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Reported quality of randomized controlled trials of physiotherapy interventions has improved over time

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Abstract

Objective: To describe the change with time of the reported methodological quality of randomized controlled trials of physiotherapy interventions.

Study Design and Setting: For all trials of physiotherapy interventions indexed on the Physiotherapy Evidence Database (PEDro), year of publication, and methodological quality scores (11-item PEDro scale and total PEDro score [range, 0−10]) were extracted. The relationship between trial quality and time was evaluated using regression analyses for the PEDro total score and individual quality items. The study was carried out in a university research center.

Results: Data from 10,025 trials published since 1960 were analyzed. The total PEDro score was related to time (year of publication), with the total score increasing by an average of ~0.6 points each decade between 1960 and 2009. The reported use of eight of the 11 individual items from the PEDro scale (intention-to-treat analysis, concealed allocation, groups similar at baseline, reporting of results of between-group statistical comparisons, point measures and measures of variability reported, subjects randomly allocated to groups, eligibility criteria specified, and blinding of assessors) also improved with time.

Conclusion: The reported methodological quality of randomized controlled trials of physiotherapy interventions has improved over time. Further improvement is still necessary.

Keywords: Randomized controlled trials as a topic; Physical therapy (specialty); Research methodology; Quality ratings; Regression analysis; Time factors

1. Introduction

The first randomized controlled trials of physiotherapy interventions were published around 1930 [1,2]. Since then, growth in the number of randomized controlled trials of physiotherapy interventions has been exponential [3,4] and by September 2007, there were over 9,000 trials of physiotherapy interventions published in peer-reviewed journals [4]. Like other areas of health care, the methodological quality of randomized controlled trials in physiotherapy is variable, with 52% of trials being of nominally moderate to high quality [3].

During this period of rapid growth in randomized controlled trials of physiotherapy interventions, there has also been an increased awareness of evidence-based practice, advances in the training of physiotherapists, and advances in the design and reporting of clinical trials. Contemporary physiotherapy aims to combine the best available research evidence with patient preferences and clinical experience to guide clinical practice [5]. This shift to evidence-based practice includes developing knowledge and skills to critically appraise reports of research [5]. Physiotherapy entry-level training has changed from diploma vocational courses to university-based baccalaureate and postbaccalaureate degrees [6,7], with a growing number of physiotherapists undertaking formal postgraduate research training [8]. The importance of several trial design features has been identified and quantified, including random allocation to groups [9], concealed allocation [9,10], blinding of subjects, therapists and assessors [10], and intention-to-treat analysis [11]. The importance of reporting these key methodological features in reports of randomized controlled trials was emphasized with the development of the Consolidated Standards of Reporting Trials (CONSORT) Statement [12]. Given these advances in the conduct and reporting of clinical trials, training of physiotherapists, and an evidence-based approach to treatment, one would anticipate that the quality of randomized controlled trials would have improved with time.

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What is new?

Key finding
The reported quality of randomized controlled trials of physiotherapy interventions has improved over time.

What this adds to what was known?
Because of limitations in the samples and analysis methods of previous studies, trends in the quality of randomized controlled trials in physiotherapy were previously unclear. This study clearly identifies improvements in overall quality and individual quality items in randomized controlled trials in physiotherapy, including intention-to-treat analysis, concealed allocation, groups similar at baseline, reporting of results of between-group statistical comparisons, point measures and measures of variability reported, subjects randomly allocated to groups, eligibility criteria specified, and blinding of assessors.

What is the implication, what should change now?
There is scope for further improvement in the conduct and reporting of randomized trials in physiotherapy. Studies of the literature in a scientific discipline need to be based on large representative samples of that literature.

Preliminary analyses suggest that there may have been an increase in the reported methodological quality of randomized controlled trials of physiotherapy interventions [3,4], with the average quality score for reports of trials published from 1929 to 1979 being 3.6 of 10 (standard deviation [SD], 1.5) compared with an average score of 5.4 of 10 (SD, 1.6) for reports published from 2005 to 2007 [4].

