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ORIGINAL RESEARCH

Methodologic Quality and Statistical Reporting of Physical Therapy Randomized Controlled Trials Relevant to Musculoskeletal Conditions

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Abstract

Objectives: To investigate the methodologic quality and statistical reporting of reports of trials indexed on the Physiotherapy Evidence Database (PEDro) classified in the musculoskeletal subdiscipline, and to analyze the characteristics of the trials that can predict trial report quality.

Design: Cross-sectional study based on a collection of randomized controlled trials. We randomly selected 19% of trials coded as musculoskeletal from PEDro. Methodologic quality was assessed using the PEDro scale. We assessed aspects of the trial using 9 items from the Consolidated Standards of Reporting Trials (CONSORT) statement. We performed multivariate linear regression analysis models to predict the total PEDro score.

Setting: Not applicable.

Participants: Not applicable.

Interventions: Not applicable.

Main Outcome Measures: Not applicable.

Results: A total of 1404 articles were included in the analysis. The mean total PEDro scale score was 5.27±1.63 points, which reflects low methodologic quality. There was a slight improvement in the quality of articles over time. The characteristics that predicted the total PEDro scale score were endorsement of the CONSORT statement, sample size calculation, lower number of primary outcomes, evaluation of electrotherapy as intervention, if the trial reported the research design in the title, reporting of participant flow diagram, years since publication (most recent trials), and trials published in English.

Conclusions: The quality of the trials in musculoskeletal physical therapy is suboptimal. The use of reporting checklists (eg, CONSORT statement) should be mandatory in all journals. Journal reviewers and journal editors should also use the CONSORT statement during the review process.

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Although the number of randomized controlled trials in physical therapy has been increasing exponentially, the methodologic quality and statistical reporting of these trials are heterogeneous.[1] Problems in both areas make it difficult for the reader to gain a clear understanding of a trial's implications for clinical practice.[2-4] This is particularly the case for trial quality because articles with low methodologic quality are more likely to provide biased estimates of treatment effects than high-quality articles.[4,5]

Given this large number of trials with a large variability of methodologic quality, physical therapists should search for the high-quality clinical research to answer their clinical questions. The Physiotherapy Evidence Database (PEDro) is an open-access database of clinical evidence for physical therapists.[6,7] PEDro was developed to provide rapid access to abstracts and bibliographic details of clinical research evaluating treatment efficacy relevant to physiotherapy and help physiotherapists

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overcome some of the obstacles to implementing an evidence-based approach to intervention.[8,9] PEDro is an important resource for physiotherapists to use to find high-quality research to answer clinical questions and is one of the most comprehensive databases indexing reports of randomized controlled trials of physiotherapy.[9] As of January 2016, PEDro indexes >32,200 reports of trials, systematic reviews, and clinical practice guidelines in physiotherapy.[10] All articles indexed on PEDro are assessed for their methodologic quality and statistical reporting using the PEDro scale.[11-13] The PEDro scale can help clinicians to discriminate articles that are valid and contain sufficient statistical information to guide clinical practice from those that are not. The total PEDro score (range, 0−10) is used to rank search results.[14]

The Consolidated Standards of Reporting Trials (CONSORT) statement[15-17] provides a checklist to guide complete and transparent reporting[18,19] of the design and conduct of a trial. The CONSORT checklist is composed of 25 items and a flow diagram covering the information an author should provide in the title, abstract, introduction, methods, results, and discussion sections of an article. Articles that follow the CONSORT checklist ideally provide sufficient information to allow a reader to judge methodologic quality of the trial but also to better understand the clinical context of a trial. The clinical context should include issues such as the characteristics of the patients, training and experience of the care providers, and precise details of the intervention to allow a researcher to replicate the intervention in a future trial or a clinician to apply the treatment to their patients.

The methodologic quality and reporting adequacy of physiotherapy trials have been investigated.[20] A recent study that investigated the quality of articles of randomized controlled trials found that one of the factors that may be associated with the quality of physical therapy trial articles is the subdiscipline of physical therapy being evaluated. Musculoskeletal had the highest mean total PEDro score of 5.08±1.7 of all the subdisciplines[20] and is the most common subdiscipline searched on the database.[21] Musculoskeletal trials are more likely to specify the eligibility criteria and source of subjects, conceal allocation, blind subjects and assessors, have >85% follow-up, and use intention-to-treat analysis than other subdisciplines. However, there is no information on which characteristics of these trials can predict methodologic quality.

