Methodological Quality of Motor Intervention Randomized Controlled Trials in Stroke Rehabilitation

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Purpose: The objective of the study was to evaluate the methodological quality of motor intervention randomized controlled trials (RCTs) published in the stroke rehabilitation literature and to examine trends in quality over time. *Methods:* A systematic literature search was conducted for all English articles (published up to December 2013) examining rehabilitation for motor recovery poststroke. All RCTs with a human sample, of which at least 50% had a stroke, were included in the analysis. A Physiotherapy Evidence Database (PEDro) score was assigned to assess methodological quality. A one-way analysis of variance was conducted to examine adherence to quality items overall and over time, with post hoc *t*-tests performed where appropriate. *Results:* Six hundred seventy-six RCTs met inclusion criteria, of which 32.0% had excellent, 42.0% good, 23.1% fair, and 3.0% poor methodological qualities. The overall mean PEDro score was 6.6 ± 1.6; with scores improving significantly between 1979-1983 and 2009-2013 (5.0 ± 1.4 versus 7.0 ± 1.5; $P = .0003$); however, no significant improvements in individual items were found ($P > .05$). *Conclusions:* This study showed improvements in the total methodological quality of motor intervention RCTs in stroke rehabilitation over time. However, no relationship was found between individual quality items and improvement over time. **Key Words:** Stroke—randomized controlled trial—rehabilitation—motor—intervention—therapy.

Introduction

After a stroke, individuals often incur an array of physical and cognitive impairments that respond best to a variety of rehabilitation interventions. A recent study conducted by McIntyre et al[1] found that the number of randomized controlled trials (RCTs) in the stroke rehabilitation literature has grown significantly between 1970 and 2012 to a total of 1063. Although RCTs are considered the standard criterion in medical interventional research, not all RCTs are performed equally; it is important to consider methodological quality when interpreting findings.

Similar to the assessment of methodological quality for systematic reviews and meta-analysis, consideration of study quality is equally as important for primary research articles to limit bias when interpreting findings. For example, Moher et al[2] found that the effectiveness of an intervention was reportedly greater in low-quality trials. Numerous quality assessment tools have been used with varying medical populations and published in scientific

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literature. Existing tools include A Measurement Tool to Assess Systematic Reviews,[3] used to assess systematic reviews, and the Downs and Black scale,[4] for assessing non-RCTs. A systematic review by Olivo et al[5] identified 21 scales used to evaluate the quality of RCTs in healthcare research. One such scale, the Physiotherapy Evidence Database (PEDro)[6] tool, was produced by the Centre for Evidence-Based Physiotherapy in Australia and was based on the Delphi list generated by Verhagen et al.[7] The PEDro scale provides a score (i.e., yes = 1, no = 0) on 11 quality items (Table 1). The first quality item measures external validity, which is not congruent with the remaining quality dimensions of the scale; thus, this item does not contribute to the overall score out of 10. The scale has demonstrated both good reliability[8] and validity.[9] The PEDro database was launched online in 1999, with the purpose of making bibliographic details and abstracts of RCTs, systematic reviews, and evidence-based clinical practice guidelines in physiotherapy easily accessible, in a timely fashion.[6] As of January 6, 2014, the database contained 26,420 reports, of which 21,406 were RCTs, 4529 were systematic reviews and 485 were evidence-based clinical practice guidelines.[10] Currently, the PEDro tool is one of the most widely utilized tools to assess the methodological quality of RCTs in multiple areas of stroke rehabilitation.

Using the PEDro tool, McIntyre et al[1] reported that the total methodological quality of all RCTs in stroke rehabilitation had improved over time; however, the specific methodological strengths and weaknesses of these studies remained unknown as a subanalysis of individual PEDro items was not performed. Furthermore, the authors noted that there were differences in the quality of RCTs based on the type of intervention provided. Motor impairments tend to be the most obvious and common complication poststroke; as such, McIntyre et al[1] found that the majority of RCTs published in stroke rehabilitation examined motor outcomes as a primary focus (58.8%). As the PEDro scale was devised to assess interventions aimed at motor recovery, an evaluation of methodological quality of only motor RCTs in stroke rehabilitation would be most appropriate. Therefore, this study had 3 objectives: (1) to evaluate methodological quality, using individual PEDro items, of all motor intervention RCTs published in the stroke rehabilitation literature; (2) to compare methodological quality by intervention type; and (3) to determine how methodological quality has changed over time. The information gleaned from this study will be critical in informing the development of methodologically rigorous stroke rehabilitation RCTs in the future.

Table 1. *Number of RCTs by intervention with corresponding mean PEDro scores (SD)*

Intervention	Number of studies (%)	Mean PEDro score ± SD
Upper extremity	275 (100)	6.0 ± 1.6
Constraint induced movement therapy	42 (15.3)	5.6 ± 1.5
Functional electrical stimulation	39 (14.2)	5.1 ± 1.4
Botulinum toxin	24 (8.7)	7.3 ± 1.5
Bilateral arm training	16 (5.8)	6.0 ± 1.2
Sensorimotor training/ somatosensory stimulation	16 (5.8)	6.6 ± 1.5
Mental practice	12 (4.4)	5.5 ± 1.4
Virtual reality	11 (4.0)	5.7 ± 1.3
Electromyography/ biofeedback	10 (3.6)	5.3 ± 1.5
Miscellaneous	105 (38.1)	6.1 ± 1.5
Hemiplegic shoulder	40 (100)	6.0 ± 1.7
Electrical stimulation	9 (22.5)	4.7 ± 1.4
Botulinum toxin	5 (12.5)	7.6 ± 1.5
Steroids/corticosteroids/ nerve block	11 (27.5)	6.5 ± 1.9
Strapping, positioning, slings, active therapy	12 (30.0)	6.0 ± 1.2
Complementary and alternative medicine	3 (7.5)	5.7 ± .6
Lower extremity	361 (100)	6.2 ± 1.5
Balance	46 (12.7)	5.5 ± 1.5
Functional electrical stimulation	25 (6.9)	5.8 ± 1.4
Acupuncture	24 (6.6)	5.8 ± 1.8
Repetitive transcranial magnetic stimulation	20 (5.5)	6.6 ± 1.0
Partial body weight support	18 (5.0)	6.4 ± 1.3
Cardiovascular conditioning/aerobic exercise	17 (4.7)	6.1 ± 1.5
Feedback	17 (4.7)	4.7 ± 1.5
Robotic devices with electrical stimulation	16 (4.4)	5.8 ± 1.1
Repetitive task training	15 (4.2)	6.3 ± 1.2
Strength training	14 (3.9)	6.2 ± 1.5
Therapy intensity	12 (3.3)	6.8 ± 1.5
Electrical stimulation	10 (2.8)	6.6 ± 1.5
Virtual reality	10 (2.8)	5.6 ± 1.5
Miscellaneous	117 (32.4)	6.2 ± 1.5

Abbreviations: PEDro, Physiotherapy Evidence Database; RCT, randomized controlled trial; SD, standard deviation.

Methods

Literature Search Strategy

To identify all appropriate studies, a literature search was performed using multiple research databases including MEDLINE, Scopus, EMBASE, Mantis, Pascal, SciSearch, and the Cochrane Library. Given the extensive number of motor interventions and outcomes that exist in stroke rehabilitation, a comprehensive list of key search terms was compiled by reviewing 3 relevant chapters of the Evidenced-Based Review of Stroke Rehabilitation (16th edition) that were motor related (e.g., upper limb, lower