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Meta-analysis of lower extremity motor function and daily activity capacity after stroke treated with Theta stimulation

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 February 2025 and was last updated on 20 February 2025.

INTRODUCTION

Review question / Objective To systematically evaluate the intervention effect of intermittent Theta stimulation (iTBS) in improving the lower limb motor function and daily activity ability of stroke patients by Meta-analysis, and to provide some reference for the clinic.

Condition being studied Stroke, as the second leading cause of death and the third leading cause of disability worldwide, has imposed a huge medical and social burden globally. It is reported that the prevalence of stroke in China is on the rise, among which 88% of patients will experience lower limb motor dysfunction, leading to difficulties in walking, decreased ability to perform daily activities and an increased risk of falls. Therefore, improving the lower limb motor function, balance and daily activity ability of stroke patients is an important rehabilitation goal.

Intermittent Theta-Burst Stimulation (iTBS), an optimized repetitive Transcranial Magnetic Stimulation (rTMS) mode, features short stimulation duration and relatively low required stimulation intensity. By releasing and simulating the theta wave frequency closer to that of the human hippocampus, it promotes changes in the excitability and plasticity of the motor cortex. Primarily targeting the affected side of the primary motor cortex (M1) and the contralateral cerebellum (CRB), it aims to generate long-term potentiation (LTP) in the cortex and enhance cortical excitability. Studies have shown that iTBS is more effective than traditional high-frequency rTMS in inducing larger motor evoked potentials and generating longer-lasting effects after stimulation. Currently, reports on the use of iTBS in post-stroke lower limb motor function disorders and daily activity abilities have issues such as small sample sizes and significant differences in stimulation parameters, leading to controversial research conclusions. Therefore, this study aims to systematically evaluate the intervention effect of

iTBS on improving lower limb motor function and daily activity abilities in stroke patients through a meta-analysis, providing certain references for clinical practice.

METHODS

Participant or population It meets the clinical diagnosis of stroke and is confirmed by MRI or cranial CT; the patient's condition is stable and there is no cognitive impairment.

Intervention Receive intermittent theta burst stimulation (iTBS) of the cerebellum/M1 area.

Comparator The control group undergoes routine rehabilitation treatment.

Study designs to be included Randomized controlled trial.

Eligibility criteria
Inclusion criteria:
Outcome indicators:
a. Assessment of lower limb motor function: Lower Extremity Fugl-Meyer assessment(FMA-LE) is used.
b. Assessment of balance function: Berg Balance Scale (BBS) is used.
c. Assessment of the ability of activities of daily living: Modified Barthel Index (MBI) is used.
Exclusion criteria:
① Duplicate publications;
② Systematic reviews, meta-analyses, conference papers, expert reviews, animal experiments, etc.;
③ Full texts that cannot be obtained.

Information sources Database resources: Systematically search the CNKI, Wanfang Data, VIP Database, China Biology Medicine Database (CBM), PubMed, Web of Science, Cochrane Library, Embase, ProQuest, and Scopus databases.
Search terms: Chinese search terms include: θ stimulation, theta rhythm stimulation, stroke, etc. English search terms include: iTBS, θ-burst stimulation, Stroke, etc.
Search time limit: From the establishment of the database to November 1, 2024.
Search strategy: By combining subject headings and free terms. Taking PubMed as an example:
(Stroke[Title/Abstract] OR Cerebrovascular Accident[Title/Abstract] OR Brain Vascular Accident[Title/Abstract] OR Apoplexy[Title/Abstract] OR CVA[Title/Abstract] OR Hemiplegia[Title/Abstract] OR hemiparesis[Title/Abstract]) AND (repetitive transcranial Magnetic Stimulation[Title/Abstract] OR rTMS[Title/Abstract] OR θ-burst stimulation[Title/Abstract] OR theta burst stimulation[Title/Abstract] OR iTBS[Title/Abstract] OR CTBS[Title/Abstract] OR Transcranial Magnetic Stimulation[Title/Abstract]) AND (RCT[Title/Abstract] OR Randomized controlled Trial[Title/Abstract] OR Trial[Title/Abstract] OR randomized[Title/Abstract]).

Main outcome(s) Outcome indicators:
a. Assessment of lower limb motor function: Lower Extremity Fugl-Meyer assessment(FMA-LE) is used.
b. Assessment of balance function: Berg Balance Scale (BBS) is used.
c. Assessment of the ability of activities of daily living: Modified Barthel Index (MBI) is used.

Quality assessment / Risk of bias analysis Two researchers conducted a qualitative assessment using the Cochrane Risk of Bias tool (RoB) to detect potential biases and evaluate the internal validity of the randomized controlled trials (RCTs). In case of any disagreements, they were resolved through discussions with a third researcher.Two researchers evaluated the 12 included studies. All the studies adopted randomization. Among them, 4 studies implemented allocation concealment, 6 studies used the double-blind method, and 10 studies blinded the assessors of the outcome indicators. There was no incomplete outcome data in all the studies, and the risk was considered to be low.

Strategy of data synthesis Data analysis was performed using RevMan 5.3 software. The baselines of the experimental group and the control group in the included studies were comparable, so the outcome data at the end of the treatment period were extracted. All the outcome indicators in this study were continuous variables, so the Weighted Mean Difference (WMD) was used as the effect size. The overall heterogeneity of the included studies was evaluated by I^2. If $I^2 > 50\%$ and $P < 0.05$, a random effects model was used; if I^2 0.05, a fixed effects model was used. Subgroup analysis was used to compare the effects of different factors and the sources of heterogeneity. Sensitivity analysis was carried out using the leave-one-out method. Egger's test was adopted to conduct a publication bias test on the included indicators. If P 0.05, it indicates a low possibility of publication bias.

Subgroup analysis It was divided into two subgroups according to the difference in the total number of stimulation pulses, namely the 600-pulse subgroup and the 1200-pulse subgroup.

Sensitivity analysis Sensitivity analysis was carried out using the method of sequential exclusion. The analysis results showed that the indicators of FMA-LE, BBS and MBI were relatively stable.

Country(ies) involved China.

Keywords theta; iTBS; stroke; lower extremity; Meta-analysis; balance; daily mobility; motor function.

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