Two recent investigations concluded that there was little change in the quality of randomized controlled trials in physiotherapy with time [13,14]. A systematic review of the trends in methodological quality [14] based its conclusion on two reviews of 89 trials [15] and eight trials [16] of physiotherapy interventions. The other investigation was a survey of 200 reports of randomized controlled trials of physiotherapy interventions [13]. These small samples are probably unrepresentative of the published reports of randomized controlled trials of physiotherapy interventions [3,4]. For other areas of health care, the review concluded that overall quality scores have increased with time (13 of 26 reviews) [14]. An examination of reports of trials indexed on PubMed (predominantly drug and surgical interventions) indicates that reporting of the sequence generation (risk ratio, 1.62; 95% confidence interval [CI], 1.32, 1.97) and allocation concealment (risk ratio, 1.40; 95% CI, 1.11−1.76) improved with time but blinding did not (risk ratio, 0.91; 95% CI, 0.75−1.10) [17].

The present study aims to describe changes in the quality of reporting of randomized controlled trials of physiotherapy interventions over time. Specifically, the study will examine the change in overall quality (i.e., total quality score) and in 11 individual quality features over time. A secondary aim was to examine the impact of the CONSORT Statement on the quality of reports of trials of physiotherapy interventions.

2. Methods

2.1. Data source

The PEDro database (www.pedro.org.au) provides an index of randomized trials, systematic reviews, and evidence-based practice guidelines in physiotherapy. Trials are located using sensitive search strategies of seven databases (Allied and Complementary Medicine Database, Cumulative Index to Nursing and Allied Health Literature, Cochrane CENTRAL, Database of Abstracts of Reviews of Effects, Embase, Medline, and PsycINFO) and citation tracking of systematic reviews that are indexed on PEDro. Randomized controlled trials are indexed on PEDro if they (1) compare at least two interventions (one of these interventions could be a no-treatment control or sham treatment), (2) at least one of the interventions evaluated is part of physiotherapy practice or could become part of physiotherapy practice, (3) the interventions are applied to subjects who are representative of those to whom the intervention might be applied in the course of physiotherapy practice, (4) the trial involves random (or intended-to-be-random) allocation of subjects to interventions, and (5) the article is a full article in a peer-reviewed journal.

Randomized controlled trials indexed on PEDro are rated for methodological quality and statistical reporting using the 11-item PEDro scale [18]. The items are (1) eligibility criteria specified; (2) subjects randomly allocated to groups; (3) concealed allocation; (4) groups similar at baseline; blinding of (5) subjects, (6) therapists, and (7) assessors; (8) outcome measures obtained from more than 85% of subjects; (9) intention-to-treat analysis; (10) reporting of results of between-group statistical comparisons; and (11) point measures and measures of variability reported. The PEDro scale is based on the Delphi list [19], a nine-item list established by expert consensus (PEDro items 1, 2, 3, 4, 5, 6, 7, 9, and 11). One item on the PEDro scale (item 1: eligibility criteria and source of subjects specified) assesses external validity, whereas the other items all reflect dimensions of internal validity. This item is not used to calculate the total PEDro score, which is why the 11-item PEDro scale gives a score out of 10.

All randomized controlled trials indexed on the PEDro database are independently evaluated by two raters for

eligibility and methodological quality. Any discrepancies are arbitrated by a third rater. The interrater reliability of these consensus ratings for total PEDro score is ''fair'' to ''good,'' with an intraclass correlation coefficient of 0.68 (95% CI, 0.57–0.76) [18]. The interrater reliability of consensus ratings of individual PEDro scale items is ''fair'' to ''substantial,'' with Kappa values between 0.50 and 0.79 [18]. The total PEDro score and eight individual scale items have construct validity, being significantly related to bibliometric indices of the impact of the journal in which the trials are published [20]. Based on a Rasch analysis, it appears to be valid to add the individual PEDro scale items to produce a total PEDro score, which can be treated as an interval level measurement [13].