To our knowledge, there are no studies to date investigating the methodologic quality and statistical reporting of physiotherapy randomized controlled trials relevant to musculoskeletal conditions using the PEDro scale and items from the CONSORT statement. Therefore, the primary aim of this study was to describe the methodologic quality and reporting adequacy of trials classified in the musculoskeletal subdiscipline indexed on PEDro using the PEDro scale and 9 items of the CONSORT statement. The secondary aim was to analyze which characteristics of the articles might predict a better PEDro score.

List of abbreviations:

CONSORT **Consolidated Standards of Reporting Trials**
PEDro **Physiotherapy Evidence Database**

Methods

Study selection

We randomly selected 1404 of all articles indexed on PEDro and coded as musculoskeletal in the subdiscipline field on May 20, 2017 (fig 1). This represents 19% of all trials classified as musculoskeletal from PEDro. Articles which did not have complete PEDro scale ratings (ie, independently assessed by 2 raters, with arbitration by a third rater where necessary) were excluded. There was no language restriction; articles written in languages other than English, Spanish, or Portuguese were sent to bilingual colleagues to extract the data. The person who selected the articles was not blinded to the title and authors of the article.

Data extraction

The assessment of methodologic quality and statistical reporting of the articles was performed using the 11 items of the PEDro scale[11] plus the 9 items of the CONSORT statement relevant for the analysis of methodologic quality.[15] The 9 items from the CONSORT statement selected for data analysis were those that did not overlap with any of the 11 items from the PEDro scale. Some items from the CONSORT statement (eg, blinding of subjects, blinding of assessors, baseline comparability) were not used because they were redundant with PEDro items. We also recorded if the journal from each of the eligible trials endorsed the CONSORT statement. The 11 items of the PEDro scale are presented in appendix 1.

The PEDro scale assessment was performed by 2 independent trained raters from PEDro, with arbitration by a third reviewer whenever necessary. The year of publication was transformed to age by subtracting the year from 2017. The language of publication was recoded as 1 for English-language articles and 0 for articles in languages other than English. Articles evaluating

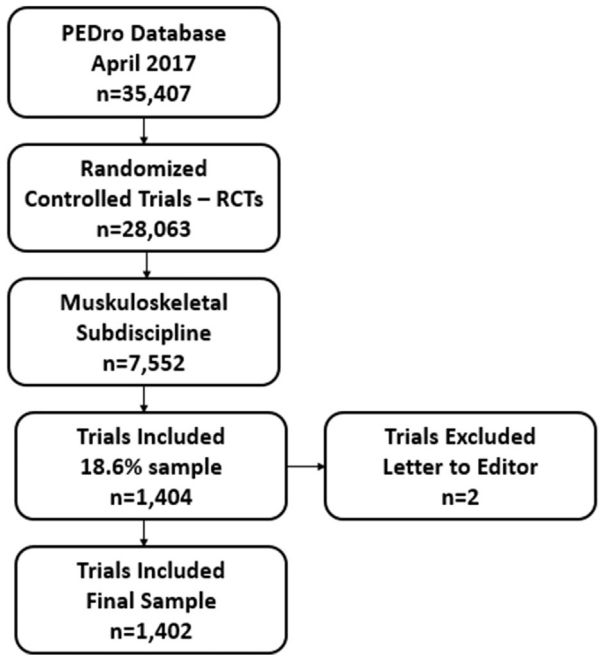

Fig 1 Study flow diagram.

electrotherapy were coded as 1, whereas all other interventions were coded as 0.

The CONSORT statement comprises 25 items; however, we only included 9 items that are not included in the PEDro scale and which are closely related to the methodologic quality of the trials. We chose not to include CONSORT statement items related to the introduction (1 item) and discussion (3 items) sections. Further, we did not extract data from items that are not related to methodologic quality (eg, description of the interventions, objectives and hypothesis of the trial, implementation, adverse events).[22,23] The 9 CONSORT items are presented in appendix 2.

