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SUMMARY WITH CRITICAL APPRAISAL

Motorized Walking Devices for Patients with Compromised Mobility: A Review of Clinical Effectiveness, Cost-Effectiveness, and Guidelines

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Abbreviations

AMSTAR 2	A Measurement Tool to Assess Systematic Reviews 2
CRD	University of York Centre for Reviews and Dissemination
EMBASE	Excerpta Medica database
MEDLINE	Medical Literature Analysis and Retrieval System Online
MeSH	Medical subject headings
PubMED	Public MEDLINE
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomized controlled trial
SR	systematic review

Context and Policy Issues

Walking aids have been resorted to for millennia,[1] by individuals requiring assistance with ambulation. Canes, crutches, braces, and orthoses comprise some of the assistive devices available to modern-day individuals with limited or compromised lower limb mobility. The late 1960s saw the development of powered, motorized, and robotic walking devices,[2] which have since improved in design and, in recent years, making their way to market.

Robotic walking assistive devices function largely by detecting the user's movement intent and by way of motorized joint modules,[2] they assist in completing the movement. Also known as exoskeletons, these devices allow the user to stand, sit, walk, use stairs, and step over obstacles with a relatively natural posture and gait. They have various design features; however, they usually include a waist harness with mechanical joints that extend partially or fully down the legs, a battery unit, and a computer control module. The device is secured around the waist, and the mechanical joints secured around the legs, by means of straps. These devices can be used in conjunction with clinical therapy (e.g., treadmill or physiotherapy exercises) for rehabilitation purposes, or outside of a clinical setting to allow the user to ambulate during their activities of daily living.[2]

In a previous CADTH report (reference list),[3] published in 2015, entitled "Wearable Motorized and Robotic Walking Assistive Devices for Patient with Compromised Mobility: Clinical and Cost-Effectiveness", three non-randomized studies were found to be relevant, while no economic evaluations were identified. The objective of this report is to update and evaluate the clinical effectiveness and cost-effectiveness, and evidence-based guidelines on the use of motorized or robotic wearable walking assistive devices for adults with compromised mobility.

Research Questions

1. What is the clinical effectiveness of motorized or robotic wearable walking assistive devices for adults with compromised mobility?
2. What is the cost-effectiveness of motorized or robotic wearable walking assistive devices for adults with compromised mobility?
3. What are the evidence-based guidelines regarding motorized or robotic wearable walking assistive devices for adults with compromised mobility?

Key Findings

One systematic review was identified but did not contain any relevant literature regarding the comparative clinical effectiveness of motorized or robotic wearable walking assistive devices for adults with compromised mobility.

No evidence for the cost-effectiveness of motorized or robotic wearable walking assistive devices for adults with compromised mobility was identified. Additionally, no evidence-based guidelines regarding motorized or robotic wearable walking assistive devices for adults with compromised mobility were identified.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were robotic assistive devices and lower extremities/walking. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 01, 2014 and July 26, 2019.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults with limited or compromised mobility (e.g., from injury, degenerative diseases, aging, or medical conditions including knee or hip osteoarthritis, multiple sclerosis or Parkinson's disease) excluding paraplegics and individuals with complete lower limb impairment
Intervention	Wearable motorized or robotic walking assistive devices (e.g., Keeogo, ReWalk, Kickstart, Honda Stride Management Assist, excluding motorized walkers
Comparator	Q1-2: Alternate wearable motorized or robotic walking assistive devices (e.g., levitation bionic knee); manual walking assistive devices (i.e., both manual devices that are custom designed for the patient and "off the shelf" devices) Q3: Not applicable
Outcomes	Q1: Clinical effectiveness (e.g., patient quality of life, falls, adverse events) Q2: Cost-effectiveness Q3: Guidelines
Study Designs	Q1: Health technology assessments, systematic reviews, meta-analyses, randomized controlled studies, non-randomized studies Q2: Economic evaluations Q3: Evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1 or they were duplicate publications. As this is an update to a previous CADTH report,[3] clinical and cost effectiveness studies were excluded if they were published prior to July 2015. Guidelines were excluded if they were published prior to 2014. Guidelines with unclear methodology were also excluded.

Critical Appraisal of Individual Studies

One reviewer critically appraised the included systematic review (SR) using the AMSTAR 2 checklist.[4] Summary scores were not calculated, rather, a review of the strengths and limitations of the included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 697 citations were identified in the literature search. Following screening of titles and abstracts, 665 citations were excluded and 32 potentially relevant reports from the electronic search were retrieved for full-text review. Five potentially relevant publications were retrieved from the grey literature search for full text review. Of these potentially relevant articles, 36 publications were excluded for various reasons, and one SR met the inclusion criteria and was included in this report. Appendix 1 presents the PRISMA[5] flowchart of the study selection.

Appendix 4 includes two additional references that did not meet the inclusion criteria of this report but may be of interest. These include an emerging technology evidence report[6] and an ongoing clinical trial.[7]

Summary of Study Characteristics

One SR[8] met the inclusion criteria for this report, however, none of primary studies included in the SR met the eligibility criteria for this report, as the scope of the SR was broader than the scope of this report. Detailed characteristics of the SR are available in Appendix 2.

