INPLASY PROTOCOL

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None.

Effect of neuromuscular electrical stimulation associated with swallowing-related muscle training for post-stroke dysphagia：a protocol of systematic review and meta-analysis

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Review question / Objective: **The aim of this review is to evaluate the effectiveness of neuromuscular electrical stimulations combined with swallowing-related muscle training in treating swallowing dysfunction after stroke.**
Condition being studied: **Swallowing dysfunction is a common dysfunction after stroke, and its incidence exceeds 50%. Aspiration pneumonia and malnutrition induced by dysphagia not only cause psychological shock to patients after stroke, but also burden the medical payment. Neuromuscular electrical stimulation, which stimulates the cortex and cortical bulb pathways to improve swallowing function, has been one of the emerging treatments for the post-stroke deglutition disorder. This therapy operators require the proficiency in professional knowledge, limiting clinical large sample studies, so there is an absence of evidence-based medicine.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 3 January 2021 and was last updated on 3 January 2021 (registration number INPLASY202110009).

INTRODUCTION

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METHODS

Participant or population: Post-stroke patients.

Intervention: Neuromuscular electrical stimulation associated with swallowing-related muscle training.

Comparator: Swallowing-related muscle training.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: According to the purpose of this research we designed the inclusion criteria as the following: We will include adults (over 18years old) suffering from dysphagia after a first or recurrent stroke. Stroke is defined as 'rapidly developed signs of focal or global disturbance of cerebral function, lasting more than 24 hours or being expected to result in death with no apparent cause other than that of vascular origin, according to WHO criteria. We consider RCTs in which a prior history of deglutition disorder before the stroke diagnosis is not investigated. And the researches will be excluded that trials reporting on patients with a history of swallowing disorder before stroke diagnosis. We will include patients with stroke irrespective of any type (ischaemic or haemorrhagic) or phase (acute, subacute or chronic).

Information sources: We will search 9 databases, which including PubMed, Embase, Web of science, Cochrane Library, ClinicalTrials, China Biomedical Literature Database (CBM), China Knowledge Network Database (CNKI), Wanfang Database (WanFang) and China VIP Database (VIP). Taking the published literature from the establishment of the database until December 20th 2020. Literature searching is related to neuromuscular electrical stimulation randomized controlled trials on the effect of swallowing in stroke. In addition, we will do the manual search in Baidu Academic and Google Academic database as a supplementary search.

Main outcome(s): Esophagus under x-ray fluoroscopy, which is treated as the gold standard of swallowing function and total effective rate, will be evaluated as the primary outcome.

Additional outcome(s): Secondary outcomes contain: the Eating Assessment Tool-10 item scores, Kubota Drinking Water Test, Swallowing Capacity Test, Functional Oral Intake Scale, Videofluoroscopic Dysphagia Scale, Dysphagia Outcome and Severity Scale and so on.

Data management: 1) EndNote X9 and Excel software will be used to extract data. At the same time, the data will be synthesized and stored in Excel chart. 2) Two researchers (Bosong Du and Yan Li) will independently assess abstracts and titles of studies identified by literature search from the electronic databases. Full texts screening and data extraction will be conducted afterwards independently. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author (Li Zhou). In this step, we will use EndNote. 3) The following data will be extracted: author, year of publication, interventions of experimental groups and control groups, time point, outcome measures, age of patients, total number of people included in the study, patients' basic information, etc. Two researchers (Bosong Du and Yan Li) will separately extract data. Any disagreement regarding data extraction will be resolved by discussion until consensus is reached or

by consulting a third author (Li Zhou). In this step, we will use Microsoft Excel.

Quality assessment / Risk of bias analysis: The overall quality of all included studies is associated with the reliability and robustness of pooled results, so the Cochrane risk of bias tool will be used to evaluate the risk of bias of the included RCTs by two reviewers (Bingran Zhang and Wenjun Zhao) independently. According to the performance of the included literature in the above evaluation items, individual study will be labeled with 'low risk of bias', 'unclear risk of bias', and 'high risk of bias'. The overall level of all included studies will be identified according to the results of assessing the risk of bias of individual study. If there is any disagreement, a discussion will be conducted. If no agreement can be reached between the two researchers, a discussion will be made by the researchers in the third researcher (Li Zhou).

Strategy of data synthesis: In this study, statistical analysis will be conducted by using RevMan 5.3 software. Risk ratio (RR) with 95% confidence intervals (CIs) will be adopted for intervention effect of dichotomous data. Mean difference (MD) with 95% CIs will be for intervention effect of continuous data. When measurement methods or units are inconsistent, the standardized mean difference (SMD) with 95% CIs will be used to present the intervention effect. If there exists heterogeneity and the final data summary analysis select random effect model statistical analyses.

Subgroup analysis: If the included studies have significant statistical heterogeneity, then the subgroup analysis will be conducted basing on varied parameters that affect the result parameters. These parameters contain the characteristics of patients (for instance, the severity degree of the disease, different stage of stroke), the characteristics of interventions (for instance, total intervention duration, intervention frequency) and so on.

Sensibility analysis: To evaluate the reliability of our study results, sensitivity analysis will be used. If there is no significant change in the results after deleting the literature, it indicates that the sensitivity is low and our results are reliable. On the contrary, if there is a big difference or even an opposite conclusion after deleting the literature, it indicates a high sensitivity and a low reliability of this study results.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: neuromuscular electrical stimulation; swallowing rehabilitation training; dysphagia; protocol; systematic review; meta-analysis.

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