The economic cost of robotic rehabilitation for adult stroke patients: a systematic review protocol

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**Review question/objective:** The objective of this review is to identify the best available evidence on the economic cost of robotic rehabilitation for adult stroke patients to improve their motor movement abilities. More specifically, the objective is to identify the evidence on the economic cost of robotic training compared to conventional physiotherapy for adult stroke patients, from the perspective of hospitals.

**Keywords** Stroke; Robotics; rehabilitation; Economic; Systematic Review Protocol


**Introduction**

Stroke is a leading cause of disability with 15 million people suffering a stroke yearly. In the United States, the annual healthcare spending for stroke patients is USD80 billion. Given the large social and economic burden of stroke, it is important to identify appropriate treatment methods that can not only reduce the disability of stroke survivors, but also do so cost effectively. Traditionally, stroke patients would undergo rehabilitation post stroke and, depending on the nature of the disability, rehabilitation would be administered by a multi-disciplinary team of physiotherapists, occupational therapists, speech therapists and neuropsychologists, who work together to offer integrated, holistic rehabilitation therapy. For physical impairments, stroke patients will usually undergo conventional physiotherapy, which involves patients undergoing repetitive, high intensity, task-specific exercises that enable them to regain their motor and functional abilities. In animal studies, it has been shown that test subjects regain motor abilities after intensive and repetitive task training. This was associated with a reorganization of the undamaged motor cortex to enable recovery of motor abilities of the affected limbs. This “neuroplasticity” is the underlying principle of motor learning involving repetitive, high intensity, task-specific exercises. However, conventional physiotherapy trainings are labor intensive and places physical strain on physiotherapists.

To facilitate the high repetitions required, robotic devices have been used to assist therapists to rehabilitate patients based on high repetitions of task specific exercises. These robotic devices provide intensive, consistent and repetitive cycles over long periods to train the impaired limbs of patients. There are two main types of robotic devices: exoskeletons or end-effectors. Exoskeletons are devices that wrap around limbs and are able to assist each limb joint to move. End-effectors are devices that assist only the extremities of a limb (either hands or feet). Regardless of the design mechanism, one key feature of robotic devices is the ability to automatically assist patients to move their limbs when they are unable to do so by themselves. This automated assistive feature enables high repetitions to be achieved.

Systematic reviews conducted on these robotic devices showed varying degrees of effectiveness. One systematic review that assessed lower limb outcomes found that robotic-assisted gait training increased the odds of participants being able to walk independently. For the sub-group of severely impaired patients, findings indicated that robotic treatment was more effective. In terms of upper limb outcomes, systematic reviews have found that robot-assisted arm training improved arm motor movement and activities of daily living scores. A recent systematic review found that robotic training was just as effective as conventional
physiotherapy for upper limb motor movement, lower limb walking and activities of daily living, but for severely impaired lower limb patients, robotic training was found to be more effective than conventional training. Overall, these reviews showed that robotic devices, at a minimum, offered equivalent treatment outcomes as conventional physiotherapy.

While robotic devices enable a high intensity training regime that can be just as effective as conventional therapy, the robotic training equipment can cost up to several hundred thousand dollars per device, which is a significant capital outlay for hospitals. Hence, the decision to introduce robotic devices into clinical settings and offer robotic stroke rehabilitation to patients has an important cost consideration for healthcare providers. Despite its cost, robotic devices may increase the work efficiency of therapists, hence more patients can be treated and this could lead to an overall reduction in cost of treatment per patient. There have been clinical studies to determine the economic cost of robotic devices in the rehabilitation of stroke patients. However, these studies presented a mixed picture of the cost impact of robotic devices. One study that compared the cost-effectiveness of robotic rehabilitation with conventional rehabilitation had an uncertain finding, while another study found that robotic devices were economically sustainable. A third study compared the treatment costs and found that robotic training was less expensive than conventional training. A preliminary search of PubMed, Embase, JBI Database of Systematic Reviews and Implementation Reports, Cochrane Library and PROSPERO was carried out to identify systematic reviews that had been conducted on this topic area and no reviews were found.

The current literature does not provide a clear determination of the cost impact of using robotic devices for stroke rehabilitation and it is the aim of this review to provide clarity to the discussion and assist healthcare providers to understand the economic cost of robotic rehabilitation.

