INPLASY PROTOCOL

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Corresponding author: Xinman Dou

dxm1812@163.com

Author Affiliation:

Department of Nursing, Lanzhou University Second Hospital, Lanzhou 730000, China

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Non-pharmacological interventions for muscles spasticity of children with cerebral palsy: Protocol for a systematic review and network metaanalysis

Qian, XL¹; Wang, HX²; Wang, YL³; Yin, LQ⁴; Dou, XM⁵; Zhang CY⁶; Hong YL⁷; Ma JX⁸.

Review question / Objective: The aim of this study is to perform a network meta-analysis to evaluate the effectiveness of different non-pharmacological interventions to treat muscle spasticity of children with spastic cerebral palsy.

Condition being studied: Cerebral palsy (CP) is a nonprogressive clinical syndrome of multiple movement dysfunctions, which may affect muscle tone, posture, and/or movement, affecting about 1 in 500 neonates with an estimated prevalence of 17 million people worldwide. The most common type of CP is spastic CP, which accounted for 78-80% of all CP cases. The main clinical feature of children with spastic CP is motor disabilities, which may cause muscle spasticity. The key clinical feature of spastic CP is spasticity, which causes significant alterations to muscle morphology and architecture over time. The spastic muscles are often shorter because of insufficient stretching and may contribute to muscle weakness and imbalance. The management for children with spastic CP is a combination of modalities, while the approach to treating spasticity is not standardized. The general approach includes pharmacologic treatments, physical and/or occupational therapy, position optimization, and surgery. Traditional Chinese medicine is also an important treatment for children with spastic CP, especially massage and acupuncture.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2021 and was last updated on 30 April 2021 (registration number INPLASY202140133).

INTRODUCTION

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METHODS

Participant or population: Children with spastic cerebral palsy.

Intervention: Any non-pharmacological interventions to treat muscle spasticity of children with spastic cerebral palsy.

Comparator: Other non-pharmacological interventions.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: We will include randomized controlled trials which involved patients diagnosed with spastic cerebral palsy.

Information sources: Search strategies will be performed in electronic databases. The reference lists of eligible studies will be checked by reviewers in order to identify other possible randomized controlled trials.

Main outcome(s): The score of spastic muscles and motor development.

Quality assessment / Risk of bias analysis: Cochrane's Risk of Bias tool.

Strategy of data synthesis: We are going to provide a narrative synthesis of the findings from the included studies, the type of intervention, the target population characteristics, the type of outcome, and the intervention content. We will use Stata 15.0 and R software (version 3.4.1) to perform a network meta-analysis. The pooled odds ratios (ORs) with 95% confidence interval (CI) and mean differences (MDs) with 95%CI were used to assess the outcomes. Treatment ranking was calculated according to the P-scores, which measured the extent of certainty that one treatment was superior to another treatment. P-scores were expressed as percentages, which 100% represented for the best treatment and 0% for the worst treatment.

Subgroup analysis: If sufficient evidence is available, we are going to conduct subgroup analyses to explore the difference between upper and lower limbs.

Sensitivity analysis: Assessment of heterogeneity between the included studies will be conducted to evaluate the feasibility of network meta-analysis. We shall assess the heterogeneity on the bias of the magnitude of heterogeneity variance parameter (I2 or Cochrane Q). If the P>0.05 for Q test or I2 <50% for I2 test, which suggests there is no statistical heterogeneity, then the Mantel-Haenszel fixed effect model will be employed, whereas the P50% for I2 test, we will explore sources of heterogeneity by subgroup analysis and meta-regression. If no clinical heterogeneity was identified, the Mantel-Haenszel random-effects model will be used. A node splitting method will be used to examine the inconsistency between direct and indirect comparisons when a loop connecting three arms exists.

Country(ies) involved: China.

Keywords: Cerebral palsy; spastic muscles; network meta-analysis.

Contributions of each author:

Author 1 - Xiaoling Qian - The author (1) conceived this study (2) designed the inclusion/exclusion criteria and the searching strategy (3) will search for the literature (4) will collect the data and make statistical analysis (5) drafted the protocol and revised the manuscript.

Author 2 - Haixia Wang - The author (1) conceived this study (2) designed the inclusion/exclusion criteria and the searching strategy (3) will search for the literature (4) will collect the data and make statistical analysis (5) drafted the protocol and revised the manuscript.

Author 3 - Yali Wang - The author will collect the data and make statistical analysis.

Author 4 - Liqin Yin - The author will collect the data and make statistical analysis.

Author 5 - Xinman Dou - The author (1) conceived this study (2) designed the inclusion/exclusion criteria and the searching strategy (3) drafted the protocol and revised the manuscript.

Author 6 - Chengyuan Zhang - The author will collect the data.

Author 7 - Yulong Hong - The author will collect the data.

Author 8 - Jiaxuan Ma - The author will collect the data.