For the CONSORT statement, a single reviewer who had received intensive training to avoid potential mistakes scored trials against the items from the CONSORT statement. The data extraction was performed using a standardized data extraction form in an Excel spreadsheet.[a] The items from the CONSORT statement of trials in Portuguese, Spanish, and English were extracted by a single reviewer. The information from articles in other languages was extracted by bilingual colleagues of PEDro. Therefore, the information of 79 trials was extracted from 7 different colleagues.

To judge if a trial was published in a journal that endorses the CONSORT statement, we accessed the Instruction for Authors section in each journal website. We coded yes for articles published in journals that follow the CONSORT statement, no for articles published in journals that did not follow the CONSORT statement, and not applicable for articles published before the existence of CONSORT (ie, August 1996).

Data analysis

The first step was to calculate a range of descriptive statistics for the identified articles, including mean total PEDro scale score ± SD (all trials, for each decade separately, and for each publication language separately) and frequency distribution of language of publication and body part. The number of articles fulfilling each of the 11 PEDro scale items and the 9 items from the CONSORT statement were computed. The median (interquartile range) was calculated for the relevant CONSORT statement items: number of randomized participants, how sample size was determined (number of participants specified in sample size calculation), locations where the data were collected (number of sites), and number of primary outcomes.

To identify trial report characteristics associated with the total PEDro score, we used multivariate linear regression. The dependent variable was the total PEDro score. The independent variables were age of publication (2017 minus year of publication; continuous variable), language of publication (coded as 1 for English, coded as 0 for other languages), trials that evaluated electrotherapy interventions (coded as 1) versus trials that did not (coded as 0), identification as a randomized trial in the title (coded as 1 for yes, coded as 0 for no), trials that described the number of randomized participants (coded as 1 for yes, coded as 0 for no), total sample size (continuous variable), trials that described how the sample size was determined (coded as 1 for yes, coded as 0 for no), trials that described the location as single center (coded as 0) or multicenter (coded as 1), trials that identified the number of primary outcomes (coded as 1 for yes, coded as 0 for no), the number of primary outcomes (continuous variable), trials that had statistical adjustment for multiple primary outcomes (coded as 1 for yes, coded as 0 for no), trials that included the participant flow diagram (coded as 1 for yes, coded as 0 for no), trials that indicated trial registration (coded as 1 for yes, coded as 0 for no), trials that received any type of funding (coded as 1 for yes, coded as 0 for no), and publishing journal endorsement of the CONSORT statement (coded as 1 for yes, coded as 0 for no or trial report published prior to the creation of the CONSORT statement).

To build the regression model, we calculated single predictor linear regression models between the dependent variable and each of the independent variables. Variables that obtained a P value $\leq .20$ were selected to build the final multivariate model. We considered the model complete when all variables reached a P value $\leq .05$. The prerequisites of linearity and collinearity were prospectively tested. The data were entered into an electronic databank (Excel) and analyzed using statistical software (SPSS 13.0[b]).

Results

On April 20, 2017, there were 35,407 reports of trials, reviews, and guidelines indexed on PEDro. Of the 28,063 articles, 7552 were coded as musculoskeletal and had complete PEDro scale scores. Data were extracted for a total of 1404 articles (19% of musculoskeletal trials with a complete rating). We excluded 2 trials[24,25] that were published as letters to the editor because the reports were considered too brief to extract the data for our study. Therefore, our analysis is based on 1402 articles.

The overall mean total PEDro score was 5.27±1.63. Only a small proportion of trials (32.6%) reached a score >6, which indicates good quality.[26] There has been a significant increase in the number of musculoskeletal physical therapy articles since 1955, when the first 2 trials were published.[27,28] In the 1960s, only 2 trials were published, increasing to 17 trials in the 1970s, 79 trials in the 1980s, 204 trials in the 1990s, 549 trials between 2000 and 2010, and 553 trials between 2011 and 2017.

The included articles were published in 300 different journals and written in 10 different languages, with English the most predominant language. Table 1 presents the total PEDro score stratified by language for the included articles. The mean total PEDro score ranged from 3.5 to 6.5 points for articles published in Japanese and Dutch, respectively.

