Effectiveness of hybrid robotic rehabilitation system on upper limb recovery of people with central injuries: a systematic review with meta-analysis

Fernanda Rodrigues Martins Ferreira, Guilherme de Paula Rúbio, Lucas Oliveira Fonseca, Charles Fattal, Adriana Valladão Novais van Petten, Claysson Santos Vimieiro, Christine Azevedo Coste

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Review question

What is the effectiveness of hybrid robotic rehabilitation system on upper limb recovery of people with central injuries?

Searches

The search for relevant studies will be conducted on PEDro (Physiotherapy Evidence Database), EMBASE (Excerpta Medica Database), MEDLINE (Medical Literature Analysis and Retrieval System Online), CINAHL (Cumulative Index to Nursing and Allied Health Literature), COCHRANE (Cochrane Collaboration), AMED (Allied and Complementary Medicine Database), IEEE Xplorer (Institute of Electrical and Eletronics Engineerinh) and Compendex (Compendex Engineering Index) without language or date restrictions. In addition, a hand searching will be conducted in the reference lists of all eligible studies and previous reviews in this area. Search terms will be related to: “Hybrid Orthosis”, “Upper limb” and “Randomized controlled trial” (see Appendix 1 on the Addenda for detailed search strategy).
This review will be included prospective randomized or quasi-randomized controlled studies including inpatients and outpatients from any primary, secondary or tertiary care setting and community. Studies will be eligible if they included participants with limited upper limb functioning caused by any health condition, regardless of age or sex (inpatients or outpatients from any clinical/hospital care settings including primary, secondary or tertiary services and community individuals). The intervention of interest will be HRRS, which is defined as the systems that rehabilitate or compensate motor functions through the combined action of muscle activation with FES and mechanical/electromechanical forces supplied to joints. Studies will be eligible if HRRS is compared with minimal intervention or other intervention (OI). We defined minimal intervention as when the control group received no intervention, received sham or placebo intervention, or was on a waiting list. We considered any other active intervention that was not hybrid orthosis, such as conventional therapy and physical therapy. The outcome of interest in this review will be related to body function and structure, activity and participation according to the International Classification of Functioning, Disability and Health

Types of study to be included

This review will be included prospective randomized or quasi-randomized controlled studies

Condition or domain being studied

People with upper limb disorders caused by central lesions

Participants/population

Studies will be eligible if they included participants with limited upper limb functioning caused by central lesions, regardless of age or sex (inpatients or outpatients from any clinical/hospital care settings including

primary, secondary or tertiary services and community individuals).

Intervention(s), exposure(s)

The intervention of interest will be HRRS, which is defined as the systems that rehabilitate or compensate motor functions through the combined action of muscle activation with FES and mechanical/electromechanical forces supplied to joints (DEL-AMA et al., 2012)

Comparator(s)/control

Studies will be eligible if HRRS is compared with minimal intervention or other intervention (OI). We defined minimal intervention as when the control group received no intervention, received sham or placebo intervention, or was on a waiting list. We considered any other active intervention that was not hybrid orthosis, such as conventional therapy and physical therapy.

Main outcome(s)

The outcome of interest in this review will be related to body function and structure, activity and participation according to the International Classification of Functioning, Disability and Health (SIVAN et al., 2011; WORLD HEALTH ORGANIZATION, 2001). Body function and structure are considered as the physiological functions of body systems, including psychological function and body structure, i.e., anatomical parts of the body, such as organs, limbs and their components. Activity refers to execution of a task or action by an individual and participation is involvement of an individual in a life situation (WORLD HEALTH ORGANIZATION, 2001).

* Measures of effect

Sample size, mean and standard deviation (SD) for each group will be extract at short, medium- and long-term follow-ups when available.Pooled effects will be estimated using standardized mean differences (SMDs) with 95% confidence intervals (CI).

Additional outcome(s)

Subgroup qualitative analysis will be conducted to investigate the impact of methodological quality issues on the pooled effects. Studies with PEDro scores of at least 6 out of 10 were considered high quality in this review.

* Measures of effect

Sample size, mean and standard deviation (SD) for each group will be extract at short, medium- and long-term follow-ups when available.Pooled effects will be estimated using standardized mean differences (SMDs) with 95% confidence intervals (CI).

Data extraction (selection and coding)

Data will be extracted by a reviewer (FMRMF) and double checked by a second reviewer (GPR). Disagreements will be resolved by consensus. Authors will be contacted to clarify eventual doubts. Data extracted at baseline will include: number of participants; mean age; percentages of males and females; cause of the upper limb disorder and its duration, evaluated joints; type of HRRS; comparison groups; frequency and total duration of intervention; and outcome measures.The outcome data extracted will included the sample size, mean and standard deviation (SD) for each group at the short-, medium- and long-term follow-ups, when available.When multiple time points are available within the same follow-up period, the time point closer to the end of the intervention will be considered.

Risk of bias (quality) assessment

The GRADE (Grading of Recommendations Assessment, Development and Evaluation) system will be used to summarize the overall quality of evidence for each outcome (BALSHEM et al., 2011) . We will rate evidence from the high-quality level and downgrade it one point if one of the following prespecified criteria is present: low methodological quality (average PEDro score < 6); inconsistency of estimates among pooled studies (I^2 > 50%) or when its assessment is not possible (no pooling); indirectness of participants (over 50% of the studies do not describe inclusion criteria); and imprecision (pooling < 400 participants for each outcome) (HIGGINS; GREEN; COCHRANE COLLABORATION, 2008).

Strategy for data synthesis

Data for each outcome will be pooled when there is sufficient homogeneity among studies. Heterogeneity

among studies will be assessed using I^2 statistics = [(Q- df)/Q] x 100%, where Q is the $?^2$ statistic and df is its degrees of freedom (HIGGINS et al., 2003; HIGGINS; THOMPSON, 2002) . Low heterogeneity is defined as I^2 ? 50%, and moderate to high heterogeneity is defined as I^2 > 50% (HIGGINS; GREEN; COCHRANE COLLABORATION, 2008). Pooled effects will be estimated using standardized mean differences (SMDs) with 95% confidence intervals (CI). A fixed-effects model will be used to conduct the meta-analysis when I^2 ? 50%, and a random-effects model otherwise. To judge the clinical relevance of HRRS, the effect size will be assessed using Cohen's d coefficient according to the following parameters: 0.2 as small effect, 0.5 as medium effect, and 0.8 as large effect (COHEN, 1988) . A funnel plot will be used to investigated publication bias when at least 10 studies are pooled (HIGGINS; GREEN; COCHRANE COLLABORATION, 2008). The meta-analysis will be performed using the software Comprehensive Meta-Analysis, version 3.3.070.

Analysis of subgroups or subsets

Central tendency and variability measures will be extracted for short-, medium- and long-term effects. Standard deviation (SD) will be imputed using 95% CI.

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Type and method of review

Intervention, Systematic review

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Conflicts of interest

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Review Ongoing

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MeSH headings have not been applied to this record

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Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

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