2.2. Data extraction

We downloaded data for all the randomized controlled trials that had complete consensus ratings for the PEDro scale from PEDro on November 3, 2008. Variables downloaded were year of publication, ratings for each of the 11 individual items of the PEDro scale, and total PEDro score. To reduce leverage of very early trials, the first 13 trials (published between 1929 and 1959) were removed from the data set.

2.3. Statistical analysis

The relationship between the total PEDro score and time (year of publication) was evaluated with linear models. Standard errors were adjusted for clustering by journal using robust (sandwich) variance estimators. Time was entered into the model as a continuous variable (years since 1996, the year the CONSORT Statement was first introduced [12]). Where necessary, additional terms were added to account for nonlinear effects of time. The relationship between each individual item on the PEDro scale and time (year of publication) was examined with logistic models, after inspecting linearity on a logistic scale using locally weighted scatterplot smoothed (Lowess) curves. Again, time was entered into the model as a continuous variable. To investigate the possible impact of the CONSORT Statement, we fitted separate regression equations for the total PEDro score data for 1960–1996 and 1996–2008 and compared these graphically. All analyses were performed using Stata software (College Station, TX, USA). The prevalence of each individual PEDro scale item plus the mean (SD) total PEDro score were calculated for reports of trials of physiotherapy interventions published in 1960–1969 and in 2008.

3. Results

There were 13,659 records indexed on PEDro as on November 3, 2008. Of these, 11,291 were randomized controlled trials, 10,038 had complete consensus ratings, and 10,025 were published in or after 1960. These trials were published in 1,306 different journals.

Total PEDro score increased with time. The relationship between the total PEDro score and time (year of publication) is illustrated in the bubble plot in Fig. 1. The weighted linear regression accounted for 8.9% of the variance. The equation is as follows: total PEDro score = 4.669 + (0.0570 × year since 1996). The 95% CIs were 4.588–4.751 ($P < 0.001$) for the constant and 0.0513–0.0627 ($P < 0.001$) for the coefficient. This indicates that the average total PEDro score for trials published in 1996 was ~4.7 points and that the total PEDro score increased by ~0.6 points each decade.

The results of the analyses of effects of time on individual scale items are summarized in Table 1 and Fig. 2. Eight of the 11 scale items improved with time. With the exception of item 3 (i.e., concealed allocation), the relationship between the logit of each individual PEDro scale item and time (year of publication) was approximately linear (Fig. 2). Because item 3 appeared linear after 1986, only data from after 1986 were analyzed. The items with improved reporting were (in descending order of magnitude of improvement) intention-to-treat analysis (item 9; odds ratio [OR], 1.123), concealed allocation (item 3; OR, 1.100), groups similar at baseline (item 4; OR, 1.059), reporting of results of between-group statistical comparisons (item 10; OR, 1.057), point measures and measures of variability reported (item 11; OR, 1.053), subjects randomly allocated to groups (item 2; OR, 1.051), eligibility criteria specified (item 1; OR, 1.044), and blinding of assessors (item 7; OR, 1.034). Note that the ORs indicate the increase in odds per year. Thus, for example, the odds of the intention-to-treat analysis item being satisfied increased by 12.3% per year and the odds of the blinding of assessors item being satisfied increased by 3.4% each year.

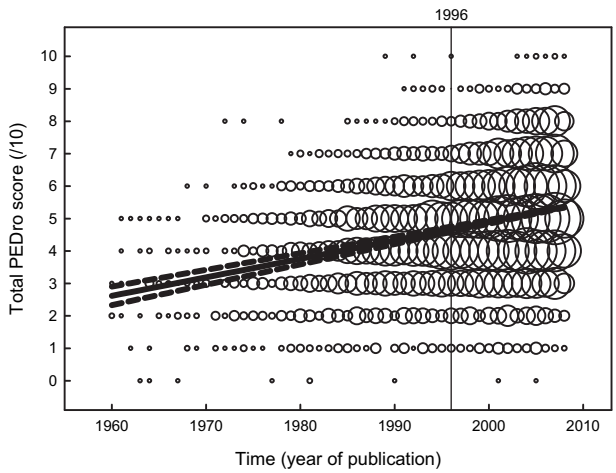

Fig. 1. A bubble plot of the total PEDro score vs. time (year of publication). The diameter of the bubble is proportional to the square root of the number of trials with each PEDro total score each year. PEDro, Physiotherapy Evidence Database.

