Neurol Sci (2010) 31:159–163
DOI 10.1007/s10072-009-0198-4

ORIGINAL ARTICLE

Reported quality of randomized controlled trials in neglect rehabilitation

Matteo Paci · Giovanni Matulli · Marco Baccini · Lucio A. Rinaldi · Stefano Baldassi

Received: 26 August 2008 / Accepted: 10 November 2009 / Published online: 10 December 2009

Abstract The aim of this study is to assess the reported quality of randomized controlled trials (RCTs) on the effectiveness of neglect rehabilitation using a standardized scale. A search of seven electronic databases was carried out. Selected articles were scored using the PEDro scale and classified as high or low quality study both with the original cut off of 6 and a modified cut off of 5. A linear regression analysis between year of publication and quality rate was used to test whether the quality of the studies improved with time. A total of 18 RCTs were selected. Six articles (33.3%) and 10 articles (55.56%) were classified as having high quality when the original cut off or the modified cut off of the PEDro scale were used, respectively. Analysis shows no time-related changes in PEDro scores. The results show that reported quality is moderate for RCTs in neglect rehabilitation.

Keywords Evidence-based medicine · Randomized controlled trials · Attentional deficits · Hemispatial neglect · Rehabilitation

M. Paci
Department of Rehabilitation Medicine,
Casa di Cura Villa Fiorita, Prato Hospital, Prato, Italy

M. Paci (✉)
Matteo Paci, Via G. Banti, 20/E, 50139 Florence, Italy
e-mail: matteo.paci@applicazione.it

G. Matulli
Centro di Riabilitazione Sestese,
Sesto Fiorentino (Florence), Italy

M. Baccini
Unit of Geriatric Rehabilitation, ASL 10, Florence, Italy

M. Baccini
Fondazione "F. Turati", Rehabilitation Centre,
Gavinana (Pistoia), Italy

L. A. Rinaldi
Motion Analysis and Neurorehabilitation Laboratory,
Department of Critical Care Medicine and Surgery,
Unit of Gerontology and Geriatric Medicine,
University of Florence, Florence, Italy

S. Baldassi
Department of Psychology, University of Florence,
Florence, Italy

Introduction

Unilateral neglect is a common consequence of right-hemisphere stroke. It is well recognized that the disorder is heterogeneous, has numerous subtypes [1, 2], and is a negative factor influencing functional outcome [3].

A number of approaches to rehabilitation have been suggested, including visual and movement imagery, and manipulation of sensory or visual input [2]. However, early reports on the effectiveness of rehabilitation techniques were based mainly on single case experimental designs rather than randomised controlled trials (RCTs) [4] that are traditionally considered the gold standard for judging the benefits of treatments. A recent Cochrane Review [5], including 12 RCTs, concluded that there is insufficient evidence to support or refute the effectiveness of rehabilitation intervention for reducing disability and improving independence. Moreover, the authors pointed out that most studies on neglect rehabilitation are classifiable as low-quality studies. In this review, the selected RCTs were classified, in terms of methodological quality, on the basis of one criterion alone, i.e., adequate allocation concealment. However, the quality of RCT depends on many important methodological features, in addition to allocation

concealment, such as randomisation methods, blinding, and intention-to-treat analysis. To evaluate the methodological reported quality of RCTs, a number of validated tools have been developed, which allow for these important features.

Despite a larger attention to quality in the last years, these fundamental factors are commonly underreported in RCTs [6]. The first aim of this study was to assess the reported quality of RCTs on the effectiveness of neglect rehabilitation using a standardized scale. Secondly, we tested the hypothesis that the quality of trials increased over time.

Methods

Search strategy

A search of the following databases was carried out in January, 2008: Medline (PubMed); Cochrane Collaboration's register of trials; EMBASE; CINAHL; PsycINFO; PEDro (Physiotherapy Evidence Database) and Database of Abstracts of Reviews of Effectiveness (DARE).

