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Language of publication has a small influence on the quality of reports of controlled trials of physiotherapy interventions

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Abstract

Objectives: To investigate whether the methodological quality is influenced by language of publication in reports of randomized controlled trials and controlled clinical trials of physiotherapy interventions.

Study Design and Setting: Bibliometric and methodological quality data from all reports of trials indexed on the Physiotherapy Evidence Database (PEDro) up to February 2011 were extracted. Descriptive statistics on the total PEDro score and the 11 individual PEDro items were calculated for each language of publication and for all non–English-language reports combined. Regression models were calculated to predict the total PEDro score and the presence of each of the 11 items of the PEDro scale using the language of publication as an independent variable.

Results: A total of 13,392 reports of trials were used for this study, 12,532 trials published in English and 860 published in other languages. Overall methodological quality was better for English reports than reports written in other languages ($\beta = 0.15$, 95% confidence interval = 0.04, 0.25). Specifically, reporting was better for items relating to random allocation, concealed allocation, and blinding of assessors, worse for more than 85% follow-up and intention-to-treat analysis, and no different for eligibility criteria and source specified, baseline comparability, blinding of subjects and therapists, reporting of between-group statistical comparisons, and reporting of point measures and measures of variability.

Conclusion: Language of publication is associated with the methodological quality of reports of physiotherapy trials. Although English reports are more likely to have better methodological quality than reports written in other languages, the magnitude of this influence is small. © 2013 Elsevier Inc. All rights reserved.

Keywords: Language; Methodological quality; Physiotherapy; Editorial policies; Risk of bias; Language bias

1. Introduction

The practice of evidence-based physiotherapy should be informed by relevant and high-quality clinical research [1]. Physiotherapy (or physical therapy) interventions broadly involve the use of education, therapeutic exercise, functional training, manual therapy, prescription of devices and equipment, airway clearance techniques, and electrotherapeutic modalities across a range of health conditions [2]. The best types of clinical research about the effects of an intervention are randomized controlled trials and systematic reviews of randomized controlled trials [3,4]. Two challenges for implementing evidence-based physiotherapy are that the quality of reports of trials varies widely [5], and trials and reviews are published in a number of different languages. Similar challenges are also experienced in other areas of health care [6].

High-quality studies are the ones that present low risk of systematic error (or bias). There is some empirical evidence that the quality of reports of controlled trials in physiotherapy are slowly improving over time [7]. This improvement in quality may be due to a better understanding of important sources of bias, such as concealed allocation, intentionto-treat analysis, and blinding [7]. As physiotherapy commonly involves the use of complex interventions, it may not be possible to use design features to control some forms of bias (eg blinding of therapists and patients) is only possible when evaluating electrotherapy interventions. Reports of randomized controlled trials and controlled clinical trials in physiotherapy are published in multiple languages; and to

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What is new?

Key findings

• Although language of publication is associated with the methodological quality and statistical reporting of physiotherapy trials, the magnitude of this influence is small.

What this adds to what was known?

• Previous studies on this topic were small and restricted to just a few languages. A more robust analysis from our study indicates that Englishlanguage trial reports have slightly higher methodological quality compared with reports published in languages other than English in the field of physiotherapy.

What is the implication and what should change now?

• As the risk of bias may be higher in reports of physiotherapy trials published in languages other than English, methodological quality and statistical reporting should be carefully evaluated for all trial reports (regardless of language of publication) before inclusion into summaries of evidence.

our knowledge, there are no studies that have investigated the influence of language of publication on the quality of trial reports in physiotherapy.

Although English-language reports appear to have similar [8,9] or slightly higher [10] methodological quality compared with reports published in languages other than English, only a few languages have been investigated (English, Chinese, German, French, Italian, Japanese, Portuguese, and Spanish) using a relatively small sample of trial reports. The largest evaluation compared 485 English-language reports with 115 non-English-language reports (42 German, 29 French, 12 Italian, 8 Japanese, 7 Spanish, 6 Portuguese, 3 Chinese, and 8 unspecified European languages) [10], whereas the other evaluations compared 133 English reports with 96 non-English reports (20 French only, 20 German only, 20 both French and German, 20 Italian, and 16 Spanish) [9] and 40 English reports with 40 German reports [8]. A more robust evaluation of the influence of language would be possible with a larger sample of published trials that included a broader range of languages. It is possible to perform this analysis with reports of trials of physiotherapy interventions because nearly all trial reports have been indexed on a single database, the Physiotherapy Evidence Database (PEDro http://pedro.org.au) [11,12]. The PEDro indexes report clinical trials [13] (both randomized controlled trials and controlled clinical trials). Furthermore, reports indexed on

PEDro are assessed for methodological quality and completeness of reporting using the PEDro scale [5,14,15].

Although English is considered a "world language," only 25% of the world population can speak or read English [16]; however, approximately 90% of all physiotherapy trials and systematic reviews are published in English. Although the Cochrane Collaboration recommends that reviews include reports of trials irrespective of language of publication [13], nearly 80% of systematic reviews of randomized controlled trials have restrictions with regards to the language of publication, mostly excluding trials published in languages other than English [17]. Perhaps these language restrictions occurred in these reviews because of the difficulty in identifying trials published in languages other than English, the languages spoken by the reviewers, or owing to the view that English language publications are sufficient for summaries of evidence such as systematic reviews or clinical practice guidelines [9]. Based on an analysis of 50 Cochrane reviews, excluding non-English language trials had little effect on the overall treatment effects [10]. One way to assess whether language restrictions are reasonable for systematic reviews is to assess the quality of reports of trials in both languages (English and non-English). If the quality of English and non-English trial reports are similar, there will be no reason for exclusion of trials based on the language of publication [9].

Our primary aim was to investigate whether the quality of trial reports is influenced by the language of publication (English vs. non-English), as rated by the 11-item PEDro scale. Our secondary aim was to describe the characteristics of the universe of physiotherapy trial reports published in each available language.

2. Methods

All trial reports (clinical controlled trials and randomised controlled trials) indexed on PEDro in February 2011 were downloaded. The variables downloaded were title, authors, journal name, year of publication, language, therapy being evaluated, and PEDro scale (ratings of each of the 11 items and the total PEDro score). We excluded trials that had incomplete PEDro scale ratings (i.e., reports that were still in the process of being indexed on PEDro) from the evaluation of the relationship between language and quality of reporting.

The PEDro scale was chosen for this study and trials indexed on PEDro are assessed for methodological quality and statistical reporting using the 11-item PEDro scale [5,14,15]. The items are: (1) eligibility criteria and source specified; (2) random allocation; (3) concealed allocation; (4) baseline comparability; blinding of (5) subjects, (6) therapists, and (7) assessors; (8) more than 85% followup; (9) intention-to-treat analysis; (10) reporting of between-group statistical comparisons; and (11) reporting of point measures and measures of variability. Each item has clearly defined scoring criteria, which are included in the electronic Appendix (see at www.jclinepi.com) to this article. The last 10 items are used to calculate the total PE-Dro score (the first item is not used as it is related to generalizability, rather than methodological quality and statistical reporting), which is calculated by summing the number of items met. The total PEDro score ranges from 0 to 10, with higher scores indicating higher methodological quality and more complete statistical reporting. Each trial report indexed on PEDro is rated by two independent assessors and, if there are disagreements, arbitration is performed by a third assessor. Trials are rated on the basis of the published report only. The PEDro items are achieved only when unambiguous evidence is included in the report.

The assessors also allocate codes for the therapy being evaluated (i.e., acupuncture; behavior modification; education; electrotherapies, heat and cold; fitness training; health promotion; hydrotherapy, balneotherapy; neurodevelopmental therapy, neurofacilitation; orthoses, taping, splinting; respiratory therapy; skill training; and strength training; stretching, mobilization, manipulation, and massage). Reports of trials written in languages other than English are rated by bilingual assessors using the English version of the PEDro scale.

2.1. Statistical analysis

The number of trial reports in each language was calculated. The mean (95% confidence interval [CI]) of total PEDro scores were calculated for trial reports in each individual language as well as for all non-English reports combined. The total PEDro score was calculated for all years of publication combined and for each decade from the 1920s to 2010s. A Student's independent *t*-test was used to compare the total PEDro score for English- with non-Englishlanguage trials. We calculated the proportion of "yes" responses for each individual item of the PEDro scale for each individual language and for all non-English reports combined.

The multivariate analyses allowed for controlling for factors other than publication language that may be associated with the quality of reporting (i.e., potential confounders). A multivariate linear regression analysis was performed to predict the total PEDro score (dependent variable) including the following terms in the regression equation (independent variables): English trial reports (coded as 1) vs. non-English trial reports (coded as 0); number of years since publication (we calculated this variable by subtracting the year of publication from 2011); if the trial evaluated electrotherapy (coded as 1) vs. non-electrotherapy trials (coded as 0), this variable was included in the analysis as a potential confounder because blinding of participants and therapists is possible in electrotherapy trials compared with other physiotherapy interventions (e.g., exercise). Multivariate logistic regression analyses were performed to predict each of the 11 items of the PEDro scale (dependent variables) for

language (English vs. non-English), adjusted for the number of years since the publication and electrotherapy (electrotherapy vs. non-electrotherapy). We used backward elimination to specify a model in which all variables achieve statistical significance (P < 0.05).

3. Results

In February 2011, PEDro indexed 14,619 reports of randomized controlled trials and controlled clinical trials. Of these trial reports, 13,392 had complete indexing-12,532 trials published in English and 860 published in languages other than English. In this study, we included only articles published in English (n = 12,532, of which 1,838 were electrotherapy trials), Chinese (n = 405, 123 electrotherapy), German (n = 253, 74 electrotherapy), Norwegian (n = 8, 2 electrotherapy), French (n = 31, 9 electrotherapy), Italian (n = 19, 6 electrotherapy), Portuguese (n = 62, 11 electro-)therapy), Spanish (n = 49, 7 electrotherapy), and Dutch (n = 33, 4 electrotherapy). The trial reports that were excluded because they did not have complete indexing were published in Bosnian/Serbian/Croatian (n = 10), Bulgarian (n = 2), Czech (n = 14), Danish (n = 61), English (n = 789), Finnish (n = 5), Greek (n = 2), Hebrew (n = 7), Hungarian (n = 8), Icelandic (n = 2), Japanese (n = 65), Korean (n = 64), Lithuanian (n = 3), Persian (n = 7), Polish (n = 36), Russian (n = 66), Slovak (n = 6), Swedish (n = 14), Turkish (n = 63), Ukrainian (n = 1), and Romanian (n = 2) languages.

Univariate analysis indicated that methodological quality and statistical reporting was similar for English and non-English trial reports. The English trial reports had a mean total PEDro score of 4.8 points (95% CI = 4.8, 4.9), whereas the non-English trial reports combined had a mean total PEDro score of 4.8 points (95% CI = 4.7, 4.9), see Fig. 1. Of the non-English trial reports, Norwegian-language reports had the highest mean total



Fig. 1. Mean (95% CI) total PEDro score by language of publication (number of trials in each bar is given in brackets). CI, confidence interval; PEDro, Physiotherapy Evidence Database.

The first English-language trial [18] was published four decades before the first non-English-language trial (see Table 1). The first non-English trial was published in 1963 (a French trial [19]), the first trials published in Dutch [20], German [21,22], and Norwegian [23,24] were published in the 1970s, and finally during the 1980s the first trials written in Chinese [25], Italian [26], Portuguese [27], and Spanish [28] were published. Although there is a trend of improvement in the quality of trials over time regardless of the language (see Table 1), English trial reports appear to have the largest improvement.

The multivariate linear regression analysis revealed that language of publication, adjusted for time since publication and electrotherapy intervention, does influence the total PEDro score. The equation to predict the total PEDro score is: total PEDro score = $5.27 + 0.15 \times \text{pub-}$ lished in English $(1 = \text{yes and } 0 = \text{no}) - 0.06 \times \text{number}$ of years before $2011 + 0.30 \times \text{electrotherapy trial}$ (1 = yes and 0 = no). This means that if a trial report is in English, 0.15 points, on average, can be added to the total PEDro score (after adjusting for number of years since publication and electrotherapy trials) compared with a trial published in a language other than English. This equation also means that electrotherapy trials have, on average, an additional 0.30 points on the total PEDro score compared with non-electrotherapy trials. Finally, for every year before 2011, a trial report has, on average, 0.06 points less on the total PEDro score compared with trials published in 2011.

Table 2 presents number of trial reports and the proportion of trial reports that satisfied each of the PEDro scale individual items. The items satisfied most often in English reports were eligibility criteria and source specified (71.8%), random allocation (95.7%), reporting of between-groups statistical comparisons (92.8%), and reporting of point measures and measures of variability (86.5%). In contrast, the items satisfied most often in non-English reports were eligibility criteria and source specified (75.2%), random allocation (88.7%), more than 85% follow-up (71.2%), and reporting of between-groups statistical comparisons (91.9%).

Compared with publishing a trial report in a non-English language, publishing in English increased the likelihood of fulfilling three PEDro scale items: random allocation, concealed allocation, and blinding of assessors. These three items had very high odds ratios (i.e., >2.0), see Table 3. In contrast, reports published in a non-English language were more likely to fulfill two PEDro items: more than 85% follow-up and intention-to-treat analysis.

Language 1920-1929 1930-19 English 3.0 (0.0), 1 6.0 (0.0) Chinese - - Dutch - -	1940–1949 	1950–1959 3.0 (1.3), 13 	1960–1969 29(13)57	1970-1979				
English 3.0 (0.0), 1 6.0 (0.0) Chinese – – Dutch – –		3.0 (1.3), 13 —	29(13)57		19801989	19901999	2000–2009	2010-2011
Chinese – – – – – – – – – – – – – – – – – –	I			3.6 (1.4), 280	4.0 (1.4), 1,329	4.6 (1.4), 3,170	5.1 (1.6), 7,316	5.5 (1.5), 365
Dutch — — —			I	I	6.0 (1.2), 5	4.9 (0.7), 35	5.1 (1.1), 364	1.0 (0.0), 1
			I	3.7 (0.6), 3	5.8 (1.9), 13	3.9 (1.4), 12	4.6 (2.6), 5	I
French — — —	I	Ι	3.0 (0.0), 1	2.0 (1.4), 2	4.9 (1.7), 11	4.2 (2.0), 9	4.0 (1.6), 8	Ι
German — — —	I	Ι	I	6.1 (1.5), 7	5.0 (1.9), 38	5.0 (1.6), 95	4.4 (1.5), 112	1.0 (0.0), 1
Italian	I	I	I	I	4.7 (2.3), 3	4.1 (1.6), 14	4.5 (0.7), 2	I
Norwegian	I	I	I	6.0 (1.4), 2	5.3 (1.3), 3	5.0 (0.0), 3	Ι	I
Portuguese — —	I	Ι	Ι	I	4.0 (0.0), 1	5.4 (2.2), 7	3.6 (1.6), 52	2.0 (0.0), 2
Spanish — — —	Ι	Ι	I	Ι	8.0 (0.0), 1	3.7 (1.6), 12	4.3 (1.3), 36	I
All non-English			3.0 (0.0), 1	5.2 (1.0), 14	5.3 (0.9), 75	5.0 (1.1), 187	4.6 (1.6), 579	1.3 (0.6), 4

/alues are mean (SD) of PEDro score and number of trials by language

Table 2. Number of trial reports (%) sati	isfying each PEDro	item by languag	e of publication							
PEDro scale item	English	Non-English	Chinese	Dutch	French	German	Italian	Norwegian	Portuguese	Spanish
Eligibility criteria and source specified	9,002 (71.8)	647 (75.2)	289 (71.4)	28 (84.8)	21 (67.7)	214 (84.6)	11 (57.9)	6 (75.0)	45 (72.6)	33 (67.3)
Random allocation	11,990 (95.7)	763 (88.7)	356 (87.9)	32 (97.0)	26 (83.9)	228 (90.1)	17 (89.5)	7 (87.5)	53 (85.5)	44 (89.8)
Concealed allocation	2,731 (21.8)	105 (12.2)	17 (4.2)	6 (18.2)	7 (22.6)	58 (22.9)	1 (5.3)	2 (25.0)	10 (16.1)	4 (8.2)
Baseline comparability	8,434 (67.3)	594 (69.1)	285 (70.4)	18 (54.5)	17 (54.8)	191 (75.5)	13 (68.4)	4 (50.0)	30 (48.4)	36 (73.5)
Blinding of subjects	1,004 (8.0)	76 (8.8)	6 (1.5)	5 (15.2)	5 (16.1)	42 (16.6)	5 (26.3)	3 (37.5)	6 (9.7)	4 (8.2)
Blinding of therapists	256 (2.0)	20 (2.3)	4 (1.0)	3 (9.1)	2 (6.5)	9 (3.6)	1 (5.3)	0 (0.0)	1 (1.6)	0 (0.0)
Blinding of assessors	4,131 (33.0)	147 (17.1)	39 (9.6)	11 (33.3)	6 (19.4)	61 (24.1)	4 (21.1)	6 (75.0)	14 (22.6)	6 (12.2)
More than 85% follow-up	7,079 (56.5)	612 (71.2)	359 (88.6)	23 (69.7)	17 (54.8)	151 (59.7)	8 (42.1)	5 (62.5)	25 (40.3)	24 (49.0)
Intention-to-treat analysis	2,560 (20.4)	259 (30.1)	186 (45.9)	11 (33.3)	5 (16.1)	44 (17.4)	3 (15.8)	4 (50.0)	3 (4.8)	3 (6.1)
Reporting of between-groups	11,630 (92.8)	790 (91.9)	401 (99.0)	24 (72.7)	25 (80.6)	227 (89.7)	17 (89.5)	0 (0.0)	44 (71.0)	44 (89.8)
statistical comparisons										
Reporting of point measures and	10,836 (86.5)	743 (86.4)	397 (98.0)	24 (72.7)	21 (67.7)	197 (77.9)	12 (63.2)	4 (50.0)	46 (74.2)	42 (85.7)
measures of variability										

neasures of variability *Abbreviation:* PEDro, Physiotherapy Evidence Database.

4. Discussion

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Our results revealed that English reports were more likely to have better quality than reports written in languages other than English, but the magnitude of this influence was small (β coefficient = 0.15 points) when the analysis was adjusted for time since publication and electrotherapy intervention. We also observed that the recent studies (β coefficient = -0.06 points) and the electrotherapy intervention trials (β coefficient = 0.30 points) have better quality. The items' random allocation, concealed allocation, and blinding of assessors were more likely to be satisfied in studies published in English and the items more than 85% follow-up and intention-to-treat analysis were more likely to be satisfied in studies published in languages other than English.

This study is the first to assess the influence of language of publication on the quality of reports of randomized controlled trials and controlled clinical trials in a universe of trials of physiotherapy. From a total of 14,619 reports of trials that were included on the PEDro database on February 2011, 1,227 reports of trials were excluded (489 trials being published in English and 738 trials published in languages other than English) as these trials had incomplete indexing, which can be considered as a possible limitation of the study. Moreover, as the PEDro scale assesses only the information that was reported in the manuscript (similarly to other risk of bias scales), we cannot rule out the possibility that the trial as conducted had different methodological quality. For example, one study that interviewed authors of 2,235 reports of randomized controlled trials published in Chinese revealed that only 9.3% of the studies adhered to accepted methodology for randomization [29]; in other words, although most of the studies reported true randomization, the interviews with the authors of these articles revealed that this was not the case. This shows a lack of understanding by the authors about key concepts of trial design, nevertheless these trial reports are usually rated positive in quality scales such as the PEDro scale, as it is impossible to audit the conduct of all trials. Another limitation of our study was that we were unable evaluate other confounding variables (like sample size and the number of centers) because these data were not readily available and would have had to be extracted for the 13,392 reports of trials we included in our study.

Only three previous studies [8-10] have investigated the influence of language on methodological quality in randomized controlled trials in general medicine. The studies were small (n = 600 [10], 229 [9], and 80 [8]) and evaluated a restricted number of languages (i.e., English vs. German, French, Italian, Japanese, Spanish, Portuguese, or Chinese; English vs. German; and English vs. French, German, Italian, or Spanish), instead of nine languages as we have evaluated. Importantly, these studies reported univariate analyses that did not adjust for possible confounders, so the conclusions may be inaccurate. Our

Table 3. Effect of language on satisfying each individual PEDro scale item

PEDro scale item	Unadjusted odds ratio (95% CI), <i>P</i> -value	Adjusted odds ratio ^a (95% CI), <i>P</i> -value
Eligibility criteria and source specified	0.84 (0.72, 0.98), 0.03	0.84 (0.71, 0.98), 0.03
Random allocation	2.81 (2.24, 3.53), 0.00	2.97 (2.35, 3.74), 0.00
Concealed allocation	2.05 (1.63, 2.47), 0.00	2.16 (1.75, 2.67), 0.00
Baseline comparability	0.92 (0.79, 1.07), 0.28	0.93 (0.80, 1.09), 0.37
Blinding of subjects	0.90 (0.70, 1.14), 0.39	1.19 (0.93, 1.54), 0.18
Blinding of therapists	0.88 (0.55, 1.39), 0.57	1.36 (0.85, 2.18), 0.20
Blinding of assessors	2.38 (1.99, 2.86), 0.00	2.69 (2.24, 3.23), 0.00
More than 85% follow-up	0.53 (0.45, 0.61), 0.00	0.54 (0.46, 0.63), 0.00
Intention-to-treat analysis	0.60 (0.51, 0.69), 0.00	0.59 (0.50, 0.69), 0.00
Reporting of between-groups statistical comparisons	1.14 (0.89, 1.47), 0.30	1.21 (0.94, 1.57), 0.14
Reporting of point measures and measures of variability	1.07 (0.82, 1.23), 0.95	1.03 (0.84, 1.27), 0.76

Abbreviations: PEDro, Physiotherapy Evidence Database; CI, confidence interval.

Values are odds ratio (95% CI) and P-values from the logistic regression (both unadjusted and adjusted).

^a Odds ratios are adjusted for number of years since publication and electrotherapy. Odds ratios higher than one signify that the odds of meeting the item were higher in English than in non-English trials.

adjusted analysis revealed that the trial reports published in English are slightly better (i.e., have higher total PEDro scores) than those published in languages other than English; however, the magnitude of this influence is small. The English-language reports were more likely to fulfill the PEDro criteria for three key features that have been closely related to bias, specifically random allocation, concealed allocation, and blinding of assessors [30]. In contrast, non-English-language reports were more likely to fulfill the more than 85% follow-up and intention-to-treat analysis items, features that have not been consistently shown to introduce bias. We would argue that trials published in languages other than English should be considered in clinical decision making as well as being included in systematic reviews and other summaries of evidence such as clinical practice guidelines.

Another interesting finding is that although electrotherapy is one of the few types of physiotherapy intervention to which subjects and therapists can be blinded (which contributes two points to the total PEDro), we observed that these electrotherapy trials add only 0.30 points to the total PEDro score (after adjustment for confounders). This shows that blinding has not been properly implemented in these trials and perhaps more improvement in the design of electrotherapy trials is possible.

This study is the largest to investigate the influence of language of publication on the quality of reports of randomized controlled trials and controlled clinical trials. This was possible because nearly all trial reports indexed on the PEDro bibliographic database are rated for methodological quality and statistical reporting using the PEDro scale. Our primary aim was to investigate whether the quality of trial reports is influenced by the language of publication. We defined "quality of trial report" as study characteristics that can help readers to distinguish between studies that are more likely to be valid (internal validity—PEDro items 2–9) and statistically interpretable (PEDro items 10 and 11) than studies that are not. These 10 items compose the total score of the PEDro scale. There are at least 21 scales and checklists to evaluate the quality of reports of physiotherapy trials [31], including the Cochrane risk of bias tool [32], and the relationship between language of publication and quality may vary based on the scale used to evaluate quality. The PEDro scale has been shown to be reliable [14] and valid [33,34]. This compares favorably with the evaluation of other quality scales, for example the Cochrane risk of bias scale.

Our findings may not be generalizable to other health disciplines (e.g., medicine, psychology, nursing, dentistry, and speech pathology). It would also be interesting to evaluate the impact of different physiotherapy subdisciplines (e.g., musculoskeletal and neurology) on trial quality. Another suggestion for future studies would be to compare more items related to external validity of studies published in different languages, for example items related to the description of the sample, sample size, and description of the interventions.

5. Conclusion

Language of publication is associated with the reporting of specific items of methodological quality of physiotherapy trials. English-language reports are more likely to fulfill the PEDro criteria for random allocation, concealed allocation, and blinding of assessors and non-Englishlanguage reports are more likely to fulfill the more than 85% follow-up and intention-to-treat analysis items. Although English reports are more likely to have better methodological quality than reports written in other languages, the magnitude of this influence is small.

Appendix

Supplementary material

Supplementary data related to this article can be found online at http://dx.doi.org/10.1016/j.jclinepi.2012.08.004.

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