INPLASY PROTOCOL

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Review Stage at time of this submission: Piloting of the study selection process.

Conflicts of interest: None declared.

INTRODUCTION

Review question / Objective: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy transcranial direct current stimulation in the treatment of cognitive function in patients with major depressive disorder, when compared with sham-control group.

Efficacy of transcranial direct current stimulation in the treatment of cognitive function in patients with major depressive disorder

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Review question / Objective: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy transcranial direct current stimulation in the treatment of cognitive function in patients with major depressive disorder, when compared with sham-control group.

Condition being studied: (1) studies that examined transcranial direct current stimulation tDCS as a treatment for adults with MDD as per DSM or ICD criteria; (2) tDCS protocols with at least two tDCS stimulation sessions on consecutive days, during which there was no concurrent training or cognitive testing; (3) randomised sham-controlled trials(RCTs); (4) administration of standardized neuropsychological tests at baseline and post.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 June 2023 and was last updated on 02 June 2023 (registration number INPLASY202360008).

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METHODS

Participant or population: Major depressive disorder.

Intervention: Transcranial direct current stimulation.

Comparator: Sham-controlled patient with major depressive disorder.

Study designs to be included: Randomised sham-controlled trials.

Eligibility criteria: 1) lack of a sham-control group interventions targeted; (2) comorbid with other psychiatric disorders; (3) the full text or original data is missing(e.g., meeting abstracts); (4) highrisk bias: studies were assessed using the Cochrane Risk of Bias Assessment Tool and excluded if four or more of them were high risk; (5) repeated published literature; (6) animal experiments, review literature, case studies.

Information sources: We conducted a systematic literature search in PubMed, Embase, Cochrane Library, PsycINFO databases and Web of Science databases, using both keywords and MeSH terms for articles published date for searched paper from the database.

Main outcome(s): The main indicators are the change score of the Hamilton Depression Scale and the score of each dimension of cognitive performance. We included continuous variables as observation indicators in this study, since the scores of each test are continuous variables and the scale version used in each document is different, the standardized mean difference (SMD) is selected as the combined effect size.

Quality assessment / Risk of bias analysis: Evaluation of literature quality by two researchers. If there is any ambiguity, a third researcher will be asked to evaluate. Using the Cochrane Quality Evaluation Scale to assess the quality of included studies: (1) Whether to assign randomly; (2) Whether to describe the allocation method; (3) Whether to blinding of participants and personnel; (4) Whether to blinding of outcome assessment; (5) Whether the outcome dates are complete, includes missed visit and dropout data and reasons; (6) Whether the results are reported selectively.

The publication bias was evaluated by using Stata to make a funnel chart and a biased score.

Strategy of data synthesis: Review Manager software was used to assess the risk bias of the included all qualifified studies, and the size of heterogeneity for the studies was assessed by combining I2 statistic and P values: $I2 \ge 50\%$ or P < 0.05 indicates high heterogeneity.

Subgroup analysis: Patients were divided into two groups for subgroup analysis according to the course of the disease (< 6 months and > 6 months).

Sensitivity analysis: Sensitivity analysis is used to fifind the reasons for the heterogeneity, the random-effects model is used for meta-analysis; I2< 50% or P > 0.1, indicating that the research is homogeneous, and the fifixed effects model is used.

Country(ies) involved: China.

Keywords: Transcranial direct current stimulation, depression, cognition, treatment.

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