

INPLASY PROTOCOL

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None.

Effects of isokinetic strength training for lower extremity motor function in stroke patients with hemiplegia: A protocol for a systematic review and meta-analysis

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Review question / Objective: The aim of this systematic review and meta-analysis is to evaluate the effects of isokinetic strength training (IST) for lower extremity motor function in stroke patients with hemiplegia.

Condition being studied: Motor dysfunction of lower extremity is one of the most common stroke sequelae which brings poor life quality and inadequate society participation. Isokinetic strength training is considered an effective and safe rehabilitation technique to improve the lower extremity motor function (LEMF) in patients with stroke. However, evidences on the efficacy of IST for LEMF are still insufficient. Here, a systematic review is proposed to provide more reliable evidence-based medicine evidences for the efficacy of IST.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 January 2021 and was last updated on 16 January 2021 (registration number INPLASY202110060).

INTRODUCTION

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motor function in stroke patients with hemiplegia.

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METHODS

Participant or population: Stroke patients suffer from motor dysfunction of lower extremity.

Intervention: Isokinetic strength training associated with conventional rehabilitation training.

Comparator: Conventional rehabilitation training.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Patients who meet the following criteria: (1) Adults (age over 18 years old) suffer from physical dysfunction after ischemic or hemorrhagic stroke; (2) Post-stroke patients have lesion that are confirmed by CT or MRI; (3) Patients suffer from motor dysfunction of lower extremity; (4) There are no limitation of sex, nationality, race, phase of stroke, etc.

Information sources: Comprehensive search will be performed in the 8 electronic databases, including PubMed, Embase, Cochrane Central Register of Controlled Trials, Web of Science, Chinese Biomedical Literatures database (CBM), Chinese National Knowledge Infrastructure (CNKI), Wan-Fang Database, and Chinese Scientific Journals Database (VIP). The retrieval time of this study will be performed from the establishment of database to January 4, 2021. Randomized controlled trials (RCTs) report effects of IST for LEMF in stroke patients with hemiplegia will be identified.

Main outcome(s): The Fugl-Meyer assessment scale-Lower extremity (FMA-UE) as the primary outcome.

Additional outcome(s): Secondary outcome measures include Peak Torque (PT), Berg Balance Scale (BBS), Timed up and Go test (TUG), and 10-metre Maximum Walking Speed (10MWS).

Data management: The EndNote document management software and Microsoft Excel will be used to extract and manage data. Meanwhile, the data will be synthesized and stored in Excel. These data are extracted from included studies: author, year of publication, interventions of experimental groups and control groups, time point, outcome measures, age of patients, total number of patients in the study, patients' basic information, etc. Two researchers are independently extract these data. The disagreements related to data extraction will be resolved by reaching a consensus or consulting another author.

Quality assessment / Risk of bias analysis: The methodological quality of included studies will be rated using the Physiotherapy Evidence Database (PEDro) scale. It is composed of 11 items, scored from 0 to 10, in which the first item related to external validity is not used in the final score. The RCTs quality will be scored independently by two researchers and disagreements will be resolved by the third investigator (RQ). It will rate into the following levels: high quality (PEDro scores ≥ 7), moderate quality (scores between 5 and 6), and low quality (scores ≤ 4). The risk of bias of the included studies were evaluated by two reviewers via the Cochrane risk of bias criteria tools. The bias would influence our study result, so these items were evaluated: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome data (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other biases. The assessment for the risk of bias categorized into three levels: low, high or unclear risk of

bias. Disagreement in judging the risk of above biases, a consultation was taken with the third researcher.

Strategy of data synthesis: Statistical analysis will be conducted by using Review Manager 5.3 software. Risk ratio with 95% confidence interval (CI) will be adopted for intervention effect of dichotomous data. The weighted mean difference with 95% CI is for intervention effect of continuous variable data. When measurement methods or units are inconsistent, the standardized mean difference with 95% CI will be used to present the intervention effect. Heterogeneity of included researches will be statistically assessed by using Chi-square test (X^2) and I-squared (I^2) will be used to describe inconsistency quantification. When conducting data consolidation for further analysis, P value in X^2 test >0.1 and $I^2 \leq 50\%$ will be considered there is no statistical heterogeneity so we can use the random effect model for data consolidation. Conversely, the fixed effect model will be used when there exists heterogeneity for merging the results of included studies. If there is a significant statistical heterogeneity in data consolidation, descriptive analysis method will be utilized for analyzing those data. The Z-test will be used for the overall effect. Additionally, funnel plot also will be used to visualize the bias of the included articles. Scattered at the bottom of the funnel plot are the studies with small sample size and low research accuracy and vice versa.

Subgroup analysis: In this review, we will consider subgroups analysis according to the size of heterogeneity of each outcome measure.

Sensibility analysis: We will conduct the sensitivity analysis to evaluate the robustness and reliability of the pooled results. 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. When interpreting the results and drawing conclusions, high sensitivity results indicate that there exist potential bias factors related to the effect of the intervention measures.

Language: There are no language limits.

Country(ies) involved: China.

Keywords: Isokinetic strength training; Lower extremity motor function; Stroke; Hemiplegia; Systematic review and meta-analysis.

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