Table 1 Number (%) of articles and mean total PEDro score ± SD by language

Language	Articles	Total PEDro Score
English	1305 (93.0)	5.3±1.62
German	31 (2.21)	5.27±1.63
Chinese	43 (3.03)	5.35±1.41
Portuguese	9 (0.64)	3.67±2.44
Spanish	6 (0.42)	5.17±0.98
Dutch	4 (0.28)	6.5±1.0
French	2 (0.14)	4.5±0.7
Japanese	2 (0.14)	3.5±0.7
Italian*	1 (0.07)	1.0
Norwegian*	1 (0.07)	6.0
Total	1404 (100.0)	5.27±1.63

NOTE. Values are n (%), mean ± SD, or as otherwise indicated.
* SD was not calculated because n = 1.

The methodologic quality and statistical reporting of the trials increased over the time, but at a very slow rate. The only trial published in the 1950s scored 2.0 points. In the 1960s, the mean score increased to 4.50±0.7 points. However, in the 1970s, this value decreased to 3.82±1.7 points. For the following decades, the average PEDro score increased gradually from a mean score of 4.1±1.5 points in the 1980s to 5.67±1.53 points for trials published between 2011 and 2017 (fig 2). The total PEDro score increased at a rate of 0.3 points per decade between 1955 and 2017 (see univariate β coefficient for age in years in table 2).

Taking into account the main body part investigated in the trials, the lumbar spine appears the most (26.1%). On the other hand, the region of the perineum (0.4%) was the least studied (table 3).

Table 4 shows the percentage of trials that met each of the PEDro scale items. The most frequently met criteria were random allocation (95.7%) and between-group statistical comparisons (93.5%). The least frequently met criteria were blinding of subjects (11.5%) and blinding of therapists (2.1%).

According to the analysis of the 9 items of the CONSORT statement (table 5), only 626 trials (44.6%) included identification as a randomized trial in the title. Only 473 (33.7%) trials indicated how sample size was determined, in which the median of participants specified was 187 compared with 60 (interquartile range, 34−109) participants randomized. Most of the trials (82.4%) were conducted in a single research center. Regarding the region of the trial, the European continent had the highest proportion of trials (49.6%), followed by North America (24%). Only 383 trials (27.3%) had statistical adjustment for primary outcomes. Although more than half of the trials (51.4%) received any type of funding, an insignificant proportion of trials registered their research protocols (16%). We observed that trials published in journals that endorse the CONSORT statement were more likely to have a higher PEDro score (mean score, 5.74±1.59) than journals that do not (mean score, 5.04±1.60; mean difference, .70; 95% confidence interval, .52−.88; $P<.001$).

The univariate analysis showed that the variables number of randomized participants described (number), location where the data were collected, number of primary outcomes (number), and statistical adjustment of primary outcomes were not associated with trial quality (see table 2). The final multivariate model is presented in table 2. Seven independent variables are associated with an increased total PEDro scale score: identification as randomized controlled trial in the title increases the total PEDro scale score of musculoskeletal physical therapy articles by .33 points, specifying how sample size was determined increases the score by .27 points, describing the number of primary outcomes increases the score by .22 points, including a participant flow diagram increases the score by .41 points, publication in English increases the score by .47 points, publication in a journal that endorses the CONSORT statement increases the score by .28 points, evaluation of an electrotherapy intervention increases the score by .43 points each. The multivariate model explains 43.5% of the total variance of the PEDro score ($R^2=.435$).

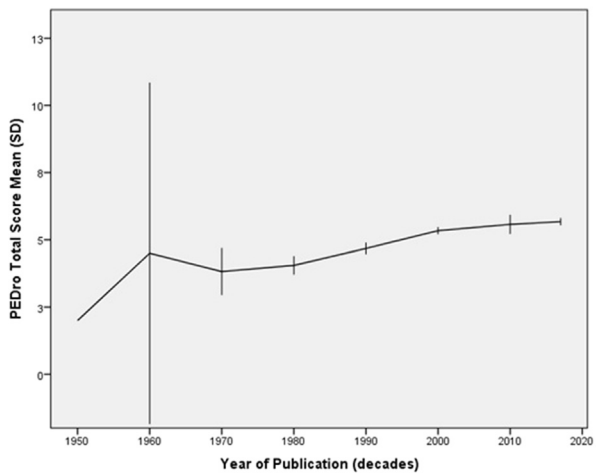

Fig 2 Mean total PEDro scores ± SD per decade. The decade of 1950 has no SD estimates because n=1.