**Inclusion criteria**

**Participants**

This review will consider studies that include adult stroke patients (18 years and over) of all genders, regardless if stroke is due to ischemic or hemorrhagic causes. Patients with pre-existing impairments that are not caused by stroke, such as disabilities due to spinal cord injuries, Parkinson’s disease, multiple sclerosis and traumatic brain injuries, will be excluded. Study participants may be new stroke patients or repeat stroke patients at acute, sub-acute or chronic stages of their stroke, as long as they have been accepted into a rehabilitation program.

**Intervention and comparator**

The review will consider studies that evaluate rehabilitation of stroke patients using robotic devices and compare the outcomes to control groups which use conventional physiotherapy. The types of robotic devices can be varied (e.g. either robotic exoskeletons or end-effectors for gait training), as long as interventions involve electro-mechanical devices with automated assistive feature to help patients regain their motor abilities.

Interventions involving the devices below are not considered as robotic rehabilitation devices as they do not exhibit assistive automation that robotic devices have:

- Non-interactive devices that deliver passive motion such as treadmills, static body-weight assisted treadmills, bicycles, static walking aids, static orthoses (such as ankle-foot orthoses addressing foot drop) or pure mechanical trainers (e.g. Reha-Slide, Reha-Slide duo).
- Standalone video games controlled solely by patient without automated assistive feature, such as Nintendo Wii.
- Rehabilitation programs using non-conventional therapies such as acupuncture, functional electrical stimulation (FES), transcranial direct current stimulation, motor imagery, biofeedback and constrain induced therapy (CIT).

The intervention group can have an added conventional physiotherapy component or not. If the intervention group has an added conventional physiotherapy component, this can involve non-interactive static devices. The intervention should not contain other types of non-conventional therapy (e.g. FES, transcranial direct current stimulation, motor imagery or CIT). For multiple-arm studies, only results of the intervention arm with robotic rehabilitation will be compared to the conventional therapy control arm. The intervention arm with a combination of robotic devices and non-conventional therapy will be excluded from analysis.
As control groups, patients do not receive robotic rehabilitation but receive only conventional physiotherapy. The conventional physiotherapy treatment may include non-interactive static devices (e.g. bicycles, treadmills, acupuncture). The amount of therapy treatment in both intervention and control groups should be the same in terms of duration, i.e. dose-matched. For example, if patients in the intervention group undergo 60 minutes of therapy using a robotic device on top of a conventional physiotherapy component, then in the control group the patients should also undergo an additional 60 minutes of conventional physiotherapy. Therefore, the total amount of therapy time planned for patients (over the intervention period) should be the same for both groups.

**Context**
Studies where the rehabilitation setting is either inpatient or outpatient will be included. Home rehabilitation patients will be excluded due to potential confounding of treatment adherence. The rehabilitation program can be conducted in hospitals, nursing facilities or across multi-centers, and only physical impairments related to upper and lower limbs will be considered.

**Outcomes**
This review will consider studies that include the following outcomes:
- **Cost minimization:** Studies that aim to compare the cost of providing robotic rehabilitation against the cost of providing conventional physiotherapy will be included.
- **Cost-effectiveness:** Studies that aim to compare the cost of providing robotic rehabilitation against the cost of providing conventional physiotherapy will be included, whereby the outcome is presented as relative costs to achieve a unit of effect. The unit of effect should reflect the motor movement ability of patients and should involve the following measurement scales:
  - For measurement scale of upper limbs, the Fugl-Meyer Assessment\(^21\) (upper extremity score) is the preferred scale. If a study does not use this scale, then an alternative measurement scale that quantifies upper limb motor movement (e.g. upper limb Motricity Index\(^22\)) will be considered.
  - For measurement scale of lower limbs, the Functional Ambulation Category\(^23\) is the preferred scale. If a study does not use this scale, then an alternative measurement scale that quantifies walking will be considered, e.g. Barthel Index\(^24\) (ambulation item) or Functional Independence Measure\(^25\) (walking item).
- **Cost utility:** Studies that aim to compare the cost of providing robotic rehabilitation against the cost of providing conventional physiotherapy will be included, whereby the outcome is presented as relative costs to achieve a unit of utility, which is measured in quality adjusted life years (QALY).
- **Cost benefit:** Studies that aim to compare the cost of providing robotic rehabilitation against the cost of providing conventional physiotherapy will be included, whereby the outcome is presented as relative costs to achieve a unit of benefit, which is also measured in monetary units.