Table 1
The OR, 95% CI of the OR, and P-value from the logistic regression analysis for each individual PEDro scale item plus the overall prevalence for each individual PEDro scale item

PEDro scale item	OR[a]	95% CI	*P*-value	Prevalence (%)
1. Eligibility criteria specified	1.044	1.036–1.051	0.000	71
2. Subjects randomly allocated to groups	1.051	1.040–1.062	0.000	95
3. Concealed allocation	1.100	1.085–1.115	0.000	20
4. Groups similar at baseline	1.059	1.052–1.066	0.000	66
5. Blinding of subjects	1.000	0.991–1.010	0.962	9
6. Blinding of therapists	0.975	0.964–0.987	0.000	2
7. Blinding of assessors	1.034	1.025–1.042	0.000	33
8. Outcome measures obtained from more than 85% of subjects	1.006	0.999–1.013	0.097	57
9. Intention-to-treat analysis	1.123	1.107–1.140	0.000	18
10. Reporting of results of between-group statistical comparisons	1.057	1.047–1.066	0.000	92
11. Point measures and measures of variability reported	1.053	1.046–1.061	0.000	85

Abbreviations: OR, odds ratio; CI, confidence interval; PEDro, Physiotherapy Evidence Database.
[a] The factor by which the odds of the item being satisfied increased every year.

There was little or no effect of the CONSORT Statement on the quality of reports of physiotherapy trials. The relationship between total PEDro score and time (year of publication) for reports of trials published in 1960–1996 and 1996–2008 are plotted in Fig. 3. The regression (and 95% CIs) for the 1960–1996 data was extended to 2008 using thin lines. The second regression for 1996–2008 (i.e., heavy dashed line in Fig. 3) falls, more or less, within the 95% CIs for the plot generated from the 1960 to 1996 data.

The mean PEDro score increased from 2.9 for reports of trials published in 1960–1969 to 5.3 for reports of trials published in 2008 (Table 2). The proportion of trials satisfying each individual PEDro scale item increased by more than 30% between 1960 and 1969 and 2008 for the following items (in descending order of magnitude of improvement): groups similar at baseline (increased by 51%), reporting of results of between-group statistical comparisons (44%), eligibility criteria specified (increased by 42%), point measures and measures of variability reported (34%), and intention-to-treat analysis (31%).

4. Discussion

The main finding is that the methodological quality of randomized controlled trials of physiotherapy interventions has improved over the past 5 decades. On average, the total PEDro score improved by ~0.6 points each decade. Eight of the 11 items on the PEDro scale were satisfied more often in more recent trials. They were intention-to-treat analysis, concealed allocation, groups similar at baseline, reporting of results of between-group statistical comparisons, point measures and measures of variability reported, subjects randomly allocated to groups, eligibility criteria specified, and blinding of assessors.

Our results do not agree with those from a recent systematic review [14] and a survey of reports of trials of physiotherapy interventions [13], which both concluded that there was little change in the quality of randomized controlled trials in physiotherapy with time. The conflicting results may be explained by the number and representativeness of trials included in the two studies. Our study included all 10,025 trials archived on the PEDro database, whereas the previous studies considered a total of 97 trials drawn from two systematic reviews [14] and the reports of 200 trials [13]. Our sample is therefore more representative of reports of trials evaluating physiotherapy interventions because we have included a higher proportion of the population of trials. We feel our approach provides a more robust evaluation of whether physiotherapy trial quality is increasing over time. Our results also demonstrate that studies of the literature in any scientific discipline need to be based on large representative samples of that literature.

For randomized controlled trials of physiotherapy interventions, there has been an improvement in reporting of design features, which have been demonstrated in empirical studies to influence the size of the estimates of the treatment effect (i.e., random allocation, concealed allocation, and blinding) [9,10] or have strong theoretical rationales (i.e., intention-to-treat analysis) [11]. These results are consistent with other areas of health care, including psychiatry [21], palliative care [22], nursing [23], assisted reproduction [24], oncology [25], anesthesiology [26], ophthalmology [27], and drugs and surgery [17].

Although there has been a slow increase in the quality of reporting of physiotherapy trials over time, there is room for improvement. It is possible for all trials of physiotherapy interventions to score at least 7 (when the key outcomes are self-reported) or 8 (when outcomes can be objectively assessed by a blinded assessor) out of 10 on the PEDro scale, but the average score of reports of trials published in 2008 was just 5.3. Random allocation, concealed allocation, blinding of assessors, and intention-to-treat analysis could be implemented and reported for all trials. The source and inclusion criteria for subjects, baseline characteristics, results of between-group statistical comparisons, and point measures and variability of key outcomes could be reported for all trials. In contrast, blinding

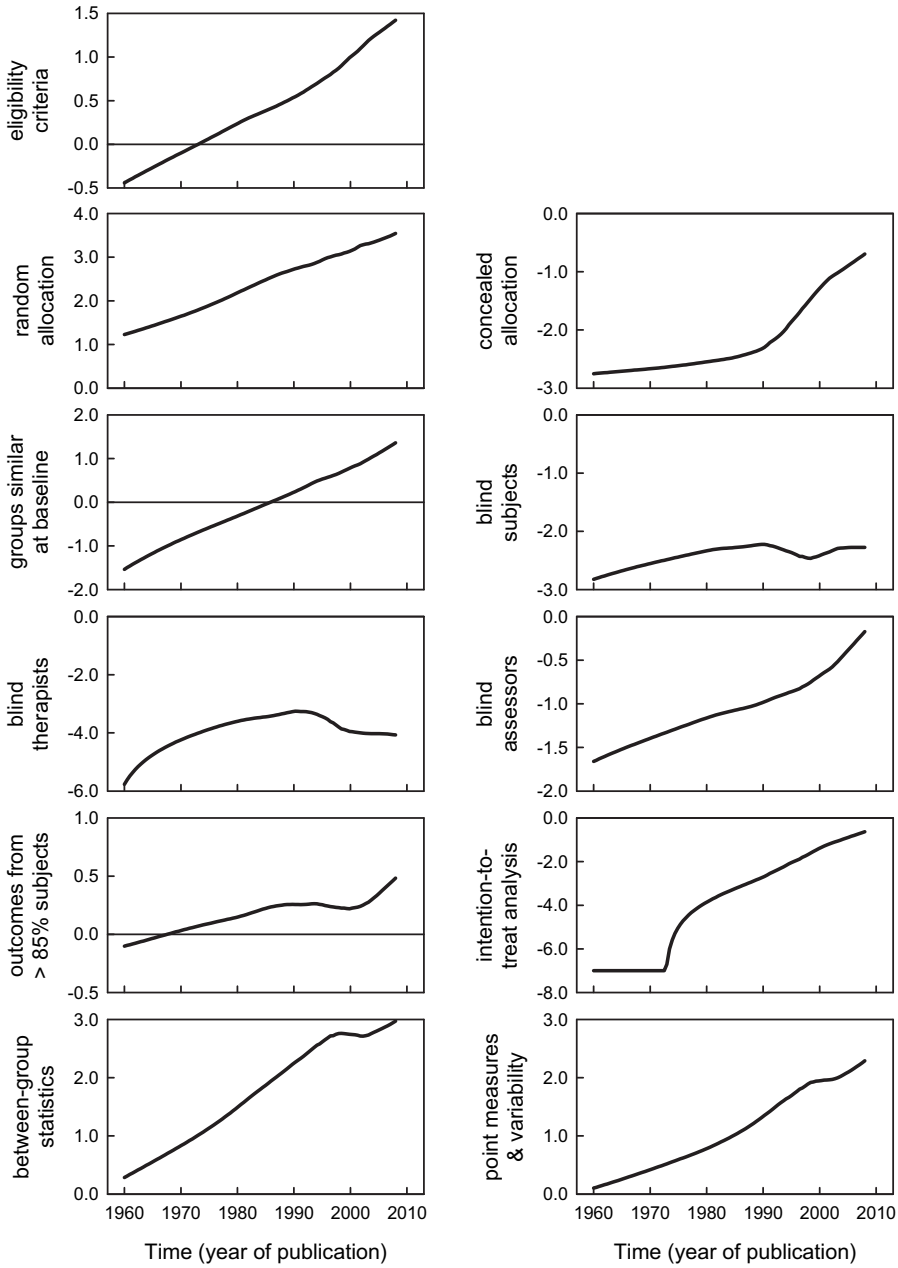

Fig. 2. Locally weighted scatterplot smoothed (Lowess) curves for each individual item of the PEDro scale vs. time (year of publication). PEDro, Physiotherapy Evidence Database.

of therapists and subjects will not be possible for most physiotherapy interventions, which involve engagement in exercise, education, rehabilitation, and physical activity. These were the only items not to show a linear increase over time (Fig. 2), and there was a low prevalence of trials achieving these items (Table 1). Blinding of therapists and subjects is possible in the evaluation of some physiotherapy interventions (e.g., electrophysical agents such as ultrasound [28]) and may necessitate the development of some convincing sham interventions (e.g., the sham acupuncture needle [29]).

From our investigation, it is not possible to distinguish between the quality of conducting the trial and reporting the trial. Evaluations of trials of medical interventions indicate that there are deficits in both the conduct and reporting of trials. For example, adequate allocation concealment was described in 44% of trial protocols but was reported in only 18% of trial publications [30], 36% of trial protocols included an adequate method of sequence generation but this was reported in only 21% of trial publications [30], and blinding of subjects, health care providers, and outcome assessors was mentioned in 63% of trial protocols and 67% of trial reports [31]. Although protocols and reports of physiotherapy trials have not been systematically compared, it is likely that they would have similar deficits to the conduct and reporting of trials in medicine. This comparison of

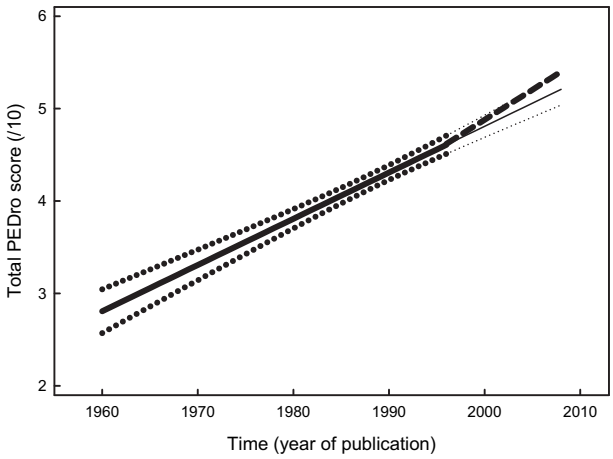

Fig. 3. Regression lines for the total PEDro score vs. time (year of publication) for reports of physiotherapy trials published in 1960–1996 (mean and 95% confidence intervals; heavy lines for 1960–1996 and thin lines for extension of these curves to 2008) and 1996–2008 (mean; heavy dashed line). PEDro, Physiotherapy Evidence Database.

protocols and reports of trials of physiotherapy interventions could be the focus of future research. Ultimately, however, it is the full reporting of trials that is required to allow clinicians to use trial reports to guide practice.

Better conduct and reporting of clinical trials evaluating physiotherapy interventions could be encouraged at several levels. First, clinical trial research training programs should include key elements of trial design and reporting. Second, key design features (such as random allocation, concealed allocation, blinding assessors, and intention-to-treat analysis) could be used as minimum standards in the scientific review of research proposals for clinical trials (e.g., by ethics review boards and granting bodies) and in the clinical trial registration process. Lastly, journal editors and reviewers could encourage better reporting of trials by adopting the CONSORT Statement. For drug and surgical trials, journals that endorse the CONSORT Statement have better reporting of key design features compared with journals that do not endorse the CONSORT Statement [17]. Evaluation of these possible strategies for improving physiotherapy trials is warranted.

