CADTH Reference List

Motorized Walking Assistive Devices for Impaired Mobility

May 2023

Summary of Abstracts

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Cite As: *Motorized Walking Assistive Devices for Impaired Mobility*. (CADTH reference list: summary of abstracts). Ottawa: CADTH; 2023 May.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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Key Message

We found 3 randomized controlled trials and 5 nonrandomized studies about the clinical effectiveness of wearable motorized or robotic walking assistive devices for adults with impaired mobility.

Research Question

What is the clinical effectiveness of wearable motorized or robotic walking assistive devices for adults with impaired mobility?

Methods

Literature Search Methods

An information specialist conducted a literature search on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were motorized walking assistive devices and impaired mobility. CADTH-developed search filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, or indirect treatment comparisons, any types of clinical trials or observational studies. The search was completed on May 2, 2023, and limited to English-language documents published since January 1, 2018. Internet links were provided, where available.

Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. The Overall Summary of Findings was based on information available in the abstracts of selected publications.

Table 1: Selection Criteria

Criteria	Description
Population	Adults with impaired mobility
Intervention	Wearable motorized or robotic walking assistive devices
Comparator	Usual care (i.e., no use of wearable motorized or robotic walking assistive devices)
Outcomes	Clinical benefits (e.g., mobility, function, quality of life, patient satisfaction) and harms (e.g., adverse events)
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, nonrandomized studies

Results

Three randomized controlled trials[1-3] and 5 nonrandomized studies[4-8] were identified regarding the clinical effectiveness of wearable motorized or robotic walking assistive devices for adults with impaired mobility. No relevant health technology assessments or systematic reviews were identified.

Additional references of potential interest that did not meet the inclusion criteria are provided in Appendix 1.

Overall Summary of Findings

Three randomized controlled trials[1-3] and 5 nonrandomized studies[4-8] regarding the clinical effectiveness of wearable motorized or robotic walking assistive devices for adults with impaired mobility were identified.

One randomized controlled trial[1] found that there were no significant differences between patients training with the Hybrid Assistive Limb (HAL) and patients receiving conventional physical therapy, in the changes in Functional Independence Measure or Functional Ambulation Category motor subscores.[1] The study by Gryfe and associates[2] found that there were no significant differences in gait speed, balance, and quality of health outcomes related to Parkinson disease between patients who exercised with the bilateral exoskeleton and those who did not. A prospective cohort study on patients with advanced heart failure found that there were no significant differences in the rate of perceived exertion and dyspnea when patients trained with or without the exoskeleton Myosuit.[4] The study by Sanz- Morere and colleagues[6] found that walking improved after training with and without the exoskeleton. The study also found that when patients trained without the exoskeleton, they walked farther and increased their walking speed, although no comparison was made when patients trained with the exoskeleton.[6] When patients trained with the exoskeleton, the metabolic efficiency decreased.[6]

A randomized controlled trial conducted with patients with severe walking disability after having a stroke found that the Apathy Scale decreased for patients training with the HAL, while it increased for patients receiving conventional physical therapy.[1] A randomized controlled trial[2] with patients with Parkinson disease found that training with the exoskeleton yielded a significant improvement in cognitive and walking functions. Likewise, a randomized controlled trial[3] with patients receiving gait training after ischemic stroke found that the group receiving exoskeleton training demonstrated an improvement of more categories associated with functional status compared with the classic mediated gait training groups. Two nonrandomized studies[5,8] found that training with a robotic assistive device resulted in an improvement in mobility. The study by Russo and colleagues[5] found that in patients with multiple sclerosis, training with the exoskeleton resulted in a significant improvement in walking ability, walking speed, and balance. The Yoshikawa et al. study[8] found that walking speed and step length was greater in patients that trained with the HAL than in those who did not. In addition, a nonrandomized study with patients who had a stroke for the first time found that patients who trained with the HAL had higher Functional Independence Measure scores compared to those who underwent conventional physical therapy.[7]

There were no adverse events associated with the robotic assistive devices used for training.[1,4,8] The Gryfe et al. study with patients with Parkinson disease noted that no serious or unanticipated adverse events occurred.[2] Two nonrandomized studies[4,5] noted that patients were satisfied with the exoskeleton. A detailed summary of the identified studies can be found in Table 2.

Table 2: Summary of Included Clinical Effectiveness Studies

Study citation	Study design, population	Intervention and comparators	Relevant outcomes	Author's conclusions
Randomized controlled trials				
Yokota et al. (2023)[1]	**Study design**: single centre RCT **Population**: Patients with severe walking disability after having their first stroke **N** = 22	**Intervention**: Training with HAL **Comparator**: Conventional physical therapy	Primary outcomes: changes in motor subscores of Functional Independence Measure or Functional Ambulation Category at the end of the second assessment[a] from baseline, change in Apathy Scale, AEs	No significant differences in primary outcomes. At the second assessment, the Apathy Scale was decreasing in the HAL group, while increasing in the conventional physical group. No AE in the HAL group.
Gryfe et al. (2022)[2]	**Study design**: open-label, parallel pilot RCT **Population**: Adults with Parkinson disease **N** = 40	**Intervention**: Bilateral exoskeleton **Comparators**: Exercise with no exoskeleton and waitlist control	Primary end point-change in cognitive function (SCOPA-COG) and mood Secondary end points: change in gait speed, 6MWT, freezing of gait, balance, and Parkinson disease specific health and quality of life outcomes, AEs	A significant improvement in the memory and learning domain of the SCOPA-COG and 6MWT were observed for the group who exercised with the exoskeleton compared to those who did not exercise with the exoskeleton and the waitlist control group. No significant between-group differences in gait speed, freezing of gait, balance, and Parkinson disease specific health and quality of life outcomes. No serious or unanticipated AEs were observed.
Rojek et al. (2019)[3]	**Study design**: RCT **Population**: Patients who have had ischemic stroke **N** = 44	**Intervention**: Ekso GT exoskeleton-assisted gait training **Comparator**: classical rehabilitation	Balance (using a stabilometric platform), load distribution (the Barthel Index), functional status (Rivermead Mobility Index)	In the group that received the Ekso GT exoskeleton, balance improved. Both forms of rehabilitation resulted in significant changes in functional status. In the group that received exoskeleton gait training, improvement was observed in a larger number of categories, possibly having a greater impact on improving functional status.

Study citation	Study design, population	Intervention and comparators	Relevant outcomes	Author's conclusions
Nonrandomized studies				
Just et al. (2022)[4]	**Study design**: Prospective cohort study **Population**: Patients with advanced heart failure **N** = 20	**Intervention**: Rehabilitation exercise with the exoskeleton-type robot Myosuit **Comparator**: Rehabilitation exercise without the Myosuit	Vital signs, AEs, rates of perceived exertion and dyspnea, ability to perform activities of daily life, ability to perform 60-minute rehabilitation exercise unit, individual acceptability	Mobilization with the Myosuit was feasible with or without minor support. No AEs occurred. There were no significant differences in the rates of perceived exertion and dyspnea with or without the device. Patients were satisfied with training with the Myosuit.
Russo et al. (2021)[5]	**Study design**: Retrospective cohort study **Population**: Patients with multiple sclerosis **N** = 20	**Intervention**: Gait training with the Ekso-powered exoskeleton **Comparator**: Traditional gait training without Ekso	Changes in gait and balance, change in walking speed, perception of mental well-being, usability, acceptability	Both groups showed a significant improvement in the ability to walk and balance. The experimental group showed a significant improvement in walking speed, mobility, and perception of mental well-being. The experimental group showed good usability and acceptance of the device.
Sanz-Morere et al. (2021)[6]	**Study design**: Prospective cohort study **Population**: Patients who had a transfemoral amputation with different mobility levels **N** = 7	**Intervention**: Training with an exoskeleton **Comparator**: Training without an exoskeleton	Performance on the 6MWT, spatiotemporal gait parameters, metabolic efficiency	Walking performance improved after the training. When patients (those who walked at maximal or self-selected) trained without the exoskeleton, they walked farther and increased their walking speed during the 6MWT. In the group training with the exoskeleton, the metabolic efficiency reduced.
Yokota et al. (2019)[7]	**Study design**: Prospective cohort study **Population**: Patients with first-ever stroke who needed a walking aid and were able to start training 1 week after stroke onset **N** = 37	**Intervention**: Training with HAL **Comparator**: Conventional physical therapy	Functional Independence Measure	The Functional Independence Measure score was higher in the group who trained with the HAL compared to the conventional physical therapy group.

Study citation	Study design, population	Intervention and comparators	Relevant outcomes	Author's conclusions
Yoshikawa et al. (2018)[8]	**Study design**: Prospective cohort study **Population**: Patients who had undergone total knee arthroplasty for arthritis **N** = 9	**Intervention**: Training with HAL **Comparator**: Conventional training without HAL	Gait speed, step length, range of motion, muscle strength, and AEs	Patients training with HAL did not experience AEs. Walking speed and step length (for patients walking at the self-selected or maximum walking speed) were greater in the group training with HAL compared to the controls. The step length for the group walking at maximum speed was greater in the group training with HAL at 2, 4, and 8 weeks. Extension lag and knee pain was lower in the group training with HAL compared to the control group at 2 weeks. The muscle strength of knee extension was greater in the group training with HAL at 8 weeks.

6MWT = six-minute walk test; AE = adverse events; HAL = Hybrid Assistive Limb; RCT = randomized controlled trial; SCOPA-COG = Scales for Outcomes in Parkinson Disease-Cognition.

[a]Second assessment was conducted after the completion of 20 sessions of gait training.

References

Health Technology Assessments

No literature identified.

Systematic Reviews

No literature identified.

Randomized Controlled Trials

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Nonrandomized Studies

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Appendix 1: References of Potential Interest

Previous CADTH Reports

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Health Technology Assessment

Population Age Not Specified

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Systematic Reviews

Unclear Comparator

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Carmignano SM, Fundaro C, Bonaiuti D, et al. Robot-assisted gait training in patients with Parkinson's disease: implications for clinical practice. A systematic review. *NeuroRehabilitation*. 2022;51(4):649-663. PubMed

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Population Age Not Specified

Hsu TH, Tsai CL, Chi JY, Hsu CY, Lin YN. Effect of wearable exoskeleton on post-stroke gait: a systematic review and meta-analysis. *Ann Phys Rehabil Med*. Feb 2023; 66(1):101674. PubMed

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Mixed Population — Children and Adults with Impaired Mobility

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Mixed Intervention

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Randomized Controlled Trials

Alternative Comparators

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Mixed Intervention

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Mixed Population — Children and Adults With Impaired Mobility

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Alternative Outcomes — Physiological Response During Robot-Assisted Gait Training

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Nonrandomized Studies

Mixed Intervention — Robot-assisted Gait Training With Inpatient Therapy

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Population Age Not Specified

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