INPLASY PROTOCOL

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Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest: **None declared.**

Comparative efficacy and cognitive function of magnetic seizure therapy versus electroconvulsive therapy for major depressive disorders: A systematic review and meta-analysis

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Review question / Objective: **(1)Patients: Subjects were depressed patients with a disease diagnosis that met the Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnostic criteria for depressive episodes (including major depression diagnostic criteria and bipolar disorder diagnostic criteria) or the patient has moderate or higher depression; (2) Intervention measures: magnetic seizure treatment ; (3) Control group: electroconvulsive therapy; (4) Outcomes: the main outcome indicator is the total score of the depression scale and the score of each dimension of the neuropsychological test; Secondary indicators are reorientation time and recovery time; (5) Study design: Control study.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 July 2021 and was last updated on 20 July 2021 (registration number INPLASY202170061).

INTRODUCTION

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moderate or higher depression; (2) Intervention measures: magnetic seizure treatment ; (3) Control group: electroconvulsive therapy; (4) Outcomes: the main outcome indicator is the total score of the depression scale and the score of each dimension of the neuropsychological test; Secondary indicators are reorientation time and recovery time; (5) Study design: Control study.

Rationale: According to the World Health Organization, depression is the leading cause of disability, affecting more than 300 million people worldwide. Approximately 33% of patients experienced relief of their depressive symptoms after an antidepressant trial. However, general treatment such as medication and psychotherapy were failed in about 30% of the patients. At present, Electroconvulsive therapy (ECT) is widely considered to be one of the effective antidepressant treatments, especially for major depressive disorder (MDD), with remission rates ranging from 40% to 70%. However, previous studies have found that ECT impairs patients' cognitive functions, especially memory function . Therefore, due to fear and concerns about cognitive impairment caused by ECT, the wide range of clinical use of ECT is limited. Magnetic seizure therapy (MST) is an emerging physical therapy method for antidepressant treatment in recent years. MST treatment is a new form of treatment with similar aims to ECT treatment and is also used to treat patients with major depressive disorder, but the efficacy and side effects of both treatments are currently controversial. This study aims to conduct a systematic review and use meta-analysis to quantitatively analyze the antidepressant efficacy of MST and ECT and its impact on cognitive function and provide a valuable reference for further promoting MST in clinical practice.

Condition being studied: According to the World Health Organization, depression is the leading cause of disability, affecting more than 300 million people worldwide. Approximately 33% of patients experienced relief of their depressive symptoms after an antidepressant trial. However, general treatment such as medication and psychotherapy were failed in about 30% of the patients. Subjects were depressed patients with a disease diagnosis that met the Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnostic criteria for depressive episodes (including major depression diagnostic criteria and bipolar disorder diagnostic criteria) or the patient has moderate or higher depression, According to Hamilton Depression Scale(HAMD), Self-rating depression scale (SDS), Beck Depression Inventory (BDI), Montgomery-Asberg Depression Rating Scale (MADRS); Clinical symptom indicators: the main outcome indicator is the total score of the depression scale and the score of each dimension of the neuropsychological test; Secondary indicators are reorientation time and recovery time.Subjects were depressed patients with a disease diagnosis that met the Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnostic criteria for depressive episodes (including major depression diagnostic criteria and bipolar disorder diagnostic criteria) or the patient has moderate or higher depression;Clinical symptom indicators: the main outcome indicator is the total score of the depression scale and the score of each dimension of the neuropsychological test; Secondary indicators are reorientation time and recovery time.

METHODS

Search strategy: We conducted a systematic literature search in PubMed, Embase, Cochrane Library, and Web of Science databases. First, The Mesh subject terms "Depression" and "Depressive Disorder" and their free terms were used in PubMed, as well as the keywords " magnetic seizure therapy" were used for the search; Second, The Emtree subject term "Depression" and its free terms, as well as the keyword "magnetic seizure therapy" were used for the search in Embase; Third, Searches in the Cochrane Library were conducted using the Mesh

subject term "depression" and its free terms, and the keyword "magnetic seizure therapy"; Finally, The web of science database was searched using the keywords "depression", "depressive disorder", and "magnetic seizure therapy". The search was carried out.

Participant or population: Subjects were depressed patients with a disease diagnosis that met the Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnostic criteria for depressive episodes (including major depression diagnostic criteria and bipolar disorder diagnostic criteria) or the patient has moderate or higher depression; age ≥ 18 years old; gender is not limited.

Intervention: Magnetic seizure therapy(It induces convulsive seizures by exciting the local cortex). There will be no restrictions on the number or strength of doses.

Comparator: Electroconvulsive therapy (the electric induction of cerebral seizure activity with or without brief general anaesthesia).

Study designs to be included: We will include controlled trials.