The low quality of reporting of trials evaluating physiotherapy interventions also has implications for the conduct of systematic reviews. There is empirical evidence that the absence of random allocation to groups [9], concealed allocation [9,10], and blinding of subjects, therapists and assessors [10] is related to larger effect sizes. For this reason, it is important that the design features of included studies are evaluated in systematic reviews [32]. Furthermore, sensitivity analyses can be conducted to investigate the effects of trial quality on the pooled results [32].

From our investigation, the CONSORT Statement appeared to have minimal impact on the reported methodological quality of randomized controlled trials in physiotherapy. Although it is not possible to determine the factors that may have contributed to the increase in quality, we speculate that those factors are likely to include entry-level and postgraduate research training of physiotherapists, the widespread attention to methodological issues over time, and the publication of key articles promoting the importance of different design features. The only items where a causal association can be inferred are concealed allocation and intention-to-treat analysis. An increase in the proportion of physiotherapy trials reporting concealed allocation was apparent in about 1986, just after the publication of the seminal article by Chalmers et al [9] on this issue. Similarly, the proportion of physiotherapy trials reporting intention-to-treat analysis rapidly increased in the 1970s, soon after discussion of this issue started to appear in the literature [33]. Examining these possible causal factors could be the focus of future investigations.

Table 2
The prevalence of each individual PEDro scale item plus the mean (SD) total PEDro score for reports of trials of physiotherapy interventions published in 1960–1969 and in 2008

Individual PEDro scale items	Reports of trials published in 1960–1969 (N=56), n (%)	Reports of trials published in 2008 (N=400), n (%)	Change in reporting between 1960–1969 and 2008 (%)
1. Eligibility criteria specified	20 (36)	310 (78)	42
2. Subjects randomly allocated to groups	43 (77)	389 (97)	20
3. Concealed allocation	3 (5)	115 (29)	24
4. Groups similar at baseline	16 (29)	320 (80)	51
5. Blinding of subjects	2 (4)	29 (7)	3
6. Blinding of therapists	0 (0)	6 (2)	2
7. Blinding of assessors	9 (16)	152 (38)	22
8. Outcome measures obtained from more than 85% of subjects	28 (50)	233 (58)	8
9. Intention-to-treat analysis	0 (0)	125 (31)	31
10. Reporting of results of between-group statistical comparisons	28 (50)	377 (94)	44
11. Point measures and measures of variability reported	33 (59)	373 (93)	34
Mean (SD) total PEDro score	2.9 (1.4)	5.3 (1.2)	

Abbreviations: PEDro, Physiotherapy Evidence Database; SD, standard deviation.

The strengths of the study are that we assessed trial quality using a scale with known measurement properties and we analyzed a large and representative data set. We also accounted for clustering (by journal) in the regression analyses. A limitation of this type of research is that we based our analyses on reported study quality rather than the conduct of randomized controlled trials. However, for the research question we investigated, we feel there are no alternatives to reliance on reports of how a study was conducted. Thus, our conclusions pertain to the reported (apparent) quality of randomized trials.

In conclusion, the reported quality of randomized controlled trials of physiotherapy interventions has improved over the past 5 decades. The reported use of eight individual design features has also improved with time (i.e., intention-to-treat analysis, concealed allocation, groups similar at baseline, reporting of results of between-group statistical comparisons, point measures and measures of variability reported, subjects randomly allocated to groups, eligibility criteria specified, and blinding of assessors). Although there was considerable improvement, less than 50% of reports of trials published in 2008 reported concealed allocation, blinding of assessors, and intention-to-treat analysis. Further improvement in the reporting of trials evaluating physiotherapy interventions is necessary to both improve the validity of systematic reviews and to inform clinical practice.

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