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Functional electrical stimulation based on brain-computer interface improves upper limb function in post-stroke patients: a meta-analysis of randomized controlled trials

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ADMINISTRATIVE INFORMATION

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 August 2023 and was last updated on 14 August 2023.

INTRODUCTION

Review question / Objective To systematically evaluate the effectiveness of brain-computer interface controlled functional electrical stimulation (BCI-FES) in improving upper limb function in post-stroke patients and explore a more efficient BCI functional electrical stimulation rehabilitation strategy to improve the upper limb function of stroke patients.

Condition being studied Most stroke survivors have varying degrees of disability, which greatly affects their functional independence and quality of life.The response of chronic stroke patients with severe motor incapacity to rehabilitation training is poor.Moreover, the impact of upper limb motor function impairment on patients' daily life is obviously more serious than lower limb function, which has been widely concerned by the neurological rehabilitation field.In the traditional rehabilitation training, there is no objective method to measure whether the patient has completed the specified motor imagination rehabilitation training,the effect is there but does not last for months after stroke.Brain-computer interface (BCI) has been shown to be a useful tool for patients to substitute communication through brain signals and to improve neuroplasticity to restore limb motor function.In the BCI system, brain activity can be translated into control signals for external devices, including computers, communication AIDS , prosthetics and exoskeletons , or functional electrical stimulation (FES).The combination of BCI technology and FES gives full play to the dual advantages of neuromodulation and neuroplasticity in improving motor function in clinic.FES is triggered only when the BCI system detects the user's intention to move, which synchronizes brain activity with the movement produced by muscle contraction.Based on the above therapeutic mechanisms, BCI-FES may be clinically more effective than BCI or FES alone.

METHODS

Participant or population Patients with stroke (including subacute and chronic stages) with upper

limb motor dysfunction (only caused by stroke disease) and no severe cognitive dysfunction were confirmed by clinical and imaging examination, regardless of age, race or region.The clinical diagnosis was revised by the fourth Academic Conference on Cerebrovascular Diseases of the Chinese Medical Association.

Intervention Experimental group: BCI-FES therapy.

Comparator Control group: rehabilitation therapy without involving BCI-FES at the same time.In addition, some experimental groups and control groups received regular rehabilitation training of equal duration in addition to their own intervention.

Study designs to be included Randomized controlled trial (RCT). The literature was in Chinese or English.

Eligibility criteria Exclusion criteria (1) Reviews, abstracts, case reports, scientific reports, academic conferences, or non-randomized controlled studies (2) literature not in Chinese or English (3) incomplete or unextractable original data, and not available through contact with corresponding authors.④ The sample size was too small (less than 10 cases).

Information sources Computer search CNKI, Pubmed, Scopus, WebofScience, WanfangData, TheCochraneLibrary, EMbase, ICTRP and CT.gov databases,RCTs on improving upper limb function of stroke patients with functional electrical stimulation based on brain computer interface were collected, and the search time was from the database to February 2023.The search was carried out in the form of a combination of subject words and free words, and the references included in the study were traced to supplement the acquisition of relevant information.

Main outcome(s) Upper limb Fugl Meyer score (FMA-UE);Fugl-meyer score before and after treatment (ΔFMA-UE);Modified Barthel Index score (MBI).

Additional outcome(s) Wolf Motor Function Test(WMFT).

Data management Two researchers independently screened the literature, extracted the data and cross-checked with each other.If there are any questions, discuss with the research team or contact the author to ask for solutions.In the literature selection process, the title of the text is read first, and the abstract and full text are further read to determine whether to include the obviously irrelevant literature.If necessary, contact the authors of the original study by email or phone for undetermined information that is important to this study.The data extraction contents include: (1) Basic information included in the study: research title, first author, journal publication, year, country, etc.;② Key elements of bias risk assessment;③ Baseline characteristics of the subjects and intervention measures;(4) Outcome indicators and outcome measurement data concerned.

Quality assessment / Risk of bias analysis The risk of bias in the included study was independently evaluated by two researchers, and finally summarized. If there was any problem, it was resolved by a third party evaluation.RCT bias risk assessment was carried out using the internationally commonly used RCT bias risk assessment tool recommended by Cochrane Manual 5.1.0.Revman5.4 software was used to draw bar charts for literature quality evaluation and summary charts for risk bias articles.

Strategy of data synthesis Meta analysis was performed using Stata16.0.The outcome indicators used in the included literatures are continuous variables, and the mean and standard deviation are calculated from the difference data before and after the intervention of the experiment. The difference between the mean and standard deviation is large, and some outcome indicators have the same effect but use different evaluation scales.So the standardized mean differences (standardedmeandifference, SMD) as the effect analysis of statistics, the effect of provide the 95% confidence interval (confidenceinterval, CI).Chi-square test (α=0.1) was used to analyze the heterogeneity among the included studies, and I2 was used to quantitatively determine the heterogeneity.If there was no statistical heterogeneity among the results, the fixed effect model was used for meta-analysis.If there was statistical heterogeneity among the results, the source of heterogeneity was further analyzed, and after excluding the influence of obvious clinical heterogeneity, the random effects model was used for meta-analysis.The meta-analysis level was set at α=0.05.If there is obvious clinical heterogeneity, this paper uses subgroup analysis or sensitivity analysis to analyze the source of heterogeneity, or only descriptive analysis.

Subgroup analysis Subgroups by ethnicity, intervention duration, intervention type, stroke duration, and year of study publication are classified to find the source of heterogeneity.

Sensitivity analysis Sensitivity analysis was carried out by eliminating individual studies one by one and to find if the outcomes are stable or not.

Country(ies) involved China.

Keywords Brain-computer interface and functional electrical stimulation;BCI-FES;stroke;upper limb rehabilitation;system review;Meta-analysis;randomized controlled trial.

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