INPLASY PROTOCOL

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None declared.

Different exercise interventions for stroke patients with balance impairment: a protocol for systematic review and network meta-analysis of randomized controlled trial

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Review question / Objective: **This study was designed to clear which exercise therapy is better than others for improving balance, improving walking ability in stroke patients with balance impairments?**
Condition being studied: **Balance impairment may cause difficulties in sitting, standing, walking, and other functional activities in stroke patients, making it difficult to safely complete ADLs, move in families and communities, and live independently. Simultaneously, impairment in balance increases the risk of falling in stroke patients. A large proportion of stroke patients have at least one fall within 6 months after onset. Up to 70% of stroke patients fall within 6 months of discharge from a hospital or rehabilitation institution. Stroke patients are twice as likely to have a hip fracture after a fall compared with people who have not suffered a stroke. Peoples with stroke with a history of falls and reduced balance are more likely to report lower self-efficacy and balance confidence, which in turn lead to limited mobility and an increased risk of falls. In this way, a vicious circle is formed.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 January 2022 and was last updated on 10 January 2022 (registration number INPLASY202210047).

INTRODUCTION

Review question / Objective: **This study was designed to clear which exercise therapy is better than others for improving balance, improving walking ability in stroke patients with balance impairments?**

Rationale: **Many therapeutic exercise interventions have been used to try to improve the balance dysfunction of patients with stroke. Content of the exercise training includes aerobic training, water-based exercise, stretching exercise, Tai Chi, Pilates, yoga, etc. Although evidence has been showed that exercise therapy can improve the balance function,**

prevent falls, and improve ADL of stroke patients, no specific exercise type has been proven to be superior, and the best time is not clear. Likewise, findings across these studies are not completely consistent on balance outcomes.

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METHODS

Participant or population: Only the studies that included patients with stroke will be included in this review. The diagnosis of all patients must consistent with the World Health Organization (WHO) definition of stroke. There is no limitation in gender, age, setting, impairment level, and duration.

Intervention: The interventions used in trials include a variety of exercises. The exercise was defined as a physical activity which is usually regular and done with the intention of improving or maintaining physical fitness or health according to the Medline Subject Heading (MeSH).

Comparator: In control group, all participants who have undergone non-exercise intervention, therapist hands-on treatment, and no intervention will be included.

Study designs to be included: Only randomized controlled trials (RCTs) will be included in our study. The non-RCTs such as case control trials, and quasi-RCTs will be excluded.

Eligibility criteria: The PICOS (Participant/Population, Intervention, Control, Outcomes, Study) framework will be used to screen the qualified literature. The details were reported at item 12-15.

Information sources: A systematic literature search will be conducted using five online most relevant medical databases including Embase (via embase.com), Medline (via PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), SPORTDiscus (via EBSCOhost) and CINAHL (via EBSCOhost). The time is from their inception to December 31, 2020 without language restrictions.

Main outcome(s): In our study, the balance function reported using any instrument (e.g. Berg Balance Scale, Time Up and Go Test, Functional Reach Test.) was considered as the primary outcome. Walking ability using any instrument (e.g. 6-minute walk test, 10 meter walk test) was considered as secondary outcome. Other outcomes include ADL, dropout, adverse events.

Data management: All data from the final inclusion list of articles will be extracted using a pre-formatted table by one and checked by another reviewer. The data management software, Excel, will be used to carry out data conversion if necessary. The information extracted include the article details (e.g. authors, title, journal, year), participants characteristic (e.g. total number, gender, average age, setting, number of drop out), design details (e.g. experimental group design, control group design, follow-up), outcomes (instruments, mean and standard deviation of outcomes, events for outcomes, point in time for evaluation, adverse event).

Quality assessment / Risk of bias analysis: For each trial, risk of bias assessment will

be performed using risk of bias tool according to guideline of the Cochrane handbook. Selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias will be assessed. Selection bias related with sequence generation, and allocation concealment. Performance bias related to binding of participants and personnel. Detection bias related to blinding of outcome assessment. Attrition bias related to incomplete outcome data. Reporting bias related with selective outcome reporting. Other bias related to small sample size, drop out earlier due to adverse events, and participants source diversity. For each entry, bias was assessed as low risk, unclear risk, and high risk according to the handbook. For the exercise intervention, it is impossible to blind the manipulator, so the bias for the performance bias was considered as high risk.

Strategy of data synthesis: For continuous data, the mean and standard deviation will be used to describe the effect of the exercise for the stroke patients with balance impairment. For categorical data, the events for the results will be described the effect of the exercise for the stroke patients with balance impairment. The data analysis includes two steps. First, conventional pairwise meta-analysis will be performed to compare the effects of exercise therapy and non-exercise therapy for the pairwise-control design. Heterogeneity will be identified by χ^2 test and quantified by I^2 statistic. If the I^2 value is more than 75%, the significant heterogeneity between the included studies will be considered. The fixed effect model or random effect model will be used to calculate effect size of the effect of the exercise for stroke patients with balance impairment. Forest plots will be used to visualize statistical results.The model will be built under Bayesian frameworks, which completed via Markov-chain-Monte-Carlo (MCMC), using R software (version 3.6.2). In NMA, goodness-of-fit will be assessed to decide whether a fixed or random effects model should be used. Inconsistency will be detected by the node analysis model if it forms a closed loop. The surface under the cumulative ranking curve (SUCRA) will be used to rank treatments. The relationship between the various interventions will be visualized through network plots.

Subgroup analysis: Subgroup analyses will be done as a mean of investigating heterogeneous results, or to answer specific questions about participant groups, types of intervention or types of study.

Sensitivity analysis: Sensitivity analyses will be done to assess the robustness of results, such as the impact of notable assumptions, imputed data, borderline decisions and studies at high risk of bias. When sensitivity analyses show that the overall result and conclusions are not affected by the different decisions that could be made during the review process, the results of the review can be regarded with a high degree of certainty. On the contrary, if the sensitivity analyses results identify that the overall result of the review was greatly influenced, greater resources can be deployed to try and resolve uncertainties. The sensitivity analyses will be performed by deleting the poor quality studies (such as ultra-wide confidence interval, small size, low methodological design, etc.).

Language: The language will be not limited.

Country(ies) involved: China.

Keywords: exercise, stroke, balance, protocol, systematic review, network meta-analysis.

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