INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None.

Electrical stimulation for limb spasticity in children with stroke: a protocol for systematic review

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Review question / Objective: **Is electrical stimulation (ES) effective and safe for limb spasticity (LS) in children with stroke?**
Condition being studied: **Electrical stimulation, limb spasticity, stroke.**
Information sources: **A systematic search will be performed from inception to the present without language and publication status limitations in Cochrane Library, EMBASE, PUBMED, PsycINFO, Scopus, OpenGrey, CINAHL, ACMD, CNKI, and WANGFANG. All eligible RCTs testing the effectiveness and safety of ES on LS in children with stroke will be included. We will build detailed search strategy for Cochrane Library, and will also adapt similar retrieval strategies for other electronic databases. In addition, this study will also examine other sources, such as conference information, ongoing or unpublished studies from clinical trial registry, and reference lists of relevant reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 May 2020 and was last updated on 31 May 2020 (registration number INPLASY202050115).

INTRODUCTION

Review question / Objective: **Is electrical stimulation (ES) effective and safe for limb spasticity (LS) in children with stroke?**

Condition being studied: **Electrical stimulation, limb spasticity, stroke**

METHODS

Participant or population: **All children under 18 years old with LS following stroke will be included, in spite of ethnicity, country, and severity of LS and stroke.**

Intervention: **In the experimental group, all patients received any types of ES, such as**

neuromuscular electrical stimulation, transcutaneous electrical nerve stimulation, and electroacupuncture.

Comparator: In the control group, no restrictions will be applied to any comparators. However, we will not consider any types of ES.

Study designs to be included: This study will consider randomized controlled trials (RCTs) on effectiveness and safety of ES for LS in children with stroke for inclusion.

Eligibility criteria: This systematic review will consider RCTs on effectiveness and safety of ES for LS in children with stroke for inclusion. We will exclude animal study, review, editorial letter, comment, case report, case series, uncontrolled trial, and quasi-RCTs.

Information sources: A systematic search will be performed from inception to the present without language and publication status limitations in Cochrane Library, EMBASE, PUBMED, PsycINFO, Scopus, OpenGrey, CINAHL, ACMD, CNKI, and WANGFANG. All eligible RCTs testing the effectiveness and safety of ES on LS in children with stroke will be included. We will build detailed search strategy for Cochrane Library, and will also adapt similar retrieval strategies for other electronic databases. In addition, this study will also examine other sources, such as conference information, ongoing or unpublished studies from clinical trial registry, and reference lists of relevant reviews.

Main outcome(s): Primary outcomes are gait velocity (as assessed by Gait Velocity Assessment Toolkit or other scales), and limb spasticity status (as evaluated by Modified Ashworth Scale or other tools). Secondary outcomes are limb function (as appraised by Disability Assessment Scale or other scales), quality of life (as detected by 36-Item Short Form Survey or other surveys), pain intensity (as measured by Visual Analogue Scale or other scales), and adverse events.

Quality assessment / Risk of bias analysis: Two independent authors will appraise study quality for eligible RCTs using Cochrane Risk of Bias Tool with predetermined criteria. Each study will be rated as a high, unclear or low risk of bias. Any divergence will be solved by a third author through consensus.

Strategy of data synthesis: We will utilize RevMan 5.3 software to pool and analyze data. All dichotomous outcomes will be estimated as relative risk/risk ratio with 95% confidence intervals (CIs), and continuous outcomes will be calculated as weighted mean difference with 95% CIs. Statistical heterogeneity will be examined using I^2 test. Values of I^2 are less than 50% will be considered as minor heterogeneity, while I^2 values over 50% will be suggested as significant heterogeneity. We will carry out meta-analysis if sufficient data are extracted. Otherwise, we will perform descriptive analyses for those studies which are deemed clinically heterogeneous or aggregate data for synthesizing.

Subgroup analysis: Where applicable, we will conduct subgroup analysis or meta-regression for factors presumed to cause significant heterogeneity or variations in study characteristics, details of interventions and controls, and outcome indicators.

Sensibility analysis: Whenever possible, we will perform sensitivity analysis to test robustness and stability of study findings based on study quality, sample size and missing or insufficient data.

Country(ies) involved: China.

Keywords: Stroke; limb spasticity; electrical stimulation; effectiveness; safety.

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