INPLASY PROTOCOL

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Review Stage at time of this submission: **Data analysis.**

Conflicts of interest:
None declared.

Comparing different non-invasive brain stimulation interventions for bipolar depression treatment: A network meta-analysis

Hsu, CW[1]; Tseng, PT[2]; Chen, YCB[3].

Review question / Objective: **PICOS criteria for this study were as follows: (1) patient: participants with a diagnosis of bipolar depression; (2) intervention: any non-invasive brain stimulation interventions; (3) comparison: sham control or active control; (4) outcome: changes in depressive symptoms, anxiety symptoms, quality of life, and overall clinical status, as well as response, remission, serious adverse event, and dropout rates; and (5) study design: limited to randomized controlled trials.**
Condition being studied: **The inclusion criteria for this study were as follows: (1) involving human participants; (2) including patients with a diagnosis of bipolar depression, either bipolar I disorder or bipolar II disorder; (3) reporting pre- and post-treatment scores or score changes on depression rating scales; and (4) RCTs with either sham-control or active control, using either cross-over or parallel study design.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 April 2023 and was last updated on 07 April 2023 (registration number INPLASY202340019).

INTRODUCTION

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METHODS

Participant or population: Participants with a diagnosis of bipolar depression.

Intervention: Any non-invasive brain stimulation interventions.

Comparator: Sham control or active control.

Study designs to be included: RCT.

Eligibility criteria: The exclusion criteria for this study were as follows: (1) involving bipolar patients in the euthymic phase;16,17 (2)including both mixed unipolar depression and bipolar depression and unable to separate the data for analysis;15 (3) not reporting outcomes of interest, such as depression rating scales; (4) not clearly defining stimulation protocols for non-invasive brain stimulation interventions, such as only describing real stimulation;18 and (5) case series or reports, conference papers, protocols, and non-peer reviewed articles.

Information sources: We conducted a systematic search of multiple databases, including PubMed, Embase, and Cochrane CENTRAL. The literature search was conducted up to April 1th, 2023, without any language restrictions. Additionally, we manually searched for potentially eligible articles cited in review articles and meta-analyses. We screened the titles and abstracts of all retrieved references and selected potentially eligible studies for full-text review.

Main outcome(s): This study had two primary outcomes: (1) efficacy, measured by changes in assessment scores of overall depressive severity after NIBS interventions; and (2) acceptability, defined as the drop-out rate, which refers to the percentage of patients who discontinued the study for any reason before completion.

Additional outcome(s): We also examined several secondary outcomes, including (1) continuous variables: improvement in anxiety severity, clinical global impression-severity (CGI-S), and quality of life; and (2) category variables: response rate, remission rate, and side effect rate.

Quality assessment / Risk of bias analysis: Risk of bias tool in the Cochrane handbook for the included trials.

Strategy of data synthesis: We assessed the pre-post changes (continuous variables) and incidence rates (categorical variables) of the aforementioned outcomes. Standardized mean differences with 95% confidence intervals were estimated for continuous variables. Odds ratios and 95% confidence intervals were estimated for categorical variables.

Subgroup analysis: This study assessed the effectiveness of different sham interventions by computing the change in depression severity relative to the tDCS, TMS, and CES sham interventions.

Sensitivity analysis: Some previous RCTs mixed samples of both unipolar and bipolar patients, although bipolar data were able to be extracted. We examined the efficacy of reducing depression severity, we performed additional analyzes excluding these studies.

Language restriction: No.

Country(ies) involved: Taiwan.

Other relevant information: 1. Bipolar[All Fields] OR affective Disorder[All Fields]
2. deep transcranial magnetic stimulation OR dTMS OR repetitive transcranial magnetic stimulation OR rTMS OR TMS OR non-invasive brain stimulation OR theta burst stimulation OR transcranial direct current stimulation OR TBS OR tDCS OR vagus nerve stimulation OR vagal nerve

stimulation OR tVNS OR nVNS OR VNS OR static magnetic field stimulation OR tSMS
3. "randomized controlled trial"[Publication Type] OR "controlled clinical trial"[Publication Type] OR "randomized"[Title/Abstract] OR "placebo"[Title/Abstract] OR "clinical trials as topic"[MeSH Terms:noexp] OR "randomly"[Title/Abstract] OR "trial"[Title/Abstract] OR "groups"[Title/Abstract]) NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms]
4. (#1) AND (#2) AND (#3).

Keywords: bipolar; affective; transcranial magnetic stimulation; repetitive transcranial magnetic stimulation; theta burst stimulation; transcranial direct current stimulation; vagal nerve stimulation; non-invasive.

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