Combinations of the following keywords were used for all the above databases: (cerebrovascular disorders OR stroke) AND (attention OR inattention OR hemi-inattention) AND perceptual disorders AND (hemineglect OR hemi-neglect) AND (neglect OR unilateral neglect). Where possible, the search was limited to "randomised controlled trials". References listed were also examined for additional trials.

All articles were collected and selected with the following inclusion criteria: (a) to be a RCT aimed at comparing the effectiveness of neglect rehabilitation in adult persons who had a stroke; (b) to be a full paper in English or Italian language.

Assessment of methodological quality

To evaluate the quality of methods of each RCT, the Physiotherapy Evidence Database (PEDro) scale with cut off at 6 was used [7]. The PEDro scale [8] was developed specifically to be used for studies aimed at comparing the effectiveness of rehabilitation interventions. A recent review on this topic concluded that it is one of the preferred tools to be used for studies on stroke rehabilitation [9].

This scale, derived from the Delphi list, rates 11 aspects of methodological quality of RCTs as being either absent or present (Table 1). Because the first item (eligibility criteria) is not scored, the total score ranges from 10 (RCT that satisfies all points) to 0 (RCT that does not satisfy anyone). The PEDro scale permits to classify high or low quality papers based on a cut off score: articles that obtain a score of fewer than six points are considered to be low quality studies, while articles with a score equal to or exceeding six points are considered to be high quality ones [10]. Considering that it is almost impossible to blind therapists or subjects in physical therapy or neuropsychological rehabilitation trials, we also use the cut off of 5 suggested by Maher [29]. The PEDro Scale has been shown to be sufficiently reliable with respect to total score for use in systematic reviews of physiotherapy RCTs [10]. There is evidence for discriminative validity for three of the scale items: randomisation, concealed allocation, and blinding [9]. The other items are reported to have face validity and content validity [9].

Table 1 PEDro scale items

1. Eligibility criteria
2. Random allocation
3. Concealed allocation
4. Baseline comparability
5. Blind subjects
6. Blind therapists
7. Blind assessors
8. Adequate follow-up
9. Intention-to-treat analysis
10. Between-group comparisons
11. Point estimates and variability

When trials were rated in the PEDro database, the database score was used. Otherwise, trials were independently evaluated by two reviewers (MB and MP). Differences in opinion regarding trial eligibility or quality were resolved by consensus.

Statistical analysis

A linear regression analysis between year of publication and quality rate was used to test whether the quality of the studies has improved with time. Data were analyzed using SPSS 12.0 software for Windows.

Results

A total of 18 RCTs were selected [11–28]. All articles were indexed and scored in PEDro database, with the exception of studies by Zeloni et al. [26] and Cherney et al. [27]. Six articles (33.3%) and 10 articles (55.56%) were classified as having high quality when the original cut off or the modified cut off of the PEDro scale were used, respectively (Table 2). The mean total score was 4.56 ± 1.54, with a range from 2 to 7. In addition to random allocation (100%), the more frequent satisfied criteria were between-group statistical comparisons (88.9%), baseline comparability (72.2%) and adequate follow-up (61.1%). No article met