Eligibility criteria: Inclusion criteria: (1) Subjects: Subjects were depressed patients with a disease diagnosis that met the Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnostic criteria for depressive episodes (including major depression diagnostic criteria and bipolar disorder diagnostic criteria) or the patient has moderate or higher depression; (2) Age ≥18 years; (3) Intervention measures: magnetic seizure therapy (4) Control group: electroconvulsive therapy. (5) Clinical symptom indicators: the main outcome indicator is the total score of the depression scale and the score of each dimension of the neuropsychological test; Secondary indicators are reorientation time and recovery time. Exclusion criteria: (1) the full text or original data is missing(e.g., meeting abstracts); (2) High-risk bias: Studies were assessed using the Cochrane Risk of Bias Assessment Tool and excluded if four or more of them were high risk ; (3) repeated published literature; (4) animal experiments, review literature, case studies; (5) unclear intervention methods, A study without a control group; (6) There is a large difference in the observed indicators, and the effect size cannot be combined(e.g.Outcome indicators do not match). According to the inclusion and exclusion criteria, the abstract and full text of the literature were screened.

Information sources: We conducted a systematic literature search in PubMed, Embase, Cochrane Library, and Web of Science databases.

Main outcome(s): The main outcome indicator is the total score of the depression scale and the score of each dimension of the neuropsychological test, such as the immediate recall of words, delayed recall of words, visual-spatial immediate memory, visual-spatial delayed memory, verbal fluency and other dimensions; And adverse events.

Additional outcome(s): Secondary indicators are reorientation time and recovery time (The reorientation time is defined until the patient correctly remembers the time of four of the following five items: name, weeks, Birthdate, age, and place; The recovery time is defined as the time until the patient opens his eyes and breathes independently).

Data management: Import the retrieved documents into EndnoteX9. The following information was extracted from all qualified studies by two researchers independently: author, publication year, study design, sample size, average age, duration of illness, clinical indicators(outcomes), ECT parameters, MST parameters, and duration for treatments. We extracted test score with standard deviation(SD), sample size, and P values for effective size(ES) generation. Use Review Manager 5.3 software to assess the risk bias of all included qualified studies and perform data analysis.Using Review Manager 5.3

software to assess the risk bias of the included all qualified studies.

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. For example, the outcome index report is not complete enough to be included in the analysis; (7) Whether there are other risks of bias (In addition to the above factors, are there other factors that cause bias, such as treatment standards, adverse events, etc). The level of risk of bias is expressed as "low risk" and "high risk" respectively, and "unclear" is used when the article has insufficient information.If each type of bias is low risk, a single study is considered to have low risk of bias and high quality;If the risk of one or more types of bias is unknown, it is considered that the risk of bias of a single study is unknown and the quality is medium;If four or more types of bias are at high risk, then a single study is considered to have high risk of bias and low quality. The publication bias was evaluated by using Stata15.1 to make a funnel chart and a biased score. The absence of obvious publication bias was suggested when the data in a funnel plot were distributed roughly symmetrically and vice versa. Egger's linear regression was used to test the symmetry of the funnel plot, and a probability value of $P < 0.05$ was considered suggestive of significant asymmetry.

Strategy of data synthesis: Using Review Manager 5.3 software to assess the risk bias of the included all qualified studies. And the size of heterogeneity of the studies was assessed by combining I2 statistic and P values: I2≥50% or P<0.05 indicates high heterogeneity, Sensitivity analysis is used to find the reasons for the heterogeneity, the random-effects model is used for meta-analysis; I20.1, indicating that the research is homogeneous, and the fixed effects model is used. Meta-analysis was carried out according to the Cochrane System Reviewer's Manual. Observation indicators included in this study are continuous variables, 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; Mean Difference (MD) for Reorientation and Recovery Time. The main indicators are the change score of the Hamilton Depression Scale and the score of each dimension of neuropsychological assessment, Secondary indicators are reorientation time and recovery time. The difference is statistically significant with P<0.05.

Subgroup analysis: When there is heterogeneity between studies, the method of subgroup analysis is often used to deal with it. Each variable such as study design, sample characteristics, length of treatment and so on can be divided into subgroups for analysis. If the results of subgroup analysis indicate that each subgroup The group does not show heterogeneity, which suggests that this variable may be one of the sources of heterogeneity, which can reduce the heterogeneity caused by the difference of this variable.

Sensitivity analysis: Using Review Manager 5.3 software to assess the risk bias of the included all qualified studies. And the size of heterogeneity of the studies was assessed by combining I2 statistic and P values: I2≥50% or P<0.05 indicates high heterogeneity, Sensitivity analysis is used to find the reasons for the heterogeneity, the random-effects model is used for meta-analysis. After excluding each low-quality study, the combined effect size was re-estimated and compared with the results of the Meta-analysis before exclusion to explore the extent to which the study influenced the combined effect size and the robustness of the results. If the results do not change significantly after exclusion,

this indicates low sensitivity and more robust results; conversely, if a large difference or even diametrically opposed conclusion is obtained after exclusion, this indicates higher sensitivity and less robust results, and the presence of important, potentially biasing factors related to the effect of the intervention is explained when interpreting the results and drawing conclusions to further clarify the source of the controversy.

Language: Only consider clinical trials published in English for inclusion.

Country(ies) involved: China.

Keywords: Depressive disorder; Magnetic seizure therapy (MST); Electroconvulsive therapy (ECT); Cognitive function; Meta-analysis.

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