The cost perspective adopted is from the viewpoint of hospitals, as hospitals are the main decision makers for introducing robotic rehabilitation to stroke patients in a clinical setting. As such, only direct medical costs (e.g. therapist time, medical devices) will be considered. Indirect costs, such as cost of patients’ caregivers or patients’ travel expenses, will be excluded. Direct non-medical costs (e.g. hospital administrative cost) will also be excluded as this type of cost is common to all patients, regardless of robotic or conventional training. Cost components during the follow-up period will be excluded, as it is the intent of the review to examine the costs associated with providing the intervention during the treatment period.

**Types of studies**
Economic studies of robotic training involving upper and lower limbs will be included. The economic component of the review will consider cost minimization, cost-effectiveness, cost utility and cost benefit studies, which compare robotic rehabilitation to conventional physiotherapy in dose-matched therapy sessions. Partial economic evaluations (i.e. cost analysis, cost-description studies and cost-outcome descriptions) of robotic rehabilitation versus dose-matched conventional physiotherapy will also be considered for inclusion. Modeling studies will not
be considered, as the review aims to collect empirical data from prospective clinical trials. Studies published in English will be considered for inclusion in this review and a date limit starting from 2000 will be set, as automated robotic devices have increasingly been used since 2000, together with an associated increase in the number of studies undertaken.

**Methods**

**Search strategy**

The search strategy will aim to find both published and unpublished studies. An initial limited search of PubMed will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the articles. This will inform the development of a search strategy which will be tailored for each information source. A full search strategy for PubMed is detailed in Appendix I. The reference list of studies selected for critical appraisal will also be screened for additional studies.

**Information sources**

The databases to be searched include: PubMed, Embase, CINAHL, Cochrane (CENTRAL), PEDro (Physiotherapy Evidence Database), NHS Economic Evaluation Database (NHS EED), Cost Effectiveness Analysis (CEA) registry, and Health Technology Assessment (HTA) database.

The search for unpublished studies will include: MedNar, ProQuest Dissertations and Theses and ClinicalTrials.gov

**Study selection**

Following the search, all identified citations will be collated and uploaded into bibliographic software or citation management system and duplicates removed. Titles and abstracts will then be screened for assessment against the inclusion criteria for the review. Studies that meet the inclusion criteria will be retrieved in full and assessed in detail against the inclusion criteria. Full text studies that do not meet the inclusion criteria will be excluded and reasons for exclusion will be provided in an appendix in the final systematic review report. Included studies will undergo a process of critical appraisal. The results of the search will be reported in full in the final report and presented in a PRISMA flow diagram.

**Assessment of methodological quality**

Selected studies will be critically appraised by two independent reviewers at the study level for methodological quality using the standardized critical appraisal instruments from the Joanna Briggs Institute for Economic Evaluation. Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer.

As economic analysis of robotic devices is an emerging research area, all studies regardless of their methodological quality will undergo data extraction and synthesis (where possible) to maximize data collection. However, study quality will be considered in the interpretation of review findings.

**Data extraction**

Data will be extracted by two independent reviewers from papers included in the review using the standardized data extraction tool from Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information (JBI SUMARI). The data extracted will include: firstly, descriptive data about the intervention/s and comparator/s examined, study population/participants and context, study methods; and secondly, results for the resource use, cost and cost-effectiveness measures; thirdly, where possible, author conclusions about factors that promote (impede) cost-effectiveness of the intervention. In the event of specific key data of interest being absent from published articles, corresponding authors will be contacted.

**Data synthesis**

Economic findings will, where possible, be synthesized and presented in a tabular summary. Where this is not possible, findings will be presented in narrative form. In general, depending on quantity, quality and nature of the economic papers identified, economic results will be subjected to:

- Narrative summary, or
- Sorting in tables by comparisons/outcomes, or
- Tabulated in a permutation matrix.

Data permitting, sub-group analysis may be conducted to shed light on whether there are differences in costs due to: i) upper limb; ii) lower limb; iii) impairment levels; and iv) stages of stroke recovery (acute/sub-acute/chronic).
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References

Appendix I: Search strategy for PubMed

PubMed search terms:


Breakdown of search terms based on key search concepts: