TITLE: Upper and Lower Extremity Robotic Therapy and Assistive Devices for Pediatric Patients with Complex Developmental Disabilities, Brain Injury, or Complex Pain Disorders: Clinical Effectiveness, Cost-Effectiveness, and Guidelines

DATE: 18 June 2015

RESEARCH QUESTIONS

1. What is the clinical effectiveness of upper or lower extremity robot-assisted therapy and robotic assistive devices in pediatric patients with complex developmental disabilities, brain injury, or complex pain disorders?

2. What is the cost-effectiveness of upper or lower extremity robot-assisted therapy and robotic assistive devices in pediatric patients with complex developmental disabilities, brain injury, or complex pain disorders?

3. What are the evidence-based guidelines regarding the use of upper and lower extremity robot-assisted therapy and robotic assistive devices in pediatric patients?

KEY FINDINGS

One systematic review, two randomized controlled trials, five non-randomized studies, and one evidence-based guideline were identified regarding the use of upper or lower extremity robot-assisted therapy and robotic assistive devices in pediatric patients with complex developmental disabilities, brain injury, or complex pain disorders.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2010 and June 8, 2015. Internet links were provided, where available.
The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

**SELECTION CRITERIA**

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

**Table 1: Selection Criteria**

| Population | Q1 and 2: Pediatric patients (0 to 18 years) with complex developmental disabilities, brain injury (acquired and traumatic), neurodegenerative and neuromuscular disorders, or complex pain disorders  
Q3: Pediatric patients (0 to 18 years) |
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<td>Intervention</td>
<td>Upper extremity robot assisted therapy (e.g., Amadeo by Tyrostation) and assistive devices (e.g., Jaco robotic arm by Kinova); Lower extremity robot assisted therapy and assistive devices (e.g., Ekso bionics)</td>
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| Comparator | Q1 and 2: Any alternate robotic assistive or therapy device; Usual care; No comparator  
Q3: No comparator |
| Outcomes | Q1: Clinical effectiveness (e.g., improvements in rehabilitation measures: gait or posture, walk tests, arm tests, balance scales, FIM, fatigue indexes); Adverse events (e.g., worsening of condition, device-related discomfort, skin irritation, training related pain)  
Q2: Cost-effectiveness outcomes  
Q3: Evidence-based guidelines regarding the use of robotic assistive or therapy devices in pediatric populations |
| Study Designs | Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations, evidence-based guidelines |

FIM = functional independence measure.

**RESULTS**

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

One systematic review, two randomized controlled trials, five non-randomized studies, and one evidence-based guideline were identified regarding the use of upper or lower extremity robot-assisted therapy and robotic assistive devices in pediatric patients with complex developmental disabilities, brain injury, or complex pain disorders. No relevant health technology assessments or economic evaluations were identified.

Additional references of potential interest are provided in the appendix.
OVERALL SUMMARY OF FINDINGS

One systematic review\(^1\) of mainly case studies reported that overall, robotic therapy had positive effects on upper limb function and clinical assessment scores in children with cerebral palsy (CP). However, the authors noted a paucity of rigorously designed studies and called for further research.

Two randomized controlled trials (RCTs) evaluated the impact of robot-assisted therapy on upper limb function\(^2\) or gait\(^3\) in children with CP. One RCT\(^2\) compared robot-assisted therapy in addition to conventional therapy sessions with conventional therapy sessions alone. The results showed that children in the robotic group demonstrated significantly greater improvements in upper limb smoothness of movement and manual dexterity than those in the conventional therapy group.\(^2\) The other RCT\(^3\) studied the effect of the Lokomat active orthosis plus a program of individual exercises compared with exercise alone. This study reported improved walking speed and a slightly decreased range of motion with both treatments, with no statistically significant differences between groups. A significantly increased range of hip flexion was reported.\(^3\) The authors of both studies concluded that further research on robot-assisted therapy in children with CP is required.\(^2,3\)

One non-randomized study\(^4\) examined robotic-aided gait training plus physical therapy versus physical therapy alone in children and adolescents with an acquired brain injury. The robotic group demonstrated significant improvements compared with the control group on the Gross Motor Functions Measure (GMFM), the 6-Minute Walk Test, gait analysis measures (i.e., stride cadence, length, and velocity), and hip range of motion.\(^4\)

Three non-randomized studies\(^5,6,8\) evaluated robot-assisted rehabilitation therapy for ankle impairments in children with CP. After treatment, patients showed significant improvements in range of motion,\(^5,6,8\) muscle strength,\(^5,6,8\) balance,\(^5,6,8\) selective control assessment,\(^5,6,8\) spasticity,\(^5,6,8\) and performance on the 6-Minute Walk Test.\(^6,8\) However, no improvements on the GMFM were observed in one study.\(^6\) The results from this study of a clinic patient sample were comparable to a previously published research cohort, with the exception of larger Selective Control Assessment of the Lower Extremity test changes reported in the research cohort.\(^6\)

One non-randomized study\(^7\) examined the effectiveness of robot-guided repetitive motion training for improvement of handwriting in children with impaired motor skills. While fine motor control improved in some patients, no improvement was observed for children with CP.\(^7\)

One evidence-based guideline\(^9\) on intensive partial body weight supported treadmill training for children with neurological disorders recommends that the decision to use robotic-assisted therapy should be based on clinical judgement, child and family preferences, and the child’s motor control and functional abilities. The guideline also offers precautions regarding the use of robotic-assisted therapy devices in children with comorbidities or other contraindications.

No evidence was identified regarding the cost-effectiveness of upper or lower extremity robot-assisted therapy and robotic assistive devices in pediatric patients; therefore, no summary could be provided.
REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses

Randomized Controlled Trials


Non-Randomized Studies


Economic Evaluations
No literature identified.

Guidelines and Recommendations

See: Major Recommendations 6
Precautions

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APPENDIX – FURTHER INFORMATION:

Systematic Reviews and Meta-analyses – Unclear Population

PubMed: PM23517734

Review Articles


PubMed: PM23948688

PubMed: PM23080043

PubMed: PM22938883

Additional References

Note: includes discussion of Ekso GT from Ekso bionics for an adult population