Discussion

We found from our univariate model that the growth rate in total PEDro score per decade was only 0.3 points. If this slow rate of improvement continues, musculoskeletal physical therapy trials will reach an average score of 8, which is considered as good quality,[26] in about 2090. Factors that predict a higher total PEDro score were specification of primary outcomes, including a participant flow diagram, publication in English, publication in a journal that endorses the CONSORT statement, evaluation of electrotherapy intervention, and identification as a randomized trial in the title. The strength of this study is the use of a representative sample of trials (n=1404, or 19% of all articles indexed on PEDro and categorized as musculoskeletal).

According to a study[20] that analyzed the methodologic quality and statistical reporting in subdisciplines of physiotherapy, musculoskeletal had the highest mean total PEDro score of 5.08±1.7 points, which matches our finding of 5.27±1.63 points. This study also found that the total PEDro scores were higher when articles are more recent, were published in English, and investigated electrotherapy interventions, which was also similar to our results. Moreover, the low prevalence of concealed allocation, intention-to-treat analysis, and blinding of therapists were also evident in physical therapy articles generally.[4,20,29]

The average quality of musculoskeletal trials published in the 2010s (ie, 5.27±1.63 points) is too low, demonstrating that an improvement in quality is needed. Articles which are low in methodologic quality (or have a high risk of bias) tend to overestimate the treatment effects.[18] High-quality clinical research is required to inform clinical decision-making and for implementation of policies of care.[30] Our results suggest some areas where future trials can be improved, including careful planning to include design features known to reduce bias (eg, concealed allocation, intention-to-treat analysis, specifying a small number of primary outcomes), participants flow diagram, and using the CONSORT statement to improve the reporting of trials.

Another study[31] designed to identify the quality of randomized controlled trials published in traditional medicine journals in Korea analyzed 105 trials and found that only a small proportion (n=28) were published in journals that endorsed the CONSORT statement. Of these 28 articles, only 3 identified the study as a randomized trial in the title, 17 specified the number of primary outcomes, and 23 presented a participant flow diagram despite the journal endorsing the CONSORT statement. These results are consistent with our findings and suggest that journal editorial

Table 2 Univariate and multivariate models to predict characteristics that were associated with PEDro total score

Variable	Constant	β Coefficient	95%CI	*P*	NA	Constant	β Coefficient	95%CI	*P*	R^2
Univariate model	NA	NA	NA	NA	Multivariate model	4.49	NA	4.08 to 4.91	<.001	.435
Identification as a randomized trial in the title	4.87	0.884	0.71 to 1.05	<.001	NA	NA	0.33	0.15 to 0.51	<.001	NA
No. of randomized participants described (no.)*	5.26	6.36	5.17 to 5.35	.654	NA	NA	NA	NA	NA	NA
How sample size was determined	4.94	0.98	0.81 to 1.16	<.001	NA	NA	0.27	0.06 to 0.47	.009	NA
Locations where the data were collected (multicenter trial)*	5.24	0.019	0.001 to 0.037	.036	NA	NA	NA	NA	NA	NA
No. of primary outcomes (no.)*	5.80	−0.037	−0.112 to −0.039	.342	NA	NA	NA	NA	NA	NA
No. of primary outcomes (stated)	4.94	0.805	0.63 to 0.97	<.001	NA	NA	0.22	0.04 to 0.41	.017	NA
Statistical adjustment for multiple primary outcomes*	5.27	-0.00	−0.004 to 0.003	.725	NA	NA	NA	NA	NA	NA
Participant flow diagram	4.87	1.10	0.93 to 1.26	<.001	NA	NA	0.41	0.20 to 0.62	<.001	NA
Clinical trial registration	5.14	0.78	0.55 to 1.01	<.001	NA	NA	NA	NA	NA	NA
Funding sources	5.24	0.00	0.000 to 0.001	.076	NA	NA	NA	NA	NA	NA
Published in a journal that endorses the CONSORT statement	5.04	0.70	0.52 to 0.87	<.001	NA	NA	0.28	0.11 to 0.46	<.001	NA
Age (y)	5.93	−0.056	−0.06 to −0.04	<.001	NA	NA	−0.03	−0.04 to −0.02	<.001	NA
Publication in English	4.65	0.65	0.27 to 1.03	<.001	NA	NA	0.47	0.11 to 0.83	.009	NA
Evaluation of electrotherapy intervention	5.22	0.21	0.01 to 0.41	.036	NA	NA	0.43	0.25 to 0.62	<.001	NA

Abbreviations: CI, confidence interval; NA, not applicable.
* Not associated with trial quality.