Study Design

One SR[8] published in 2016 met the inclusion criteria for this report. The review included literature from three databases from inception to May 2016. This SR aimed to determine whether powered exoskeletons are effective as assistive and rehabilitation devices in improving locomotion in patients with spinal cord injuries. The SR had three questions, one of which was in line with the research question of this CADTH report, however no primary studies were found that answered that research question.

Country of Origin

The first author of the SR[8] was from the United States of America.

Patient Population, Interventions and Comparators, and Outcomes

No relevant primary studies were included in the SR,[8] therefore no summary can be provided.

Summary of Critical Appraisal

Systematic Reviews

The strengths and limitations of the SR[8] were assessed using the relevant components of AMSTAR 2,[4] however, as none of the primary studies included in the SR were relevant to this report, a number of the items in the checklist were not applicable.

This SR[8] made no mention of a written protocol, and thus it is unknown if any changes to the protocol were made throughout the process. The research questions and the inclusion criteria were well described, the search strategy was thorough. However, the SR did not report how many people were involved in selecting the primary studies, and it is unclear whether study selection and data extraction were performed in duplicate. In addition, the report only includes randomized controlled trials, and it is possible that additional evidence may have been available in non-randomized studies. The authors did provide a list of the excluded studies as well as the reasons for their exclusion. Finally, there were no conflicts of interest with the funding source.

Additional details are available in Appendix 3, Table 3.

Summary of Findings

Clinical Effectiveness of Motorized or Robotic Wearable Walking Assistive Devices for Adults with Compromised Mobility

The SR did not include any relevant primary studies comparing the clinical effectiveness of motorized or robotic wearable walking assistive devices versus alternate wearable motorized or robotic or manual walking assistive devices for adults with compromised mobility; therefore, no summary can be provided.

Cost-Effectiveness of Motorized or Robotic Wearable Walking Assistive Devices for Adults with Compromised Mobility

No relevant evidence regarding the comparative cost-effectiveness of motorized or robotic wearable walking assistive devices versus alternate wearable motorized or robotic or manual walking assistive devices for adults with compromised mobility was identified; therefore, no summary can be provided.

Evidence-based Guidelines Regarding Motorized or Robotic Wearable Walking Assistive Devices

No relevant evidence-based guidelines were identified for motorized or robotic wearable walking assistive devices; therefore, no summary can be provided.

Limitations

A primary limitation of this report is the paucity of comparative evidence. One SR[8] was identified but did not contain any relevant literature regarding the clinical effectiveness of motorized or robotic wearable walking assistive devices versus alternate wearable motorized or robotic or manual walking assistive devices for adults with compromised mobility.

In addition, no cost-effectiveness studies or evidence-based guidelines were identified.

Conclusions and Implications for Decision or Policy Making

No relevant literature or evidence-based guidelines were identified regarding the clinical or cost effectiveness or recommendations for motorized or robotic wearable walking assistive devices as compared with alternate wearable motorized or robotic or manual walking assistive devices; therefore no conclusions can be provided.

These findings are similar to the previous CADTH report[3] on wearable motorized and robotic assistive devices published in 2015, which did not identify any relevant health technology assessments, SRs, or randomized controlled trials. The previous CADTH report[3] identified three non-randomized studies but they were not comparative studies.

There is a distinct lack of comparative studies regarding motorized or robotic wearable walking assistive devices versus alternative devices. Future studies that directly compare motorized or robotic wearable walking assistive devices to alternate devices may help reduce uncertainty.