Table 2 PEDro scale scores for each study

Reference	Eligibility	1	2	3	4	5	6	7	8	9	10	Score	Quality
Weinberg et al. [11]	1	1	0	1	0	0	1	0	0	1	1	5/10	Low
Weinberg et al. [13]	1	1	0	1	0	0	1	0	0	0	1	4/10	Low
Weinberg et al. [12]	1	1	0	1	0	0	1	1	0	1	0	5/10	Low
Hommel et al. [15]	0	1	0	0	0	0	1	1	0	1	0	4/10	Low
Rossi et al. [16]	1	1	0	1	0	0	0	0	0	1	1	4/10	Low
Robertson et al. [17]	1	1	0	1	0	0	1	1	0	1	1	6/10	High
Cubelli et al. [18]	1	1	0	1	0	0	0	1	0	1	1	5/10	Low
Antonucci et al. [19]	1	1	0	0	0	0	0	0	0	1	1	3/10	Low
Lincoln [4]	1	1	0	1	0	0	1	0	0	1	1	5/10	Low
Fanthome et al. [20]	1	1	0	1	0	0	1	1	0	1	1	6/10	High
Wiart et al. [21]	1	1	0	1	0	0	0	1	1	1	1	6/10	High
Kalra et al. [22]	0	1	0	1	0	0	1	1	1	1	0	6/10	High
Beis et al. [23]	0	1	0	0	0	0	0	0	0	1	0	2/10	Low
Edmans et al. [24]	1	1	1	1	0	0	1	1	0	1	1	7/10	High
Rusconi et al. [25]	0	1	0	0	0	0	0	0	0	1	0	2/10	Low
Zeloni et al. [26]	1	1	0	1	0	0	0	1	0	1	0	4/10	Low
Cherney et al. [27]	1	1	0	0	0	0	0	1	0	0	0	2/10	Low
Fong et al. [28]	1	1	0	1	0	0	1	1	0	1	1	6/10	High
Total	14	18	1	13	0	0	10	11	2	16	11		

blind subjects and blind therapists criteria, while only 5.6% and 11.1% satisfied concealed allocation and intention-to-treat analysis criteria, respectively. Moreover, 77.8% of trials used eligibility criteria. The linear regression analysis shows no time-related changes in PEDro scores ($R^2 = -0.049$, $P = 0.655$). In fact, as shown in Fig. 1, as time goes on, there is an increase in the variability of PEDro scores.

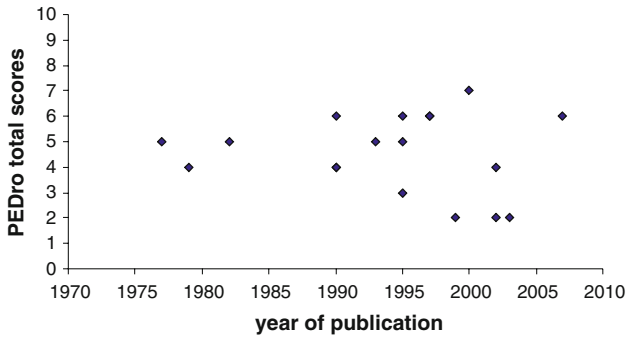

Fig. 1 Distribution of PEDro scores of selected articles over time

Discussion

The first aim of this study was to assess the reported quality of RCTs in neglect rehabilitation. The results show that reported quality of the published RCTs is moderate, when the original cut off was used. However, two criteria from PEDro scale (blind subjects and therapists) are very difficult, or even impossible, to achieve in rehabilitation settings, and particularly in neglect rehabilitation. In fact, none of the RCTs included satisfied these criteria. This may be the main reason why the highest score was 7/10. The other two less frequently satisfied criteria were concealed allocation and intention-to-treat analysis, in accordance with a previous study conducted on five leading general medicine journals [6].

Considering that it is almost impossible to blind therapists or subjects in physical therapy trials, Maher [29] proposed reducing the PEDro cut off from the original strict cut off of 6 to a less strict cut off of 5 (or even 4). This is also true in neuropsychological rehabilitation. Then, in the present study both the original cut off and the modified cut off of 5 were used. The original cut off of the scale was used because the PEDro scale is specifically designed for physiotherapy interventions and we can assume that these limitations were considered in the developmental process of the scale. However, we also accept the proposal by Maher [29], because it seems to be more appropriate for neuropsychological interventions. Removing the items 6 and 7 (blind subjects and blind therapists, respectively), the scale have a total score of 8. We choose the cut off score of 5, instead of 4, because, as for the original cut off, it represent the middle of the modified scale plus 1. Using this cut off score, the reported

quality of RCTs on neglect rehabilitation results much better overall.