Table 3 Main body parts investigated in musculoskeletal physical therapy trials

Body Part	n (%)
Head or neck	263 (18.7)
Upper arm, shoulder, or shoulder girdle	143 (10.2)
Forearm or elbow	64 (4.3)
Hand or wrist	60 (4.3)
Chest	6 (0.4)
Thoracic spine	38 (2.7)
Lumbar spine, sacroiliac joint, or pelvis	366 (26.1)
Perineum or genitourinary system	5 (0.4)
Thigh or hip	81 (5.8)
Lower leg or knee	236 (16.8)
Foot or ankle	122 (8.7)
No appropriate value*	20 (1.4)
Total	1404 (100.0)

* Corresponds to trials that did not identify the body part investigated in their study.

policies and reviewers could play a significant role in the transparent reporting of trials.[18]

Study limitations

A possible limitation of this study is that the CONSORT items analyzed were collected by a single data extractor and using information contained in the trial report only. Although extensive training was provided for the data extraction, it is possible that some errors have occurred. Searching trial registries and contacting authors for additional data (eg, funding) may have also made our evaluation more robust, but this was not practical. We were reliant on the information in the published article being both comprehensive and transparent.

Conclusions

Our findings reflect some unawareness by the authors about fundamental points of methodology and reporting of clinical trials.[1] Similarly, publishers and journal editors have a key role in guiding authors for more clear and transparent trials.[18] Therefore, the use of reporting checklists such as the CONSORT statement for writing clinical trials can help authors to better

Table 4 Percentage of articles meeting each PEDro item (N = 1404)

PEDro Item	%
Eligibility criteria and source of subjects	77.0
Random allocation	95.7
Concealed allocation	31.2
Baseline comparability	73.9
Subject blinding	11.5
Therapist blinding	2.1
Assessor blinding	40.0
>85% follow-up	62.2
Intention-to-treat analysis	28.8
Between-group comparisons	93.5
Point measures and variability	88.6

Table 5 Characteristics of articles according to the CONSORT statement items

Item	n (%)	Median (IQR)
Identification as a randomized trial in the title	626 (44.6)	
No. of randomized participants		
Reported	1404 (100.0)	
Sample size		123 (107)
How sample size was determined		
Reported	473 (33.7)	
Sample size		187 (146)
Locations where the data were collected		
Multicenter trials	246 (17.5)	
No. of trial centers		1 (0)
Continent where trial was conducted		
Europe	694 (49.6)	
North America	336 (24.0)	
Asia	216 (15.0)	
Oceania	99 (7.1)	
South America	43 (3.1)	
Africa	11 (0.8)	
Missing	5 (0.4)	
No. of primary outcomes		
Primary outcome(s) identified	581 (41.4)	
No. of primary outcomes		2 (2)
Statistical adjustment for multiple primary outcomes	383 (27.3)	
Participant flow diagram	510 (36.3)	
Clinical trial registration	225 (16.0)	
Funding sources	722 (51.4)	

Abbreviation: IQR, interquartile range.

describe their trials. Therefore, while reviewing an article, editors and reviewers should also use the CONSORT statement to increase the transparency and quality of reporting; this can reflect better quality. This would allow readers a better understanding of the methodologic quality of physical therapy trials. It is likely that the other areas of physical therapy present similar results to those found in this study.

Suppliers

a. Excel; Microsoft.
b. SPSS 13.0.

Keywords

Musculoskeletal system; Randomized controlled trial as topic; Rehabilitation

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Appendix 1 PEDro Scale

1. Eligibility criteria were specified;
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received);
3. Allocation was concealed;
4. The groups were similar at baseline regarding the most important prognostic indicators;
5. There was blinding of all subjects;
6. There was blinding of all therapists who administered the therapy;
7. There was blinding of all assessors who measured at least 1 key outcome;
8. Measures of at least 1 key outcome were obtained from >85% of the subjects initially allocated to groups;
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated, or where this was not the case, data for at least 1 key outcome were analyzed by intention to treat;
10. The results of between-group statistical comparisons are reported for at least 1 key outcome; and
11. The study provides both point measures and measures of variability for at least 1 key outcome.

These PEDro scale scores were downloaded from the PEDro website along with the full citation of the trial report (including the year of publication), the language of publication, and whether the trial evaluated a form of electrotherapy (ie, coded as electrotherapy, heat, or cold for therapy) and the main body part investigated (head or neck; upper arm, shoulder, or shoulder girdle; forearm or elbow; hand or wrist; chest [for cardiothoracic trials]; thoracic spine; lumbar spine, sacroiliac joint, or pelvis; perineum or genitourinary system; thigh or hip; lower leg or knee; foot or ankle; no appropriate value in this field).

Appendix 2 Nine CONSORT Items

1. Identification as a randomized trial in the title (CONSORT item 1a): The authors must use the word "randomized" in the title. This helps to ensure that the trial report was properly indexed in databases and easily identifiable by readers. This criterion was rated as yes (coded as 1) or no (coded as 0).
2. Number of randomized participants (CONSORT item 4a): This item refers to the number of participants initially allocated to groups. Larger sample size increases the probability of the article as greater external validity and increases statistical precision. The number of randomized participants was extracted from the methods section. This was coded as 1 for the number of randomized participants specified and 0 if not specified.
3. How sample size was determined (CONSORT item 7a): Authors must have identified how the sample size was calculated, so that the trial report would have a high probability to detect a clinically important difference. Trials fulfilled this criterion if the authors stated that a sample size calculation was performed

prospectively and were coded as 1. Retrospective calculations were not considered and were coded as 0 along with articles which did not include a sample size calculation. We also extracted the number of participants specified from the sample size calculation.

4. Locations where the data were collected (CONSORT item 4b): This information was important to judge the applicability and the generalizability of the trial results. Social, economic, cultural, or environmental aspects can affect the external validity. The country was extracted from the methods section, and in the absence of this information we assumed that the trial took place in the country of the first author of the trial. We collapsed the countries into regions (ie, Africa, Asia, Europe, North America, Oceania, South America, missing). In the case of multicenter trials, we recorded the number of centers involved. In the absence of this information, the trial was considered to be a single-center trial. Multicenter trials were coded as 1, and single-center trials were coded as 0.
5. Number of primary outcomes (CONSORT item 6a): Trials may have $\geq$1 primary outcomes. The other outcomes of interest are secondary outcomes. We used the following keywords (or variants of these) to determine if $\geq$1 primary outcomes were specified: *primary outcomes*, *main outcomes*, *major outcomes*, or *end point.* The number of primary outcomes was recorded. Articles which specified primary outcomes were coded as 1, whereas those which did not were coded as 0.
6. Statistical adjustment for multiple primary outcomes (CONSORT Item 12b): This adjustment is necessary to avoid a false-positive result (type 1 error). This information was extracted from the statistical analysis section, and the following keywords (or variants of these) were used: *adjustment for primary outcomes*, *Bonferroni*, *Tukey*, or *Duncan.* This criterion was rated as yes (coded as 1) or no (coded as 0).
7. Participant flow diagram (CONSORT item 13a): A diagram describing the number of participants in each treatment group, those who actually received the treatment, those who were excluded, and those who were analyzed for the primary outcomes should be presented. We did not consider flowcharts of the trial design. This criterion was rated as yes (coded as 1) or no (coded as 0).
8. Clinical trial registration (CONSORT item 23): The trial must have been registered in a public domain to avoid selection bias.[23,24] We did not check if the registration was prospective or not. This information was solely based on the trial report. This criterion was rated yes (the trial was registered; coded as 1) or no (if there was no explicit evidence of registration; coded as 0).
9. Funding sources (CONSORT item 25): Trials can receive various types of funding. Trials that received funding from scientific agencies are more likely to have better quality because they were peer reviewed prior to the inception of the trial. In contrast, trials funded by the private sector may have conflicts of interest and may have bias. This criterion was rated as yes (coded as 1) or no or not reported (both coded as 0).

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