ Intervention method: The control group receives sham stimulation treatment, while the experimental group receives anodal tDCS treatment; ⑤ The study outcome must include at least seizure frequency. Exclusion criteria: ① Duplicate publications; ② Reviews, systematic reviews/meta-analyses, case reports, conference papers, animal experiments, letters, patents, and irrelevant literature; ③ Literature that cannot be accessed in full text; ④ Literature without seizure frequency as a study outcome.

**Information sources** The Medline/PubMed, Cochrane, Embase, Web of science database were searched.

**Main outcome(s)** Seizure reduction rate; Responder rate (percentage of patients with  $\geq 50\%$  seizure frequency reduction).

**Additional outcome(s)** Adverse effects; Neuropsychological outcomes; fMRI and EEG results.

**Quality assessment / Risk of bias analysis** We assessed the quality of these RCT studies using the Cochrane Collaboration's risk-bias assessment tool. We will assign studies to one of three categories: "low risk", "high risk" or "risk uncertain". Two raters independently evaluate the quality of each study. Any different results are resolved by inviting a third evaluator to award consensus.

**Strategy of data synthesis** The data were pooled using REVMAN 5.1 software (The Nordic Cochrane Center, Copenhagen, Denmark). The odds ratio (OR) were used as the effective index for binary variables and the standardized mean difference (SMD) for continuous variables. SMD is the mean difference divided by the standard deviation (MD/SD), which is used in cases where the unit of measure or method of measurement is inconsistent. Due to different study designs, epileptic seizure types, non-invasive neurostimulation protocols, and the assessments used, variability and heterogeneity across studies to measures were expected. The chi-square Q-test evaluated the heterogeneity assumption, and a P value  $50\%$  indicating substantial heterogeneity. The summary effect estimate of each study was calculated by the fixed-effects model if there was no significant heterogeneity. Otherwise, the random-effects model was employed. Pre-planned subgroup and meta-regression analyses were carried out to explore potential sources of heterogeneity. Egger's test examined the potential for publication bias, and a P value  $< 0.05$  is considered statistical significance.

**Subgroup analysis** Temporal lobe & extra-temporal lobe; treatment session  $< 5$  or reverse.

**Sensitivity analysis** Sensitivity analysis was performed to determine the source of heterogeneity.

**Language restriction** English.

**Country(ies) involved** China.

**Keywords** epilepsy ; Transcranial Direct Current Stimulation.

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