Although the use of a less strict cut off seems to be more appropriate for neuropsychological interventions, results suggest that trials on neglect rehabilitation show on average a moderate methodological quality.

It is noteworthy that the reported quality may differ from the true methodological quality, because trial reports frequently omit important methodological details, as Huwiler-Muntener et al. [6] demonstrated. Therefore, the true methodological quality of trials may be misjudged when considering only the reported quality. However, reported trial quality is generally the only available information for considering the published results from individual trials and for the conduct of unbiased systematic reviews.

The second aim of this article was to investigate changes in the reported quality over time. An improvement in among years was expected. However, no improvements over time were found. Indeed, the three studies [23, 25, 27] with the lowest PEDro total score (=2) were all published in the last decade. However, no high quality study was published before 1990, and 5/6 high quality studies were published in 1995 or later. The lack of significant time-related changes in PEDro scores as regards reported quality of published papers on neglect rehabilitation is due to an increase of the variability in PEDro scores. In fact, in more recent years, along with high quality studies, more studies with very low PEDro scores were published. These results demonstrate the need to pay more attention on that reporting quality because, sometimes, it continues to be low in recent years.

In this study, a standardized scale was used to assess RCTs reporting quality. The PEDro scale is considered the most useful tool to assess the RCTs in stroke rehabilitation [9, 30], it is easy to interpret, because it reports the number of satisfied criteria, and it has guidelines for scoring criteria. However, none of the scale items had perfect reliability for the consensus ratings displayed on the PEDro database. Then, the use of the default PEDro scores may contain some error, since the standard error of the measurement for total scores is 0.70 units, and this should be considered when distinguishing between low- and high-quality RCTs [10].

This limit must be taken into consideration particularly in this study, since 50% of trials have total scores of 5/10 or 6/10 (i.e., near the original cut off score), and more than 40% have total score near the modified cut off score.

Further RCTs should improve the methodological and/or reported quality in terms of concealed allocation and intention-to-treat analysis overall. In fact, in several trials, it is not expressly stated that allocation was concealed, and probably this item shares in decrease reported quality. Moreover, as previously discussed by Bowen and Lincoln [5], included trials do not report adequately information about the acceptability of rehabilitation to patients. High drop out should be considered an important measure of effectiveness and an indicator of methodological quality of the trial.

In conclusion, continued efforts are required to improve methodological quality and, especially, reported quality of RCTs in neglect rehabilitation.