References

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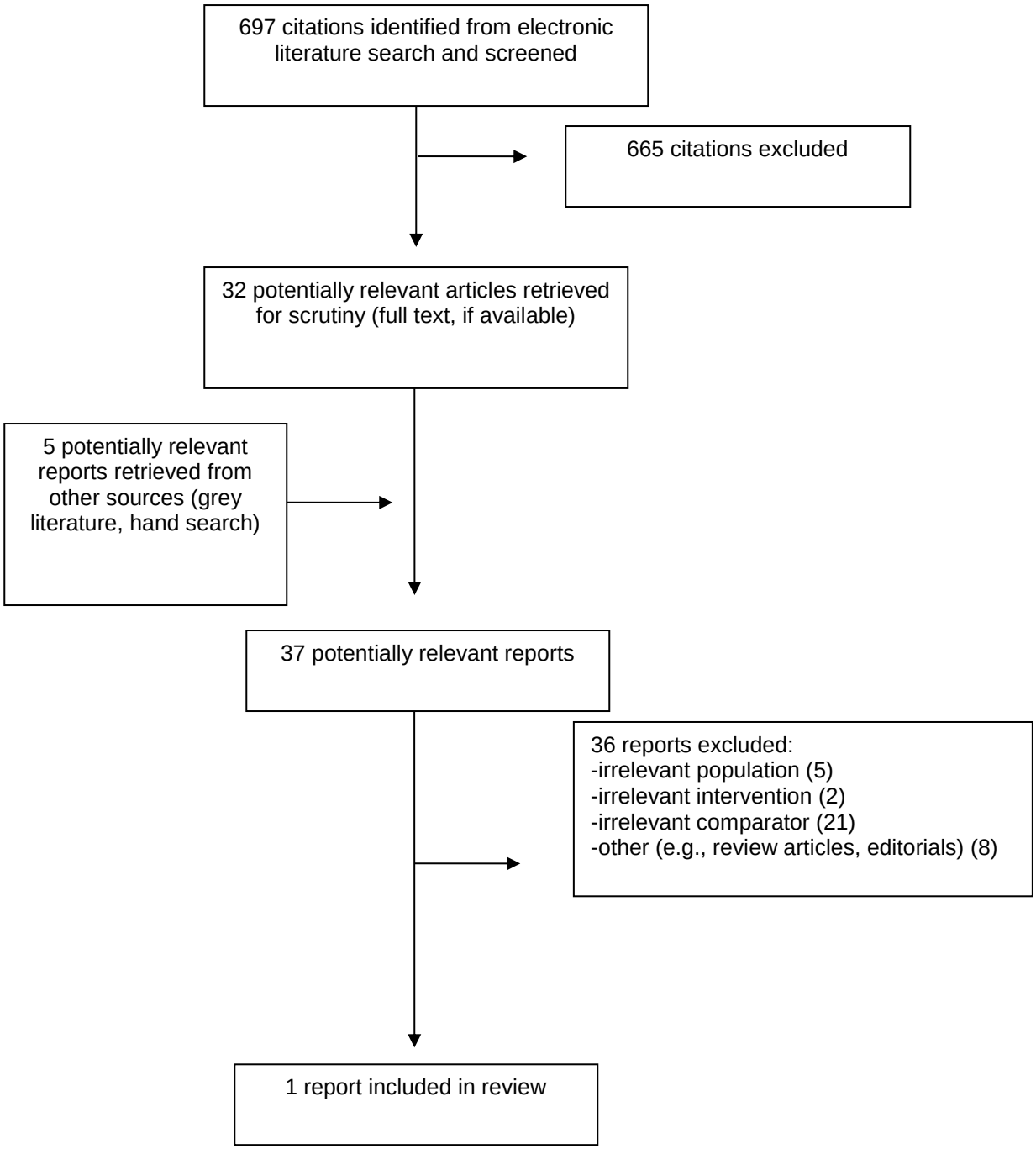
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Health Technology Assessments and Systematic Reviews and Meta-Analyses

First Author, Publication Year, Country	Literature Searched, and Numbers of Primary Studies Included	Eligibility criteria	Intervention and Comparator	Clinical Outcomes
Fisahn 2016[8] **United States of America**	**Search:** PubMed, Cochrane, and EMBASE were searched from database inception to May 2, 2016; bibliographies of included articles were also searched. **Included studies**: No primary studies relevant to this report. (11 RCTs were relevant to other questions in the review) **Aim:** To determine if powered exoskeletons are effective as assistive and rehabilitation devices in improving locomotion in patients with spinal cord injury.	**Inclusion criteria:** RCTs, patients with spinal cord injury aged 18 to 75 **Exclusion criteria:** Neurologic conditions other than spinal cord injury; no neurologic gait disorder; studies where the intervention was a robotic end-effector device; studies measuring only upper extremity outcomes; and studies measuring only physiologic or metabolic outcomes	**Intervention:** Assistance or rehabilitation with a wearable exoskeleton of the lower extremity **Comparator:** Conservative physiotherapy or powered gait orthosis	**Primary outcomes:** Gait outcomes, functional improvements **Secondary outcomes:** Neurologic improvement, motor strength, bladder and bowl function, spasticity, requirement of walking aid, safety

EMBASE = Excerpta Medica database; MEDLINE = Medical Literature Analysis and Retrieval System Online; PubMED = Public MEDLINE; RCT = randomized controlled trial;

Appendix 3: Critical Appraisal of Included Publications

Table 3: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR 2[4]

Strengths	Limitations
Fisahn 2016[8]	
• Well described research questions and inclusion criteria • Comprehensive search strategy • Authors provided a list of excluded studies with reasons for their exclusions • No conflicts of interest with funding source	• No written protocol • Only includes RCTs; including non-randomized studies may have been appropriate given the lack of primary studies on certain topics • Unclear if study selection was performed in duplicate

RCT = randomized controlled trial;

Appendix 4: Additional References of Potential Interest

Emerging Technology Report

Wearable powered exoskeleton use after spinal cord injury. Plymouth Meeting (PA): ECRI Insitute; 2017: www.ecri.org. Accessed 2019 Aug 01.

Ongoing Clinical Trials

VA Office of Research and Development. NCT02658656: Powered exoskeletons in persons with SCI ((PEPSCI)). *ClinicalTrials.gov*. Bethesda (MD): U.S. National Library of Medicine; 2019: https://www.clinicaltrials.gov/ct2/show/NCT02658656. Accessed 2019 Aug 01.