INPLASY PROTOCOL

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Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest: None declared.

Effects of robot-assissted gait training on cardiopulmonary function and lower extremity strength in patients with spinal cord injury: A protocol for meta-analysis

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Review question / Objective: Systematically evaluate the effect of robot-assissted gait training (RAGT) training on the cardiopulmonary function and lower extremity strength in patients with spinal cord injury.

Eligibility criteria: Inclusion criteria: (1) patients had been diagnosed with spinal cord injury; (2)randomized controlled trials (RCTs) comparing robotic-assisted training with Non-robotic-assisted training for RAT in SCI; (2) treatment of cardiopulmonary function or lower extremity strength were clearly stated; (3) Studies must have reported at least one outcome among cardiopulmonary function, and LEMS at baseline and end of treatment. Exclusion criteria:(1) they compared the effects of 2 different types of robot; (2)The study is designed as self-crossover controlled trial, uncontrolled clinical trial and other non-RCTs; (3) studies without accessible data and contacts of the authors.(4) they were case reports and pre-post design studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 February 2022 and was last updated on 18 February 2022 (registration number INPLASY202220066).

INTRODUCTION

Review question / Objective: Systematically evaluate the effect of robot-assissted gait training (RAGT) training on the cardiopulmonary function and lower extremity strength in patients with spinal cord injury.

Condition being studied: Spinal cord injury (SCI) is a partial or total disorder of sensory and motor function below the level of injury due to trauma, disease, or congenital factors, which causes patients to lose some or all motor ability, living ability, and work ability.In recent years, the incidence of SCI has been approximately 20 – 140 cases/million people/year around the world. In addition to the severe sensory and motor function loss below the injury plane, SCI can also be associated with cardiopulmonary dysfunction. The vicious cycle of limitation in mobility state and reduction in cardiopulmonary function is frequently observed in people with SCI. Prolonged immobilization as well as reduced mobility states can lead to poor cardiopulmonary function. This limits social integration and increases the risk of developing other comorbidities including heart disease and pneumonia. Robot-assissted gait training（RAGT） has received much attention in gait rehabilitation for people with neurological conditions. RAGT provide guidance in the lower limbs movement during walking training that enables prolonged walking training with afferent input of normal gait pattern. This extensive exposure of task-specific repetitive training helps promote reorganization of the primary motor cortex, and functional outcomes can be improved in patients with neurological conditions like spinal cord injuries (SCI). Numerous RCTs have investigated the effects of RAGT on lower extremity strength in spinal cord injury patients, and some have also addressed the effects on cardiopulmonary function. Although some studies have shown Significant effects of RAGT on lower limb strength or cardiopulmonary function, some have shown opposite results. The overall goal of this study is to summarize the evidence from RCTs comparing RAGT with other treatments in SCI patients, focusing on cardiopulmonary function and lower extremity strength.

METHODS

Search strategy: Relevant articles published up to January 16, 2022, were searched in Pubmed/Medline, Embase , Web of Science, Cochrane Database of Systematic Reviews, Physiotherapy Evidence Database (PEDro), CNKI, VIP、Wanfang. The following search terms were used for RAGT: robotic-assisted training, robotic-assisted lokomat training, robotic-assisted gait training, lower limb robot, lower limb exoskeleton robot, lokomat and robot. The following search terms were used for CPF: cardiopulmonary function, pulmonary, endurance, maximal oxygen consumption , peak expiratory flow(PEF), FEV1 , FVC , MVV. Other keywords included spinal cord injury and lower extremity strength. We combined multiple terms about RAGT with "OR", multiple terms about CPF with "OR" and then combined the four parts with "AND."

Participant or population: Spinal cord injury patients; Race, nationality and duration of disease are not limited.

Intervention: Robot-assissted gait training. There was no restrictions on robot types, training intensity, rating for RAGT.

Comparator: Control group: conventional overground training, conventional physical therapy, or other therapeutic modalities.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: Inclusion criteria: (1) patients had been diagnosed with spinal cord injury; (2)randomized controlled trials (RCTs) comparing robotic-assisted training with Non-robotic-assisted training for RAT in SCI; (2) treatment of cardiopulmonary function or lower extremity strength were clearly stated; (3) Studies must have reported at least one outcome among cardiopulmonary function, and LEMS at baseline and end of treatment. Exclusion criteria:(1) they compared the effects of 2 different types of robot; (2)The study is designed as self-crossover controlled trial, uncontrolled clinical trial and other non-RCTs; (3) studies without accessible data and contacts of the authors.(4) they were case reports and pre-post design studies.

Information sources: We conducted a Systematic literature search in Pubmed, Embase , Web of Science, Cochrane Database of Systematic Reviews, Physiotherapy Evidence Database (PEDro), CNKI, VIP databases, Wanfang Data.

Main outcome(s): The main outcome indicator is cardiopulmonary function: Maximal oxygen consumption (VO2max, peak oxygen consumption (VO2peak, peak expiratory flow (PEF, forced expiratory volume in first second(FEV1) ,forced vital capacity (FVC), maximal voluntary ventilation(MVV).

Additional outcome(s): Secondary indicators are the lower extremity motor score(LEMS).

Data management: Import the retrieved documents into EndnoteX9. The following information was extracted from all qualified studies by two researchers independently: study design, intervention, number of participants, characteristics of participants, outcome measures (mean, standard deviation) for cardiopulmonary function, as well as lower extremity strength of treatment group and control group. A third reviewer participated in discussions and made decisions on any discrepancies. Use STATA 12.0 software to assess the risk bias of all included qualified studies and perform data analysis.

Quality assessment / Risk of bias analysis: Study quality was assessed using the Physiotherapy Evidence Database (PEDro) scale ,which was designed to measure the methodological quality of randomized controlled trials. The PEDro scale is an 11-item scale with a maximum score of 10. If a study was rated at least 4, it would be considered as moderate to high quality. Quality assessment for each study was done by two independent reviewers, and any disagreement was resolved upon discussion involving a third reviewer.

Strategy of data synthesis: Meta-analysis was performed using STATA 12.0 software. The pooled effect size was weighted mean difference (WMD) or standardized mean difference (SMD) and its 95% CI. The heterogeneity test was performed first, and the χ2 test was used to analyze the heterogeneity between the study results, combined with I2 judgment, with a test level of α = 0.1. If the study results are homogeneous (P > 0.1, I2 < 50%), the fixed-effect model is used for meta-analysis; if the study results are statistically heterogeneous (P ≤ 0.1, I2 ≥ 50%), the causes of heterogeneity are analyzed. If there is clinical heterogeneity, sensitivity analysis or meta-analysis can be performed according to its source; if there is no significant clinical heterogeneity, the random-effect model is used for meta-analysis. Z-test was used for the pooled effect value, and the test level was α = 0.05.

Subgroup analysis: When there is heterogeneity between studies, the method of subgroup analysis is often used to deal with it. Each variable such as study design, sample characteristics, length of treatment and so on can be divided into subgroups for analysis, If the results of subgroup analysis _ indicate that each subgroup The group does not show heterogeneity, which suggests that this variable may be one of the sources of heterogeneity, which can reduce the heterogeneity caused by the difference of this variable.

Sensitivity analysis: Using STATA 12.0 software to assess the risk bias of the included all qualified studies. The size of heterogeneity of the studies was assessed based on the P value: I 2 ≥ 50% or P < 0.05 indicated high heterogeneity. Sensitivity analysis is used to find the reasons for the heterogeneity, the random-effects model is used for meta- analysis.

Country(ies) involved: China.

Keywords: Spinal cord injurie; Robotic-assisted gait training; Cardiopulmonary; lower extremity; Function; Meta-analysis.

Contributions of each author:

Author 1 - Wan Chunli - Study design, guidance and drafted the manuscript.
Email: wanchunliw@163.com
Author 2 - Huang Sisi - Involved in the design of the study.
Author 3 - Wang Xue - Literature search and selection.
Author 4 - Ge Panli - Literature search and selection.
Author 5 - Wang Zhixiang - Data collection and synthesis.
Author 6 - LI Yongqiang - Study design, guidance.