References

1. Swan L (2001) Unilateral spatial neglect. Phys Ther 81:1572–1580
2. Pierce SR, Buxbaum LJ (2002) Treatments of unilateral neglect: a review. Arch Phys Med Rehabil 83:256–268
3. Cherney LR, Halper AS, Kwasnica CM et al (2001) Recovery of functional status after right hemisphere stroke: relationship with unilateral neglect. Arch Phys Med Rehabil 82:322–328
4. Lincoln NB (1995) The assessment and treatment of disorders of visual perception. Rev Clin Gerontol 5:77–82
5. Bowen A, Lincoln NB (2007) Cognitive rehabilitation for spatial neglect following stroke. Cochrane Database Syst Rev (2):CD003586. doi:10.1002/14651858.CD003586.pub2
6. Huwiler-Müntener K, Jüni P et al (2002) Quality of reporting of randomized trials as a measure of methodologic quality. JAMA 287:2801–2804
7. Moseley AM, Herbert RD, Sherrington C et al (2002) Evidence for physiotherapy practice: a survey of the Physiotherapy Evidence Database (PEDro). Aust J Physiother 48:43–49
8. Sherrington C, Herbert RD, Maher CG et al (2000) PEDro: a database of randomised trials and systematic reviews in physiotherapy. Man Ther 5:223–226
9. Armijo Olivo S, Macedo LG, Gadotti EG et al (2008) Scales to assess the quality of randomized controlled trials: a systematic review. Phys Ther 88:156–175
10. Maher G, Sherrington C, Herbert R et al (2003) Reliability of the PEDro scale for rating quality of randomized controlled trials. Phys Ther 83:713–721
11. Weinberg J, Diller L, Gordon W et al (1977) Visual scanning training effect on reading-related tasks in acquired right brain damage. Arch Phys Med Rehabil 58:479–486
12. Weinberg J, Piasetsky E, Diller L et al (1982) Treating perceptual organization deficits in non neglecting RBD stroke patients. J Clin Neuropsychol 4:59–75
13. Weinberg J, Diller L, Gordon WA et al (1979) Training sensory awareness and spatial organization in people with right brain damage. Arch Phys Med Rehabil 60:491–496
14. Lincoln NB, Whiting SE, Cockburn J et al (1985) An evaluation of perceptual retraining. Int Rehabil Med 7:99–101
15. Hommel M, Peres B, Pollak P et al (1990) Effects of passive tactile and auditory stimuli on left visual neglect. Arch Neurol 47:573–576
16. Rossi PW, Kheyfets S, Reding MJ (1990) Fresnel prisms improve visual perception in stroke patients with homonymous hemianopia or unilateral visual neglect. Neurology 40:1597–1599
17. Robertson IH, Gray JM, Pentland B et al (1990) Microcomputer-based rehabilitation for unilateral left visual neglect: a randomized controlled trial. Arch Phys Med Rehabil 71:663–668
18. Cubelli R, Inzaghi G, de Tanti A (1993) La rieducazione della negligenza spaziale unilaterale: verifica sperimentale della sua efficacia [Italian]. Eura Medicophys 29:111–121

19. Antonucci G, Guariglia C, Judica A et al (1995) Effectiveness of neglect rehabilitation in a randomized group study. J Clin Exp Neuropsychol 17:383–389
20. Fanthome Y, Lincoln NB, Drummond A et al (1995) The treatment of visual neglect using feedback of eye movements: a pilot study. Disabil Rehabil 17:413–417
21. Wiart L, Come AB, Debelleix et al (1997) Unilateral neglect syndrome rehabilitation by trunk rotation and scanning training. Arch Phys Med Rehabil 78:424–429
22. Kalra L, Perez I, Gupta S et al (1997) The influence of visual neglect on stroke rehabilitation. Stroke 28:1386–1391
23. Beis JM, Andre JM, Baumgarten A et al (1999) Eye patching in unilateral spatial neglect: efficacy of two methods. Arch Phys Med Rehabil 80:71–76
24. Edmans JA, Webster J, Lincoln NB (2000) A comparison of two approaches in the treatment of perceptual problems after stroke. Clin Rehabil 14:230–243
25. Rusconi ML, Meinecke C, Sbrissa P et al (2002) Different cognitive trainings in the rehabilitation of visuo-spatial neglect. Eura Medicophys 38:159–166
26. Zeloni G, Farne A, Baccini M (2002) Viewing less to see better. J Neurol Neurosurg Psychiatry 73:195–198
27. Cherney LR, Halper AS, Papachronis D (2003) Two approaches to treating unilateral neglect after right hemisphere stroke: a preliminary investigation. Top Stroke Rehabil 9:22–33
28. Fong KN, Chan MK et al (2007) The effect of voluntary trunk rotation and half-field eye-patching for patients with unilateral neglect in stroke: a randomized controlled trial. Clin Rehabil 21:729–741
29. Maher CG (2000) A systematic review of workplace interventions to prevent low back pain. Aust J Physiother 46:259–269
30. Bhogal SK, Teasell RW, Foley NC et al (2005) The PEDro scale provides a more comprehensive measure of methodological quality than the Jadad scale in stroke rehabilitation literature. J Clin Epidemiol 58:668–673